MINERVA
UROLOGY
and
NEPHROLOGY

VOLUME 75 · SUPPL. 1 · No. 5 · OCTOBER 2023

Libro Abstract
96° CONGRESSO NAZIONALE SIU
7-9 ottobre 2023
Roma

SIU Società Italiana di Urologia dal 1908

EDIZIONI · MINERVA · MEDICA

PUBBLICAZIONE PERIODICA BIMESTRALE - POSTE ITALIANE S.P.A. - SPED. IN A.P. D.L. 353/2003 (CONV. IN L. 27/02/2004 N° 46) ART. 1, COMMA 1, DCB/CN - ISSN 2724-6051 TAXE PERÇUE

MINERVA UROLOGY AND NEPHROLOGY

Vol. 75 October 2023 Suppl. 1 to No. 5

96° CONGRESSO NAZIONALE SIU

7-9 ottobre 2023

ROMA

CONTENTS

Introduzione

Dear Colleagues and Friends,
I would like to thank all the authors and co-authors of the abstracts submitted to the 96th Edition of the Italian Society of Urology (SIU) Congress. We received a total of 835 high-quality smart communications and videos, covering the most actual and controversial topics in Urology. Only the hard, qualified, and precise job of our reviewers allowed us to select the best contributions included in this supplement of *Minerva Urology and Nephrology* (MUN).
After several years, our old society comes back having an official journal printing the abstract book. The MUN journal has been selected by the Executive Committee as the new official journal of the society, considering its rigorous peer-review process, high-quality editorial board, and significant Impact Factor (IF 5.214). The scientific committee will work very close to the Editor-in-Chief Francesco Porpiglia to offer very high-level papers to all SIU members and MUN readers.
This book collects the abstracts of the 482 accepted smart communications that will be presented during the "Nuvola" SIU meeting, a real important scientific event for our society. "La Nuvola" is an architectural masterpiece signed by Massimiliano Fuksas, and one of the most prestigious convention centers in Rome. A beautiful, elegant location to host our members and above all our patients. Indeed, the 96th SIU Congress will mark an important paradigm shift for our society, celebrating the covenant between urologists and the most representative patient associations working in the urology area. For the first time ever, patients will participate actively in dedicated scientific sessions together with their urologists.
The Scientific Committee is confident that this abstract book will help participants, authors, and readers of MUN fix the scientific contributions over time, stimulating young and old urologists to build new studies with the final aim to improve the quality of care of our patients.
We wish you a good read of the abstract collection of the 2023 Congress of the Italian Society of Urology, the oldest, largest, and most prestigious Italian urological community.

On behalf of the SIU Scientific Committee
Vincenzo Ficarra

Scientific Committee


Vincenzo Ficarra


Mauro Gacci


Nicola Longo


Luciana Mariani


Nazareno Suardi

The Committee is assisted in its activities by:

Barbara Fiorani, Capo Segreteria - SIU Executive Manager
educational@siu.it

Carla Ceniccola, Amministrazione - Segreteria Scientifica
segreteria@siu.it

Ilaria Giamminonni - Segreteria Scientifica
formazione@siu.it

Annalaura De Maria - Segreteria Scientifica
info@siu.it

Abstract Reviewers 2023

Daniele Amparore
Davide Arcaniolo
Riccardo Autorino
Matteo Balzarro
Paolo Beltrami
Elisa Berdondini
Alfredo Berrettini
Riccardo Giuseppe Bertolo
Carlo Bettocchi
Lorenzo Bianchi
Marco Borghesi
Nicolò Maria Buffi
Tommaso Cai
Gianluigi Califano
Riccardo Campi
Marco Capece
Umberto Capitanio
Paolo Capogrosso
Marco Castagnetti
Daniele Castellani
Giuseppe Celentano
Antonio F.M. Cicione
Luca Cindolo
Francesco Claps
Roberto Contieri
Alessandro Crestani
Massimiliano Creta
Vito Cucchiara
Francesco Curto
Federico Dehò
Pier Andrea Della Camera
Paolo Dell'Oglio
Elisa De Lorenzis
Stefano De Luca
Pietro Diana
Ugo Giovanni Falagario
Mario Falsaperla
Matteo Ferrow
Nicola Fossati
Ferdinando Fusco
Stefania Ferretti
Giorgio Gandaglia
Michele Gnech
Rosa Giaimo
Antonella Giannantoni
Isabella Greco
Francesco Greco
Ester Illiano
Carlo Introini
Roberto La Rocca
Costantino Leonardo
Giovanni Liguori
Beatrice Lillaz
Chiara Lonati
Giuseppe Lucarelli
Giovanni Lughezzani
Stefano Luzzago
Vito Mancini
Francesco Mangiapia
Guglielmo Mantica
Debora Marchiori
Andrea Mari
Giancarlo Marra
Serena Maruccia
Lorenzo Masieri
Elio Mazzone
Giorgio Mazzon
Eugenio Miglioranza
Giulio Milanese
Gabriella Mirabile
Francesco Mistretta
Lorenzo Montesi
Simone Morselli
Marco Moschini
Giuseppe Mucciardi
Nicola Nicolai
Giorgio Napodano
Richard Lawrence
John Naspro
Antonio Luigi Pastore
Nicola Pavan
Fabrizio Presicce
Silvia Proietti
Stefano Puliatti
Michele Rizzo
Marco Roscigno
Marta Rossanese
Claudia Collà Ruvolo
Stefano Salciccia
Salvatore Sansalone
Giulia Sbrollini
Marcello Scarcia
Arcangelo Sebastianelli
Silvia Secco
Omidreza Sedigh
Maria Chiara Sighinolfi
Alchiede Simonato
Diego Signorello
Marta Signoretti
Francesco Soria
Pietro Spatafora
Armando Stabile
Angelo Territo
Ettore Di Trapani
Agostino Tuccio
Gabriele Tulone
Manuela Tutolo
Alessandro Ulteri
Eugenio Ventimiglia
Paolo Verze
Ida Vici
Graziano Vignolini
Francesca Vedovo
Alessandro Volpe
Claudia Zaccaro
Alessandro Zucchi

Bladder cancer: diagnosis and staging

SC1
Alpha reductase inhibitors (5-ARI) with or without alpha-blockers (α-B) for benign prostatic hyperplasia do not lower the risk of incident bladder cancer: United States insurance claims data

SC2
Developing biomarkers for bladder cancer BCG resistant: early detection in patients candidates for radical cystectomy

SC3
Oncological outcomes and prognostic implications of T1 substaging in overall management of HG NMIBC: results from a large single center series

SC4
Clinical validation of the intermediate-risk non-muscle invasive bladder cancer substratification model proposed by the International Bladder Cancer Group (IBCG): a multicenter YAU urothelial collaboration

SC5
Is the radiological response rate a predictive factor for response to neoadjuvant chemotherapy in patients with bladder cancer treated with radical cystectomy? A single-center study

SC6
Biology and performance of pre- and postpembrolizumab vesical imaging–reporting and data system (VI-RADS) to predict the pathological response and outcome in muscle-invasive urothelial bladder cancer

SC7
Validation of the novel risk-class for non-muscle invasive bladder cancer: comparison of oncological outcomes between "very high-risk" and "high-risk" patients

SC8
A novel pathway to detect muscle-invasive bladder cancer (MIBC) combining clinical features and preoperative VI-RADS scoring criteria: results from a prospective multicenter validation analysis

SC9
Multiparametric MRI of the bladder as a predictive factor of histopathology at reTUR in T1GH with presence of detrusor muscle: could it have a role?

SC10
A viable alternative to urine cytology in urothelial cancer detection: a non-inferiority trial

SC11
Diagnostic performance of node-rads by preoperative CT scan for prediction of pathological nodal (PN) status from muscle-invasive bladder cancers (MIBCS) undergoing radical cystectomy (RC) with extended pelvic lymph-node dissection (EPLND)

SC12
XPERT® bladder cancer detection in emergency setting assessment (XESA project) of patients presenting with hematuria

SC13
Prognostic stratification of bladder cancer patients with a microRNA-based approach

SC14
Prognostic value of Systemic Immune Inflammation Index in bladder cancer treated with radical cystectomy

SC15
Evaluation of the Bladder Epicheck® RT-PCR based urinary marker as a diagnostic tool in upper urinary tract tumors (UTUC)

SC16
A novel bladder cancer diagnostic technique based on urine multimodal spectroscopy

SC17
Accuracy of the CUETO, EORTC 2016 and EAU 2021 scoring models and risk stratification tables to predict outcomes in high-grade non-muscle-invasive urothelial bladder cancer

SC1

Alpha reductase inhibitors (5-ARI) with or without alpha-blockers (α-B) for benign prostatic hyperplasia do not lower the risk of incident bladder cancer: United States insurance claims data

L. Gobbi, C.M. Scornajenghi, V. Asero, P. dipinto, E. De Berardinis, A. Sciarra, S. Basran, M.L. Eisenberg, B.I. Chung, F. Del Giudice (Rome)

BACKGROUND: The chemoprotective effect of 5-alpha reductase inhibitors (5-ARi) on bladder cancer (BCa) risk in men with benign prostatic hyperplasia (BPH) has been explored with conflicting results over the last two decades. The aim of this study was to examine the effect of 5-ARi on new BCa diagnoses in a large US database.

METHODS: We selected men ≥50 years/old with a prescription for 5-ARi after BPH diagnosis were identified in the IBM Marketscan® (IBM Corp., Armonk, NY, USA) Research de-identified databases between 2007 and 2016 outcome measurements and statistical analysis were evaluated through Propensity Score Matching (PSM) for age, Charlson Comorbidity Index (CCI), smoking status, and diabetes. Incident BCa diagnoses were identified after BPH diagnosis and/or pharmacologic treatment. Multivariable regression modeling adjusting for relevant factors was implemented. Sub-group analyses by exposure risk were performed to explore the association between 5-ARi and BCa over time. Administration of alpha-blockers (α-B) w/o 5-ARi was also examined.

RESULTS: In total, 24,036 men on 5-ARi, 107,086 on 5-ARi plus alpha-blockers, and 894,275 without medical therapy for BPH were identified. The median at-risk time for 5-ARi and 5-ARi plus alpha-blocker men was 4.3 years (inter quartile range [IQR] 3.1-5.9) and 4.8 years (IQR 3.4-6.5), respectively. The percentage of men diagnosed with BCa was 0.8% for the 5-ARi, 1.4% for the 5-ARi+α-B, and 0.6% for the untreated BPH group. of incident BCa (adjusted hazard ratio [aHR], 0.90, 95% confidence interval [CI] 0.56-1.47), and 1.08, 95% CI 0.89-1.30, respectively). This was also true at both shorter (≤2 year) and longer-term (>2 year) follow-up. In addition, men on α-B alone had no change in BCa risk compared to controls (HR 1.06, 0.86-1.30).

CONCLUSIONS: In the US, we found no diminished risk of new BCa in men treated with 5-ARi (*i.e.*, chemoprotective effect). The current report suggests that 5-ARi do not change a man's BCa risk.

SC2

Developing biomarkers for bladder cancer BCG resistant: early detection in patients candidates for radical cystectomy

G. Tulone, N. Pavan, C. Minasola, A. Turdo, S. Di Bella, M. Todaro, R. Giaimo, G. Stassi, A. Simonato (Palermo)

BACKGROUND: The primary aim of the study was to retrospectively identify predictive biomarkers in T1 high grade (HG) bladder cancer patients, responder, and non-responder to BCG.

METHODS: The transcriptome profile of 73 samples has been retrieved and analyzed from Robinson *et al.* dataset. Population has been subsequently divided into clusters using k means 2. Two clusters have been generated, one cluster containing only one responder sample has been excluded from the analysis and the second cluster comprising 65 samples, 39 non-responders and 26 responders, has been further analyzed. Non responders and responder groups are used to perform a gene differential analysis, of the almost 59,000 initial genes, 18,267 genes remain after the DE analysis performed with the R edgeR library, 1246 genes have a P value <0.05. These differential genes are used for an enrich analysis using the EnrichR library in ontology terms, biological process, molecular function, and cellular component. In addition, a GSEA was performed with the MSigDB library in the C2 class under Reactome level. The study obtained the research ethics approval from the ethics committee (number 11/2021).

RESULTS: The precise mechanisms involving immunologic cell responses in BCG action is still unclear. To identify a predictive gene signature to determine the response to BCG in T1 HG bladder cancer patients, we analyzed RNA-Seq data obtained from of 73 samples retrieved from a publicly available dataset. Transcriptome analysis revealed the expression of 10 coding genes (*TRD12*, *TNNT3*, *CYP4F2*, *KCTD16*, *SCN11A*, *TCAP*, *UGT2B15*, *ATPBA2*, *PTPRZ1*, *IDO1*) differentially expressed.

in BCG responder *versus* non responder patients, with a fold change ≥2. In addition, the enriched top pathways, and the gene set enrichment analysis (GSEA) showed a significant modulation of the signaling ERBB2 in cancer, interferon alpha beta signaling and smooth muscle contraction in responder *versus* non responder patients. Thus, our data identified a 10-gene expression signature able to predict BCG-therapy response in T1 HG bladder cancer patients.

CONCLUSIONS: Based on the obtained data, our study will aim to evaluate the expression levels of the new identified differentially expressed genes in our cohort of BCG responder and non-responder patients. Thus, transcriptome analysis on RNA extracted from formalin-fixed paraffin-embedded (FFPE) bladder carcinoma specimens, obtained from 12 non-responder patients and from 16 responder patients to BCG and collected before treatment and at the time of recurrence, in follow-up at the Units of Urology will be performed to evaluate the expression of signatures associated with immunotherapy response.

SC3

Oncological outcomes and prognostic implications of T1 substaging in overall management of HG NMIBC: results from a large single center series

A. Fanelli, M. Finati, F.P. Cinelli, N. Schiavone, M. Chirico, B. Calò, L. Martino, E. Tocci, O. Selvaggio, C. Bettocchi, G.M. Busetto, L. Cormio, G. Carrieri (Foggia)

BACKGROUND: A wide variation of recurrence and progression rate are observed among high grade (HG) T1 non-muscle invasive bladder cancer (NMIBC). Despite the efforts of the European Association of Urology (EAU) NMIBC committee, current risk calculators struggle to accurately predict prognosis among this heterogeneous group. Our study evaluated how T1 substaging may improve the overall management of these patients.

METHODS: Our cohort enlisted 444 patients who recei-

ved a diagnosis of primary T1G3 BCa at our Institution. Data from diagnosis to subsequent RE-TURBT, eventual bacillus Calmette-Guérin (BCG) treatment and follow-up were collected. Cystoscopy and urine cytology were performed following EAU NMIBC guidelines recommendation, while computed tomography (CT) scan was yearly performed. All specimens were analyzed by two dedicated uropathologists. The population was stratified into T1a (focal infiltration of the lamina propria) and T1b (extensive) for statistical analyses, whenever possible. Differences in medians and proportions were assessed using Wilcoxon-Mann-Whitney Test and Pearson's χ^2 test. Kaplan-Meier and multivariate Cox regression analyses regarding recurrence-free survival (RFS), progression-free (PFS) and cancer-specific survival (CSS) were performed. We included clinicopathological characteristics at first TURBT and BCG treatment as variables.

RESULTS: Median age at diagnosis was 75 years (IQR 66-81). 388 were male (87.4%) and 56 (12.6%) were female. At first TURBT, T1b patients showed larger tumor (>3 cm: 55.4% *vs.* 36.6%, P value 0.003) when compared with T1a. At RE-TURBT, residual HG BCa was found in 23% of T1a and 14.5% of T1b (P value 0.1), while pathological upstaging (T≥2) was shown in 1.3% T1a *vs.* 6.6% T1b patients (P value = 0.04). At a median follow-up of 40 months (IQR 17-72), RFS was 39.7% in T1a group and 38.8% in T1b. Progression was observed in 27 (11.2%) T1a and 21 (18.1%) T1b patients (P=0.07). CSS was 75% in T1b group and 83% in T1a, while cystectomy was performed in 19% T1b *vs.* 16.5% of T1a. Overall, T1b patients showed worse survival curves when compared to T1a, albeit this statement reached statistical significance only for PFS (P=0.01). At multivariable analyses, an adequate BCG course was an independent predictor for all outcomes evaluated (all P values <0.01), while T1 substaging did not independently predict any endpoints evaluated.

CONCLUSIONS: An extensive invasion of the lamina propria in primary T1 BCa was associated with overall PFS and higher risk of upstaging to MIBC at RE-TURBT. Even if T1 substaging alone is suboptimal to predict oncological outcomes of HG T1 NMIBC, its combination with other factors (lymph vascular invasion, multifocality, associated carcinoma in situ, no prior BCG treatment, >3 cm tumor size, and older age) may improve risk stratification and guide overall management disease.

SC4
Clinical validation of the intermediate-risk non-muscle invasive bladder cancer substratification model proposed by the International Blader Cancer Group (IBCG): a multicenter YAU urothelial collaboration

S. Livoti, F. Soria, M. Rosazza, M. Moschini, F. Del Giudice, R. Pichler, R. Hurle, D.M. Carrión Monsalve, W. Krajewski, L. Mertens, D. Dutto, L. Ola, F. Colucci, C. Fiameni, B. Lillaz, P. Gontero (Turin)

BACKGROUND: Based on the EAU2021 scoring model, intermediate-risk NMIBC includes a wide spectrum of disease for whom treatment may vary from adjuvant chemotherapy to intravesical BCG. The choice between intravesical therapies as well as the intensity of follow-up is left at physician discretion, leading to treatment heterogeneity. A substratification of IR disease seems appropriate to improve risk-stratification and to aid in the clinical decision-making regarding adjuvant therapy and follow-up. The International Bladder Cancer Group (IBCG) proposed a substratification model based on the presence of additional risk factors (multifocal tumor, tumor size, early recurrence, frequent recurrence, previous intravesical treatment failure). Based on this model, IR patients may be divided in three different risk categories, to be treated either with only one-shot chemotherapy instillation, adjuvant chemotherapy or adjuvant BCG. However, a clinical validation of this model is lacking and needed before considering its adoption in clinical practice. The aim of our study was to provide the first clinical validation of the IBCG substratification model for IR NMIBC disease.

METHODS: This is a multicenter cooperation involving 9 European referral Centers of the YAU Urothelial working group. Primary or recurrent NMIBC treated with adjuvant intravesical chemotherapy and stratified as having IR disease according to the 2021 EAU scoring model were included. Main endpoint was to validate the IBCG substratification model. Based on the presence of additional risk-factors, IR patients were stratified into IR-low, IR-intermediate, and IR-high groups. One-year and 3-year RFS and PFS rates of each subgroup were evaluated, and KM curves were built to evaluate the risk of disease recurrence and progression. Log-Rank Test and Cox-regression analyses were used to compare the oncological outcomes between groups.

RESULTS: A total of 786 IR NMIBC patients were included. No risk factors, 1-2 and ≥3 risk factors were present in 299 (38%), 400 (51%) and 87 (11%) patients. One-year and 3-year recurrence rates for IR-low, IR-intermediate, and IR-high group were 10.4% and 28.9%, 14% and 36.6%, 35.2% and 68.1%, respectively. One-year and 3-year progression rates for IR-low, IR-intermediate, and IR-high group were 0% and 0.4%, 0.5% and 1.8%, 3.6% and 9%, respectively. RFS and PFS rates significantly differ between groups (P<0.001 and P=0.004, respectively). IR-low patients carry a risk of disease progression like those belonging to the low-risk NMIBC group (0.4% at 3 years) while IR-high patients present a very-high risk of progression (9% at 3 years), similar to high-risk NMIBC patients.

CONCLUSIONS: We provided the first clinical validation of the IBCG substratification model for IR NMIBC. This model correctly discriminate patients in those at low, intermediate, and high risk for developing disease recurrence and progression. These results pave the way towards the implementation of this substratification model into clinical practice.

SC5
Is the radiological response rate a predictive factor for response to neoadjuvant chemotherapy in patients with bladder cancer treated with radical cystectomy? A single-center study

P. Russo, F. Marino, F. Rossi, M. Ragonese, S. Moretto, F. Fantasia, G. Filomena, E. Sacco, N. Foschi (Rome)

BACKGROUND: The aim of this study was to assess the predictive value of the radiological response rate (RRR) for pathological response to neoadjuvant chemotherapy (NAC) and clinical outcomes after radical cystectomy (RC) in urothelial bladder cancer (UBC) patients.

METHODS: The medical records of 315 consecutive patients with clinical non metastatic urothelial bladder cancer

(UBC) who underwent RC at our hospital between January 2016 and November 2022 were retrospectively reviewed. Overall, 105 patients undergoing NAC before surgery were analyzed. Patients who did not undergo RC for disease progression during NAC were excluded. Pretreatment transurethral resection was performed in all patients to confirm the presence of the urothelial cancer and to determine the histological grade. The radiological response rate (RRR) was evaluated by a radiologist by monitoring the diameter of the primary tumor at computer tomography scans performed pretreatment and post-NAC. The primary outcome was the assessment of association between the radiological response rate and the histological examination of RC specimen. Secondary outcomes were clinical outcomes after RC.

RESULTS: The pathological complete response rate was observed in 38 patients (36%). The radiological response rate was associated with £ pT1. In patients with pathological downstaging to pTa/is or pT1, compared with those with pT2 £ cancer, was observed a significantly better post radical cystectomy recurrence free survival (2 years survival 90, 86, 32 respectively, P<0.0001), disease specific survival (2 years survival 92.4%, 87%, 48%, respectively; P<0.0001) and overall survival (2 years survival 92.6%, 89%, 43%, respectively; P<0.0001). Multivariate analyses using the Cox proportional hazard model revealed that the radiological response rate was an independent predictor for favorable pT stage and recurrence free survival.

CONCLUSIONS: The radiological response rate evaluated by pretreatment and post-NAC computer tomography scans could be used to predict the pathological outcomes and post RC prognosis. Further studies with larger cohorts are necessary for the application of RRR to predict the therapeutic response to NAC and possible non-invasive monitoring of disease progression with MIBC.

SC6
Biology and performance of pre- and postpembrolizumab vesical imaging-reporting and data system (VI-RADS) to predict the pathological response and outcome in muscle-invasive urothelial bladder cancer

G. Basile, E. Gibb, D. Raggi, G. Calareso, T. Costa de Padua, D. Patanè, E. Crupi, C. Mercinelli, A. Del Prete, P. Giannatempo, M. Bandini, G. Gandaglia, A. Messina, J.S. Ross, D.C. Pavlick, F. De Cobelli, M. Moschini, A. Briganti, G. Brembilla, F. Montorsi, A. Necchi (Milan)

BACKGROUND: The aim of this study was to evaluate the predictive capability of pre- and postpembrolizumab vesical imaging-reporting and data system (VI-RADS) to identify the ypT0N0 or the ypT≤1N0 response in muscle-invasive bladder cancer (MIBC) within the PURE-01 trial.

METHODS: Patients were staged with bladder multiparametric magnetic resonance imaging (mpMRI) before and after treatment (3 cycles of pembrolizumab) prior to radical cystectomy (RC). Logistic regression models analyzed pre- and postpembrolizumab VI- RADS, with clinical and tumor-related variables, against ypT≤1N0 (primary endpoint) and ypT0N0 (secondary endpoint). VI-RADS scores were dichotomized between 0-3 (0 = no evidence of disease) and 4-5. Event-free survival (EFS) and overall survival (OS) analyses based on VI-RADS were performed. Comprehensive genomic profiling and transcriptome-wide expression profiling data were matched with VI-RADS scores.

RESULTS: In total, 110 patients had centrally reviewed scans (N.=220 mpMRI), treated between 02/17 and 07/20. As far as prepembrolizumab is concerned, 21 patients (19.1%) had no measurable disease (VI-RADS=0), 34 (30.9%) a VI-RADS 1-3 Score, and 55 (50%) had a VI-RADS 4-5 Score. Both prepembrolizumab and postpembrolizumab VI-RADS 0-3 scores were the only significant covariates that predicted the ypT≤1N0 endpoint on multivariable analyses (MVA): the strongest effect was seen with postpembrolizumab VI-RADS 0-3 predicting the ypT≤1N0 response (odds ratio [OR]: 23.4, 95% CI: 7-95.3, P<0.0001). The Area Under the Curve (AUC) of this model was 0.90. Decision curve analyses demonstrating the net benefit associated with the use of pre- and postpembrolizumab VI-RADS models for the detection of ypT≤1N0 and ypT0N0 response were supported in the range of threshold probabilities of 10-100% and 10-80%, respectively. After a median follow-up of 39 months (IQR: 31-47), the 36-month EFS was 89.5% (95% CI: 82.5-97.2) *vs.* 67.8% (95% CI: 54.7-84.0, P<0.001) for VI-RADS 0-3 *vs.* VI-RADS 4-5, and the 36-mo OS was 90.9% (95% CI: 84.3-98.1) *vs.* 77.8% (95% CI: 64.9-93.3, P=0.04), respectively. The scores of several gene signatures from baseline tumors differed between prepembrolizumab VI-RADS 0-3 and 4-5 categories. *RAF1* mutations were enriched in prepembrolizumab VI-RADS 0-3 group (P=0.04).

CONCLUSIONS: VI-RADS scores postpembrolizumab revealed a robust association with pathological downstaging and survival. VI-RADS scores were also characterized by distinct biomarker features. These results indicated that VI-RADS is emerging as an important tool to design next-generation trials in MIBC.

SC7
Validation of the novel risk-class for non-muscle invasive bladder cancer: comparison of oncological outcomes between “very-high risk” and “high-risk” patients

M. Longoni, P. Scilipoti, M. De Angelis, C. Re, A. Bertini, G. Avesani, G. Avesani, G. Gandaglia, R. Colombo, U. Capitanio, A. Salonia, F. Montorsi, A. Briganti, M. Moschini (Milan)

BACKGROUND: A novel risk-class of non-muscle invasive bladder cancer (NMIBC) defined as “very high-risk” (VHR) has recently been introduced within the latest update of the European Urology Association (EAU) Guidelines. Considering the possible implications on disease management, our study aimed at comparing recurrence-free survival and progression leading to radical cystectomy (RC) rates between VHR and high-risk (HR) patients.

METHODS: We identified 432 patients who underwent transurethral resection of bladder tumor (TURBT) between 2012 and 2022 at a tertiary referral center and diagnosed with NMIBC that felt within the criteria for HR or VHR, according to EAU guidelines, which identifies 3 additional risk factors (age >70, multifocality, dimension ≥3cm). Recurrence and RC free survival were analyzed and compared with the Kaplan-Meier (KM) method at 12, 24, and 48 months since TURBT. Univariable Cox’s regression models were used to estimate the risk of recurrence and RC between HR and VHR patients.

RESULTS: Overall, 324 (75%) and 108 (25%) patients were

diagnosed with HR and VHR NMIBC, respectively. Among VHR patients, 3 (2.8%) presented with TaHG, CIS and all 3 risk factors, 3 (2.8%) presented with T1G2, CIS and ≥2 risk factors, 76 (70.4%) presented with T1HG, CIS and ≥1 risk factors, and 26 (24%) presented with T1HG without CIS and all 3 risk factors. Median follow-up and age at diagnosis was 40 months (IQR 20-69) and 72 years (IQR 65-78) respectively. Death from disease occurred in 30 cases (7%). Overall, recurrence and RC free survival at 48 months were 63.3% (CI 58.3-68.8) and 84.6% (CI 80.7-88.8), respectively. Comparing HR *vs.* VHR patients at landmark time of 12, 24 and 48 months, recurrence-free rates were 85.8% *vs.* 80.9%, 76.7% *vs.* 71.2%, and 62.7% *vs.* 66.0%. At the very same timepoints, RC-free rates were respectively 97.8% *vs.* 83.9%, 94.2% *vs.* 80.5%, and 87.1% *vs.* 77.5%. At univariable analysis, VHR patients did not show a significantly higher risk of recurrence (P=0.9) while they had a 2-fold risk of undergoing RC (HR=2.66, P<0.001).

CONCLUSIONS: Our analysis proved that VHR class for NIMBC may identifies patients at higher risk of progression and who eventually undergo RC, compared to the existing class of HR patients.

SC8
A novel pathway to detect muscle-invasive bladder cancer (MIBC) combining clinical features and preoperative VI-RADS scoring criteria: results from a prospective multicenter validation analysis

F. Del Giudice, M. Pecoraro, M. Bicchetti, G. Giannarini, A. Briganti, B.I. Chung, R.S. Flammia, A. Sciarra, C. Leonardo, E. De Berardinis, C. Catalano, V. Panebianco (Rome)

BACKGROUND: The diagnostic pathway for bladder cancer (BCa) patients has been mostly unchanged for more than 30 years, with trans-urethral resection of bladder tumor (TURBT) as the initial diagnostic and staging tool. While the accuracy of VI-RADS has been reasonably proven, it is not clear yet whether clinical and/or tumor pathological features can influence VI-RADS categorization, and whether VI-RADS may better predict the risk of MIBC alone or rather in combined models including extra-radiological factors. As consequence, we sought to determine the clinical, radiological, and pathological features associated with pre-TURBT MIBC detection. We tested the hypothesis that multi-level variables might improve the current treatment paradigm of BCa in the pretreatment setting.

METHODS: Patients with BCa suspicion were offered magnetic resonance imaging (MRI) before trans-urethral resection of bladder tumor (TURBT). According to VI-RADS, a cutoff of ≥3 and ≥4 was assumed to define MIBC. Trans-urethral resection of the tumor (TURBT) and/or radical cystectomy (RC) reports were compared with preoperative VI-RADS scores to assess accuracy of MRI for discriminating between NMI *vs.* MIBC. Performance was assessed by ROC curve analysis. Two univariable and multivariable logistic regression models were implemented including clinical, pathological, radiological data, and VI-RADS categories to determine the variables with an independent effect on MIBC detection.

RESULTS: One hundred thirty-nine patients were enrolled (median age 70 [IQR: 64, 76.5]) at 4 BCa tertiary centers. MRI showed sensitivity, specificity, PPV, NPV, and accuracy for MIBC diagnosis ranging from 83-93%, 80-92%, 67-81%, 93-96%, and 84-89% for the more experienced readers. The Area Under the Curve (AUC) was 0.95 (0.91-0.99). In the multivariable logistic regression model, VI-RADS Score, using both a cutoff of 3 and 4 (P<0.0001), hematuria (P=0.007), tumor size (P=0.013), and concomitant hydronephrosis (P=0.027) were the variables correlating with a bladder cancer staged as ≥T2. The inter-reader agreement was substantial (k=0.814).

CONCLUSIONS: VI-RADS Score proved to be an independent predictor of muscle-invasiveness, which might implicate a shift toward a more aggressive selection approach of patients at high risk for primary detection of MIBC, according to a novel proposed predictive pathway.

SC9
Multiparametric MRI of the bladder as a predictive factor of histopathology at reTUR in T1GH with presence of detrusor muscle: could it have a role?

A. Giordano, E. Dalmasso, E. Alessandria, R. Aimar, P. Ornaghi, F. Pini, P. Violino, I. Morra (Cuneo)

BACKGROUND: The role of re-TUR in patients with T1 bladder tumor and muscle in TUR specimen remains controversial. Furthermore, re-TUR is an invasive procedure and a non-negligible source of logistic difficulties. On the other hand, the role of multi- parametric magnetic resonance imaging (mpMRI) for bladder cancer is growing, thanks to its high sensibility and specificity in the identification of local invasiveness of the tumor. We analyzed the role of MRI in the setting of repeated transurethral resection (reTUR) to predict absence of residual tumor (T0), persistence or understaging at first resection and we present our experience.

METHODS: From April 2021 to September 2022 patients with diagnosis of T1HG bladder cancer and presence of detrusor muscle at first resection underwent a bladder MRI before reTUR, after 4 or 5 weeks from the first procedure. Ethical Committee approval has been obtained. Results were classified as no evidence of residual tumor, its evidence or understaging (according to the VI-RADS Score). MRI was 1.5 T. Accuracy was determined using histopathology as the reference standard. Images were analyzed by a dedicated radiologist, resections performed by expert urologists.

RESULTS: A total of 85 MRI was performed: 68 (80%) were classified as no residual tumor, 15 (17%) as residual tumor, and 2 (3%) as suspected understaging at first resection. Accordance with histopathology was 88%. Only in 10 (12%) cases MRI did not correctly predict results of reTUR: in 7 cases MRI classified no residual tumors but histopathology found persistence of disease (of high grade), and 3 cases were classified as residual tumor (but reTUR was negative). All 10 cases were intraoperatively macroscopically negative. The 2 cases of understaging were correctly predicted by MRI. Patients' characteristics, tumor size, focality, site, prior recurrence rate, lymphovascular invasion, histological variants and hydronephrosis at staging CT-scan did not affect MRI accuracy.

CONCLUSIONS: MRI is effective for prediction of histopathology at reTUR and could represent a useful tool in stratifying patients with T1HG who need second resection. Better instrumentation (3T-MRI), increasing experience and integration of modern prediction models can improve our preliminary results, even including accurate cost analysis.

SC10

A viable alternative to urine cytology in urothelial cancer detection: a non-inferiority trial

A. Manera, S. Morselli, E. Baria, R. Cicchi, A. Liaci, L. Moscardi, A. Romano, F. Peschiera, L. Mazzola, R. Campi, A. Sebastianelli, F.S. Pavone, G. Nesi, M.J. Ribal, S. Serni, M. Gacci (Florence)

BACKGROUND: Multimodal fiber optic spectroscopy (MFOS) has proven effective in detection, grading, and staging of urothelial cancer (UC) *ex vivo*. A new possible application under evaluation is to test the same technique in UC diagnosis in urine samples, comparing it to current gold standard urinary cytology.

METHODS: A prospective non-inferiority case control study trial started in January 2021 in an academic hospital after ethical appraisal. Urine samples were collected before urological endoscopic surgical intervention, from cases (patients with UC) and controls (patients without UC). Patients with kidney or prostate tumors were excluded Presence/absence of UC was assessed during surgery, combining direct visualization of the mucosa and through biopsy of any suspect area during surgery even in controls. The same urine specimen was then divided and sent to urine cytology and MFOS analysis. Cytologist did the measurement in blind, as well as MFOS was applied in blind after previous calibration of the machine.

RESULTS: A total of 164 patients were enrolled, of whom 6 were excluded for incidental prostate cancer diagnosis and 2 for insufficient sample; therefore, we evaluated 156 patients of whom at ITT there were 87 cases and 69 controls. All cases underwent TURB, while controls were patients who underwent TURP or HOLEP or URS or RIRS. At PPA, there were 72 cases (46.2%) and 84 controls (53.8%), because 1 control carried UC at endoscopic and pathologic finding, while 16 cases at ITT had no UC at pathology. Patients with UC at PPA were in 3 cases low grade UC and in 69 high grade UC of whom 16 with muscle invasive disease and 5 with CIS. In the evaluated sample, with 30 positive and 126 negative results, cytology yielded sensibility of 33% and specificity of 84%, meanwhile MFOS provided a sensibility of 89% and specificity of 99%. Comparison of the techniques showed a statistically significant difference ($P<0.05$), with a superiority of MFOS. Indeed, according to cubic Support Vector Matrix plus Principal Component Analysis mathematic model, MFOS provided an AUC of 99% at ROC curve.

CONCLUSIONS: Despite the experimental nature of the current technique, operator independent MFOS appeared non-inferior to gold standard urine cytology in a direct comparison. Further larger trials might confirm these results.

SC11

Diagnostic performance of node-rads by preoperative CT scan for prediction of pathological nodal (PN) status from muscle-invasive bladder cancers (MIBCS) undergoing radical cystectomy (RC) with extended pelvic lymph-node dissection (EPLND)

F. Del Giudice, R.S. Flammia, M. Pecoraro, M. Bicchetti, S. Lucciola, B.I. Chung, B. Bucca, F. Proietti, L.C. Licari, E. Bologna, V. Asero, C.M. Scornajenghi, E. De Berardinis, A. Sciarra, V. Panebianco (Rome)

BACKGROUND: Current cross-sectional imaging modalities yielded low sensitivity for evaluation of lymph node invasion (LNI) in bladder cancer (BCa) patients. Moreover, diagnostic performance varied widely according to adopted definitions. Recently, the Node Reporting and Data System v1.0 (Node-RADS) Score was introduced to provide a standardized comprehensive evaluation of LNI based on five-items Likert Scale accounting for both size and configuration criteria. In the current study for the first time, we hypothesized Node-RADS Score to provide accurate and reliable diagnostic performance for pN+ status determination in MIBCs undergone Radical Cystectomy with extended Pelvic Lymph-node Dissection (ePLND).

METHODS: We reviewed MIBCs patients treated with RC plus bilateral extended PLND from January 2019 to June 2022. Patients receiving neoadjuvant systemic chemotherapy were excluded. Logistic regression analysis tested the association between Node-RADS Score and LNI. ROC curves and AUC depicted overall diagnostic performance. Moreover sensitivity, specificity, positive predictive value (PPV), and negative predicting value (NPV) were calculated for each cutoff (>1, >2, >3, >4).

RESULTS: Overall, 49 patients were identified. LNI rates ranged from 0 to 83.3% with increasing Node-RADS Score ($P<0.001$). Moreover, Node-RADS independently predicted LNI after multivariable adjustments (OR 3.36, 95% CI 1.68-9.40, $P=0.004$). Node-RADS exhibited an AUC of 0.87. According to increasing Node-RADS cutoff, specificity and PPV raised from 57.1% to 97.1% and from 48.3% to 83.3%, respectively. Conversely, sensitivity and NPV decreased from 100% to 35.7% and from 100% to 79.1%, respectively. Potentially, Node-RADS >3 could be considered as the best cutoff because of balanced sensitivity (57.1%) and specificity (87.5%) values.

CONCLUSIONS: The current study laid the foundation for the introduction of Node-RADS for regional lymph-node evaluation in MIBC patients. Interestingly, Node-RADS Score exhibited a moderate-to-high overall accuracy for identification LNI, with the possibility of setting different cutoff according to specific clinical scenarios. Further multicenter, multi-readers experiences on larger cohort population are mandatory before drawing definitive recommendations.

SC12

XPERT® bladder cancer detection in emergency setting assessment (XESA project) of patients presenting with hematuria

F. Sordelli, F. Dagnino, D. Maffei, S. Giuriolo, A. Desai, S. Mancon, R. Contieri, A. Voza, F. Maura, G.F. Guazzoni, G. Lughezzani, N. Buffi, P. Casale, M. Lazzeri, R. Hurle (Rozzano, Milan)

BACKGROUND: Emergency department (ED) admission with hematuria is a common presentation of bladder cancer (BC). The widespread application of standard diagnostic work-up with ultrasonography and/or cystoscopy (CS) and urine citology (UC) in this setting determines significant time and resource consumption. Among BC diagnostic tools, Xpert® (Cepheid, Buccinasco, Milan, Italy) is a new mRNA-marker test for BC detection and follow-up, which measures the levels of five target mRNAs in a voided urine sample by real-time (RT)-PCR within 90 minutes. In this study we

aimed to evaluate the clinical performance of Xpert® urine test as screening tool for BC detection in patients accessing the ED for hematuria to reduce resource consumption, as well as comparing Xpert and UC in BC identification.

METHODS: Xpert® bladder cancer detection in Emergency Setting Assessment (XESA project) is a single center, single arm, prospective, observational study (ICH-015 N. 306) with local ethical committee approval for patients accessing the ED with hematuria. Inclusion criteria are gross hematuria within 48h, age ≥18 years old, emergency triage 4-5. Exclusion criteria are BC history, indwelling ureteral stent, suspect of tumor of upper urinary tract and any conditions preventing compliance with study protocol. All patients included perform urine culture, UC and Xpert® BC detection test, followed by outpatient flexible white light CS. In case of BC suspicion at standard work-up with UC or CS, patients underwent trans-urethral resection of bladder within 45 days. Clinical performance was assessed by sensitivity (Sn), specificity (Sp), positive (PPV) and negative (NPV) predictive values.

RESULTS: Between February 2022 and February 2023, a total population of 66 patients was enrolled. We included in our analysis 42 patients, who completed all the diagnostic process with UC, Xpert® test and CS. Median age was 73 years. Xpert® test was positive in 24 out of 42 (57.1%) patients; UC showed malignant cells in 3/42 (7.1% patients). Xpert® identified BC in 8/42 individuals (19.0%), showing 88% Sn, 51% Spand PPV and NPV of 33% and 94%, respectively. On the other hand, UC demonstrated a 33% Sn and 100% Sp, with 100% PPV and 84% NPV for all BC diagnosis. With regards to HG, pT>1 detection, Xpert® showed a Sn, Sp, PPV and NPV of 100%, 51%, 29% and 100%, respectively, compared to UC Sn and Sp of 42% and 100% and PPV and NPV of 100% and 89%, respectively. Using Xpert® as a screening test for BC diagnosis would have avoided 43% CS, missing only one low grade NMIBC. In addition, Xpert® test missed no HG or pT≥1 BC. On the contrary, urine cytology used as a screening test would have prevented 93% of cystoscopies, while missing 57% of HG or pT≥1 cancers.

CONCLUSIONS: In conclusion, Xpert® has higher sensitivity than UC for all-grade BC and in particular HG or pT ≥1 diseases. The use of Xpert as a screening test for patients with hematuria in the emergency department may improve resource utilization and reduce costs and time to endoscopic resection.

SC13
Prognostic stratification of bladder cancer patients with a microRNA-based approach

G. Lista, L. Di Gianfrancesco, A. Crestani, A. Amodeo, P. Corsi, E. Miglioranza, D. De Marchi, C.G. Cargnel, F. Simonetti, I. Cavallari, V. Ciminale, A. Porreca (Castelfranco Veneto, Treviso)

BACKGROUND: Most patients with bladder cancer (BCa) are diagnosed with non-muscle invasive disease and can be treated conservatively. It is known that these patients have a high risk of recurrence and progression to muscle-invasive disease, and must be strictly followed-up, with periodic cystoscopy and urine cytology, procedures that are uncomfortable and burdensome for the patient and for the healthcare system. Robust non-invasive tests for prognostic stratification of bladder cancer (BCa) patients are in high demand. We explored the abilities of a test in the follow-up/risk assessment by analyzing the levels of a specific class of RNA molecules (microRNAs) in urine samples.

METHODS: Based on a comprehensive analysis of BCa studies, we selected and used a panel of 29 microRNAs (miRNAs) to analyze their levels in both urine and plasma samples; we prospectively included 63 BCa patients (32 at high risk of recurrence and 31 low-risk cases) and 37 healthy controls using RT-qPCR.

RESULTS: With the aim to design an assay suitable for large-scale testing, we applied a hierarchical pipeline to select the miRNAs not affected by confounding factors (such as hematuria and urine specific gravity) and exceeded stringent cutoff criteria (fold change >2.5 and P value <0.005). By using a two-step decision tree based on the urine levels of miR-34a-5p, miR-200a-3p and miR-193a-5p, normalized against miR-125b-5p, patients could be classified as higher low-risk according to a sensitivity of 0.844, specificity of 0.806 and accuracy of 0.825. The increased urine levels of miR-29a-3p, miR-34a-5p, miR-193a-5p, miR-200c-3p, miR-205-5p and miR-532-5p were associated with a shorter event-free survival (HR>3.1, P value <0.05) in univariate Cox proportional hazards regression analyses.

CONCLUSIONS: The urinary measurement of miRNAs levels could provide a novel cost-effective, noninvasive test for risk assessment of patients with BCa. The identified panel of microRNAs in urine samples might identify high-risk BCa patients with high accuracy to predict event-free survival. The urinary miRNA assay thus holds promise as a noninvasive alternative to current methods for bladder cancer follow-up.

SC14
Prognostic value of Systemic Immune Inflammation Index in bladder cancer treated with radical cystectomy

P. Russo, F. Marino, F. Rossi, G. Maioriello, D. Nigro, S. Moretto, F. Fantasia, G. Filomena, F. Gavi, M. Ragonese, M. Racioppi, N. Foschi (Rome)

BACKGROUND: To assess the prognostic value of the preoperative Systemic Immune Inflammation Index (SII) in patients undergoing radical cystectomy (RC) and lymphadenectomy for muscle invasive bladder cancer (MIBC) and high risk or *Bacillus* Calmette-Guérin (BCG) unresponsive non muscle invasive bladder cancer (NMIBC).

METHODS: Overall, 315 patients with clinically non-metastatic urothelial bladder cancer (UBC) who underwent RC between January 2016 and November 2022 were reviewed retrospectively. Exclusion criteria were neoadjuvant chemotherapy, previous abdominal surgery, previous radiotherapy, and a history of autoimmune disease. A total of 144 patients was included in the analysis. We constructed a receiver operating characteristic (ROC) curve to identify the optimal SII cutoff value for predicting cancer-specific survival. The cohort was stratified in two groups (high SII and low SII) according to the identified optimal cutoff. The overall survival (OS) was calculated using the Kaplan-Meier survival curves. Uni- and multivariable logistic and Cox regression analyses were performed. The additional clinical net-benefit was assessed using decision curve analysis (DCA).

RESULTS: High SII was observed in 81 (56%) patients. On multivariable preoperative logistic regression, high SII was associated with pT3/pT4 disease (OR 2.75, 95% CI: 1.4-5-5; P=0.003), lymph node involvement (OR 5.48, 95% CI: 1.97-15.29; P=0.0003), and recurrence (OR 3.74, 95% CI: 1.80-7.77; P=0.0002). We also evaluated the association between SII and ureteroenteric anastomosis stricture after RC and no statistically significant association was observed (OR: 1.60, 95% CI: 0.8-3.17 P=0.54). On multivariable Cox regression including preoperative clinicopathologic values, high SII was associated with recurrence- free survival (P=0.028), cancer specific survival (P=0.005), and overall survival (P=0.006). On DCAs, the inclusion of SII did not improve the net-benefit for clinical decision making.

CONCLUSIONS: High preoperative SII could be a prognostic and independent significant indicator of poor prognosis after RC in bladder cancer and there are possible pathways to explain the importance of SII in cancer. The results of the present study should be confirmed by future prospective randomized controlled studies with large cohorts.

SC15
Evaluation of the Bladder Epicheck® RT-PCR based urinary marker as a diagnostic tool in upper urinary tract tumors (UTUC)

M. Palermo, C. D'Elia, E. Trenti, E. Comploj, C. Schwienbacher, C. Mian, A. Pycha, E. Vjaters (Latvia)

BACKGROUND: Upper urinary tract urothelial carcinoma (UTUC) represents about 5-10% of all urothelial neoplasm with increasing incidence in the last few decades. The current standard tools in the diagnosis of UTUC include cytology, computed tomography (CT), urography and ureterorenoscopy (URS). The aim of this study was to evaluate the usefulness of Bladder Epicheck® (Resnova, Rome, Italy) test as diagnostic tool in the diagnosis of UTUC.

METHODS: One hundred thirty-six urine samples collected from upper urinary tract (UUT) before URS for suspicion of UTUC were analyzed with Cytology and Bladder Epicheck® Test. Sixteen analyses were excluded due to a non-diagnostic Bladder Epicheck® or cytology. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of both markers were calculated and compared using URS and/or histology as reference.

RESULTS: A tumor was found in 40 cases (33.3%): 30 were low grade (LG) and 10 were high grade (HG). Overall sensitivity was 65% for Bladder Epicheck® and 42.5% for cytology, increasing to 100% for Bladder Epicheck® and 90% for cytology if we consider only HG tumors. Overall specificity of Bladder Epicheck® was 81.2% and of cytology 93.7%. The PPV and the NPV were 63.4% and 82.2% for Bladder Epicheck® and 77.2% and 76.5% for cytology. Considering an EpiSCORE cutoff >75 instead of 60, the specificity of Bladder Epicheck® improves to 89% and the PPV to 74.2%. If we evaluate the 2 tests together, we assist only to a slight improvement of sensitivity and NPV.

CONCLUSIONS: Due to the high sensitivity for HG tumors, the Bladder Epicheck® test can be used in the follow-up of the patients with UTUC after conservative treatment to reduce the unnecessary procedure with a very low risk to miss a HG recurrence or progression.

SC16
A novel bladder cancer diagnostic technique based on urine multimodal spectroscopy

S. Morselli, A. Manera, E. Baria, R. Cicchi, A. Liaci, L. Moscardi, A. Romano, F. Peschiera, L. Mazzola, R. Campi, A. Sebastianelli, G. Nesi, F.S. Pavone, M.J. Ribal, S. Serni, M. Gacci (Florence)

BACKGROUND: Past studies have demonstrated the effectiveness of multimodal fiber optic spectroscopy (MFOS) to correctly assess urothelial cancer (UC) presence in *ex-vivo* tissue, plus providing reliable grading and staging information. A further evolution of the methodic is represented by the possibility to provide this information from urine samples analysis.

METHODS: A clinical study started in January 2021 in an academic referral hospital, after an ethical appraisal. Patients undergoing urological endoscopic surgical operations (*i.e.*, TURB, TURP, Holep, Greenlep, URS or RIRS) were prospectively enrolled and urine samples were collected from each one before surgery. UC presence was assessed through endoscopy at first and then with confirmatory pathological analysis. Confounding factors – such as concomitant or incidental kidney or prostate cancer diagnosis – were considered as exclusion criteria. All patients signed informed consent for participation. A principal component analysis (PCA) plus cubic support vector machine (SVM) mathematic model was used to define the cutoff for MFOS in the first 100 patients and then applied to the subsequent patients, to verify the reliability of MFOS.

RESULTS: A total of 410 patients were enrolled, of whom 8 were excluded for incidental prostate cancer diagnosis, 1 for kidney cancer diagnosis and 12 for insufficient sample; therefore, a total of 389 patients were included in the study. Patients with UC were 175 (45.0%), while 214 (55.0%) were negative. In the first 100 patients (calibration), MFOS provided a 100% sensibility and specificity, plus providing the same results for grading. Regarding the technique, the model developed kept a high accuracy in correctly assessing UC presence even in the largest sample, while the discrimination between high- and low-grade UC slowly dropped in a larger sample.

CONCLUSIONS: Despite being an experimental methodic, MFOS showed the possibility to correctly assess UC presence at surgery and pathology from just a urine sample, thus demonstrating its feasibility. Strength points are the calibration of the methodic that can be further improved with larger samples (not only first 100), and the possibility to predict grading compared to gold standard cytology. However, larger randomized clinical trials are mandatory to verify these results.

SC17
Accuracy of the CUETO, EORTC 2016 and EAU 2021 scoring models and risk stratification tables to predict outcomes in high-grade non-muscle-invasive urothelial bladder cancer

B. Bucca, V. Asero, C.M. Scornajenghi, P. Dipinto, A. Sciarra, E. De Berardinis, S. Basran, M.L. Eisenebrg, B.I. Chung, W. Krajewsk, Ł. Nowak, T. Szydełko, B. Małkiewicz, F. Del Giudice (Rome)

BACKGROUND: Non-muscle-invasive bladder cancers (NMIBC) constitute 3-quarters of all primary diagnosed bladder tumors. For risk- adapted management of patients with

NMIBC, different risk group systems and predictive models have been developed. This study aimed to externally validate EORTC2016, CUETO and novel EAU2021 risk scoring models in a multi-institutional retrospective cohort of patients with high-grade NMIBC who were treated with an adequate BCG immunotherapy.

METHODS: The Kaplan-Meier method estimates for recurrence-free survival and progression-free survival were performed, predictive abilities were assessed using the Concordance Index (C-Index) and Area Under the Curve (AUC).

RESULTS: One thousand six hundred ninety patients were included, and the median follow-up was 51 months. For the overall cohort, the estimates recurrence-free survival and progression-free survival rates at 5 years were 57.1% and 82.3%, respectively. The CUETO scoring model had poor discrimination for disease recurrence (C-Index/AUC for G2 and G3 grade tumors: 0.570/0.493 and 0.559/0.492) and both CUETO (C-Index/AUC for G2 and G3 grade tumors: 0.634/0.521 and 0.622/0.525) EAU2021 (C-Index/AUC: 0.644/0.522) had poor discrimination for disease progression.

CONCLUSIONS: Both the CUETO and EAU2021 scoring systems were able to successfully stratify risks in our population but presented poor discriminative value in predicting clinical events. Due to the lack of data, model validation was not possible for EORTC2016. The CUETO and EAU2021 systems overestimated the risk, especially in highest-risk patients. The risk of progression according to EORTC2016 was slightly lower when compared with our population analysis.

SMART (SC18-SC30)

Prostate cancer: diagnosis and screening 1

SC18
Gleason Score 6 prostate cancer recurring after radiotherapy or ablation: an indolent disease. Outcomes from a large multicenter salvage radical prostatectomy cohort

SC19
The microUS preoperative prediction in detection of extraprostatic extension of prostate cancer: an update of a single institutional prospective series

SC20
The impact of a standardized pathway in reducing morbidity after transrectal prostate biopsy

SC21
Impact radiologic center on diagnostic test accuracy of PI-RADS category 3 on MRI for detecting clinically significant prostate cancer

SC22
Comparing target prostate biopsy alone approach *vs.* target plus standard in naïve patients with positive MPMRI: an institutional study

SC23
Peritumoral inflammation in prostate biopsy core: deciphering the immune infiltrate

SC24
Micro-ultrasound guided prostate biopsies: results from a single high-volume center

SC25
Lesions' location in prostate cancer: agreement between multiparametric magnetic resonance, targeted, cognitive and systematic biopsy, and radical prostectomy specimens

SC26
Use of PSA density for risk stratification of PIRADS 3 lesions in prostate biopsy

SC27
Diabetes and prostate cancer: clinical characterization at diagnosis from a large cohort of patients from PROST IT 2

SC28
Diet quality and prostate cancer, is there any association? results from a case-control study in Mediterranean population

SC29
The role of PSA doubling time thresholds in predicting clinical recurrence after biochemical recurrence in surgically treated prostate cancer patients: a stage-by-stage analysis

SC30
Prostatic inflammation impact on PSA values and prostate cancer diagnosis: implication for prostate cancer screening

SC18

Gleason Score 6 prostate cancer recurring after radiotherapy or ablation: an indolent disease. Outcomes from a large multicenter salvage radical prostatectomy cohort

G. Calleris, G. Marra, F. Conte, M. Oderda, N. Benfant, P. Rajwa, M. Ahmed, A. Abreu, G. Cacciamani, L. Ribeiro, T. Westhofen, Y. Raskin, J.A. Smith, S. Joniau, L. Rodriguez-Sanchez, R. Sanchez-Salas, A. Kretschmer, P. Cathcart, I. Gill, R.J. Karnes, D. Tilki, S.F. Shariat, K. Touijer, P. Gontero (Turin)

BACKGROUND: Salvage radical prostatectomy (sRP) is associated with poor functional outcomes and relatively high complication rates. In a primary setting, Gleason Score 6 (GS6) prostate cancer (PCa) shows little if any metastatic dissemination potential, having a peculiar genetic and clinical profile. However, the behavior of ISUP 1 PCa recurring after previous PCa treatment including radiotherapy and/or ablation is scarcely reported in the literature. We aim to assess oncological and survival outcomes of radio- and/or ablation-recurrent GS6 PCa.

METHODS: We retrospectively collected clinical and pathological data of 1265 sRP for biopsy-proven locally recurrent prostate cancer (PCa) after radiotherapy or ablation treatment at 14 tertiary referral centers from 2000 to 2021. We included in this analysis all GS6 patients at confirmatory biopsy pre-sRP (cohort 1) and at sRP histology (cohort 2). Kaplan-Meier survival analysis was performed and concordance between pre-sRP biopsy and sRP histology was assessed. Predictors of upgrading at sRP histology in cohort 1 were investigated by logistic regression.

RESULTS: We included GS6 recurrent PCa at biopsy pre-sRP (cohort 1: N.=142) and at sRP (cohort 2: N.=52). The majority had radiotherapy and/or brachytherapy (83.8% in cohort 1; 78.8% in cohort 2) and whole-gland treatments (91% cohort 1; 85.7% cohort 2). In cohort 1, 10-year metastasis-free survival (MFS), CSS and OS were 79% (95% CI 61-89), 98% (95-99) and 89% (78-95), respectively. Upgrading at sRP occurred in 63.7%, 35.5% had a pT3 stage and 13.4% positive nodes. We could not identify reliable predictors of upgrading at sRP definitive histology based on preoperative data in cohort 1, irrespectively of initial biopsy GS, preoperative PSA, and primary treatment type. In cohort 2, 10-year MFS, CSS and OS were 98% (86-100), 98% (86-100) and 88% (60-97); pT3 and pN1 disease were found in 13% and 1.9%, respectively. Overall complications, high-grade complications and severe incontinence were experienced by >50%, >10% and >18% of men respectively. We acknowledge the retrospective nature of the study, the absence of preoperative MRI data and of centralized pathological review as the main limitations.

CONCLUSIONS: GS6 sRP-proven PCa recurring after non-surgical primary treatment has almost no metastatic potential whilst the morbidity of the procedure remains remarkable. However, a significant proportion of GS6 at pre-sRP biopsy is upgraded at sRP. Overtreatment should be avoided and methods to improve pre-sRP biopsy accuracy and risk-stratification are urgently needed.

SC19

The microUS preoperative prediction in detection of extraprostatic extension of prostate cancer: an update of a single institutional prospective series

F. De Carne, V. Fasulo, E. Beatrici, P. Arena, P.P. Avolio, D. Maffei, M. Paciotti, S. Mancon, G. Chiarelli, A. Saita, R. Hurle, M. Lazzeri, N.M. Buffi, G. Lughezzani (Rozzano, Milan)

BACKGROUND: An optimal stratification of patients with localized prostate cancer (PCa) before robotic-assisted radical prostatectomy (RARP) allows performing a tailor-made surgery, potentially providing a nerve-sparing procedure even in those patients with high-risk disease. Nowadays, the accuracy of clinical parameters to determine extraprostatic extension (EPE) is moderate; therefore, a new imaging tool capable of providing a more accurate assessment is in order. The aim of this study was to evaluate the added value of microUS in the preoperative prediction of EPE.

METHODS: Our prospective single-institutional cohort study enrolled patients with histology-proven PCa scheduled for RARP. We included patients with PSA<20 ng/mL, prostate volume <100 mL and a preoperative microUS investigation. MRI-derived features (curvilinear contact length [CCL], capsular bulging, visible extracapsular extension [ECE]), along with microUS features (such as the presence of hypoechoic halo and obliteration of the vesicle-prostatic angle) were tested as predictors of EPE. Multivariable logistic regression models were fitted to test the accuracy of clinical parameters (total PSA, ISUP biopsy and digital rectal examination [DRE]) plus microUS parameters for the prediction of EPE.

RESULTS: Overall, 230 patients were prospectively recruited. Besides CCL, all predictors were associated with non-organ confined disease (P<0.001). Histological findings showed that 131 (56.9%) and 99 (43.0%) had respectively a pT2 and a pT3 or greater disease. Individuals with only 1 predictor had a rate of non-organ confined PCa of 16.7% (OR 3.12), compared to 93.8% in those where 4 predictors were simultaneously observed (OR 75.0). At MLRM, the most significant risk factors for EPE were visible ECE (OR 3.23; P<0.004), positive DRE (OR 2.5; P=0.015), and PSA (OR 1.06; P=0.03). The AUC increased from 0.809 to 0.841 when considering the clinical model alone and the model including both clinical and microUS features respectively. The DeLong test for equality showed a significant difference between the two curves (P=0.04).

CONCLUSIONS: Our results confirm that microUS may represen0t an accurate tool for the evaluation of non-organ confined PCa. Future studies should externally validate our findings and determine the impact of this tool in the surgical and oncological outcomes of RARP.

SC20

The impact of a standardized pathway in reducing morbidity after transrectal prostate biopsy

A. Alberti, R. Nicoletti, E. Dibilio, G.R. Resta, I. Mattei, D. Paganelli, E. Ciaralli, D. Stracci, P. Polverino, A. Pecoraro, A. Manera, F. Sessa, A. Sebastianelli, S. Giancane, P. Spatafora, R. Campi, S. Serni, M. Gacci (Florence)

BACKGROUND: According to the EAU Guidelines, transrectal prostate biopsies (TRPB) should be put aside in favor of the transperineal (TP) approach, due to the reported lower infectious risk. However, TRPB is still widely adopted, and no significant differences have been established considering other complications and overall cancer detection rate (CDR). Our study aims to evaluate the impact of a standardized pathway for TRPB on the rates of postoperative complications, while assessing its CDR.

METHODS: After Ethical Committee approval, we retrospectively collected data from all patients who underwent MRI-targeted TRPB at a single Academic Center from January 2020 to March 2022. In our structured multistep pathway, all patients received one prophylactic dose of Fosfomycin Trometamol 3g and a cleansing enema 3 hours before TRPB. Local disinfection with povidone-iodine and local anesthesia with Lidocaine/Prilocaine 5% cream was performed. All biopsies were performed under real-time ultrasound guidance with a dedicated fully integrated mobile fusion imaging platform (KOELIS Trinity® MRI TPUS Biopsy System; KOELIS, Grenoble, France). After the biopsy, the patients were asked to stay at least 1 hour in a discharge room, waiting for the first spontaneous urination, with subsequent evaluation by a healthcare professional to rule out any adverse events. Upon discharge, a dedicated emergency phone number was provided to patients. A second dose of Fosfomycin Trometamol 3 g after 24h was administered. Complications were classified according to Clavien-Dindo (CD) Classification. Multivariable logistic regression analysis assessed the independent predictors of complications.

RESULTS: Overall, 344 patients were included, of which 57 (16.5%) were lost to follow-up. Median age was 66 years old (IQR: 61-72). Median number of bioptic cores was 16 (IQR: 15-18), with a median of respectively 4 (IQR: 4-6) and 12 (IQR: 10-12) cores for target and random samplings. Of the 287 patients who completed follow-up, 151 (44%) didn't report any complication after TRPB. CD grade 1 complications were reported by 125 (43.6%) patients, including short-lasting gross hematuria (85/287, 29.6%), hematochezia (12/287, 4.2%), hemospermia (16/287, 5.6%) and urinary retention (12/287, 4.2%) with the need of temporary catheterization. Infections treated with oral antibiotics (CD grade 2) occurred in 11 (3,8%) patients. No major complication (CD>2), including sepsis, was observed; no hospital re-admissions were registered. At multivariable analysis, the only independent predictors of complications were age at biopsy <75 years (OR 0.188 [CI:0.065–0.545], P=0.002) and Charlson Comorbidity Index ≤2 (OR 0.580 [CI:0.357–0.943], P=0.028). Overall CDR was 59.9%, with 43.3% of "clinically significant" tumors (Grade Group ≥2).

CONCLUSIONS: Our experience suggests that a standardized TRPB pathway could be as safe and effective for PCa detection as the TP approach. Further research is needed to identify which patients may benefit the most from each approach.

SC21
Impact radiologic center on diagnostic test accuracy of PI-RADS category 3 on MRI for detecting clinically significant prostate cancer

A. Totaro, M. Campetella, V. Panebianco, V. Di Paola, M. Pecoraro, R. Manfredi, P. Bassi, C. Gandi, E. Scarciglia, A. Creti, F. Marino, M. Racioppi, E. Sacco (Rome)

BACKGROUND: High variability in diagnostic test accuracy (DTA) of multiparametric prostate magnetic resonance imaging (MRI) still exists. The aim of our study is to assess the accuracy of MRI across academic (AC) and non-academic radiologic centers (NAC).

METHODS: In this prospective observational study, we evaluated patients who underwent prostate MRI and MRI-fusion biopsy (MRI-TBx) between February 2017 and April 2020 for prostate cancer suspicion. We evaluated the probability of getting an inaccurate diagnosis among AC and NAC for PI-RADS v2 Score 3 lesions using a bivariate probit model.

RESULTS: We analyzed 514 subjects with 686 MRI lesions. In 243 of cases (47.3%), MRIs was performed in ACs and 52.7% (271) in NACs. The detection rate (DR) of clinically significant prostate cancer (csPCa) for PI-RADS-3 lesions significantly differed across ACs and NACs (15.4% *vs.* 54.1%; P<0.001). In the AC cohort, PI-RADS-3 lesions were associated to ISUP GG1 in 84.6% and ISUP GG2 in 15.4% of cases. In NACs the distribution of ISUP GG among PI-RADS-3 lesions was 45.9%, 27%, 5.4% and 13.5% for ISUPGG 1, 2, 3, and 4-5, respectively. The bivariate probit model showed that the predicted conditional probability of getting an inaccurate diagnosis for PI-RADS-3 significantly decreased among ACs compared to NACs (marginal effect = -4.10%, P=0.001). MRIs by academic centers have a higher level of accuracy.

CONCLUSIONS: Radiologic center significantly impact the DTA of PI-RADS category 3 lesions on MRI for csPC detection. The results of this study shed a light on the importance of deliver a high-quality prostate cancer pathway. Further development of quality criteria, assessment and training platforms is needed.

SC22
Comparing target prostate biopsy alone approach *vs.* target plus standard in naïve patients with positive MPMRI: an institutional study

S. Rapisarda, A. Pecoraro, M. Marini, S. Grosso, R. Bertoloni, L. Aresu, A. Nazaraj, A. Marciano, G. Grosso (Peschiera del Garda, Verona)

BACKGROUND: In the era of mpMRI guided target fusion biopsy (FB), the role of concomitant standard biopsy (SB) in naïve patients remains under scrutiny. The aim of this study was to compare the incidence of the overall and clinically significant prostate cancer (PCa) detection rate (DR) between FB *vs.* FB+SB.

METHODS: We reviewed our institutional prospectively maintained database. FB was performed under ultrasound guidance using the Stereotatic Navigated biopsy BiopSee® (Tema Sinergie S.p.A, Faenza, Ravenna, Italy); three to six target samples were obtained for each index lesion. T2-weighted axial, sagittal and coronal sequences of the mpMRI were upload into MRI/US fusion device Hitachi Arietta v90 (EOS S.r.l., Padua, Italy) with integrated real time ultrasonography. SB was performed in accordance with the protocol by Rodríguez-Covarrubias. DR of PCa and clinically significant PCa (any cancer with Gleason Score ≥4+3 and/or any cancer occupying ≥6 mm of a biopsy core) were evaluated. Concordance between FB *vs.* SB was evaluated. Fisher's Exact Test and Mann-Whitney Test were applied.

RESULTS: We analyzed 100 naïve biopsy patients who performed FB+SB from January 2020 to April 2021. The overall DR was 85% *vs.* 87%, for the SB *vs.* FB, respectively (Δ2%; P=0.85). The overall clinically significant PCa DR was 40 *vs.* 42%, for the SB *vs.* FB, respectively (Δ2%; P=0.94). The addition of SB within the 6 patients with negative FB allowed the diagnosis of 4 additionally patients; of those only no one had a clinically significant PCa (Δ3%; P=0.95).

CONCLUSIONS: Our results showed that our biopsy protocol (FB+SB) in naïve biopsy patients has a high DR, with

no statistical difference between FB *vs.* FB+SB. According to our results, SB did not add any clinical advantage in the diagnosis of clinically significative PCa within biopsy naïve patients who underwent FB alone.

SC23
Peritumoral inflammation in prostate biopsy core: deciphering the immune infiltrate

F. Guzzi, F. Sanguedolce, U. Falagario, M. Finati, A. Ninivaggi, A. Fanelli, L. Montrone, O. Selvaggio, P. Annese, G.M. Busetto, C. Bettocchi, G. Carrieri, L. Cormio (Foggia)

BACKGROUND: We recently developed the Prostate Inflammation Score (PIS) as a readily available parameter that can be assessed by the pathologist during microscopic evaluation of the prostate. This study aims to evaluate the immune infiltrate in prostate biopsy cores using immune histochemistry (IHC) and decipher the type and number of immune cells of each PIS class.

METHODS: The PIS was used to categorize patients in 3 group: 1) PIS 1

no inflammatory cells or scattered inflammatory cell infiltrate without nodules; 2) PIS 2

interstitial Inflammatory cell infiltrate organized in lymphoid nodules but no glandular disruption; and 3) PIS 3

interstitial infiltrate with glandular disruption. For the present study we randomly selected 21 patients with PIS 2 and 18 patients with PIS 3. CD8, CD20 and CD4 antibodies were used for IHC. Each slide was digitally scanned, manual segmentation of the areas of interest (cancer foci and glandular tissue) was performed by the pathologist and an artificial intelligence algorithm determined the connectivity of membranes stained for each marker by automated image analysis. We compared clinical and IHC quantitative features in PIS 2 *vs.* PIS 3 patients. As a sensitivity analysis, all calculation were repeated in patients with a negative biopsy and patients with a positive biopsy. Finally, we compared IHC quantitative features in patients with no cancer or low-grade PCa *vs.* patients with csPCa.

RESULTS: CD4 connectivity values were consistently increased in negative biopsies and those with low-grade cancer as compared to samples with high-grade cancer (P=0.021). Significantly higher CD8 connectivity values were seen in PIS 3 *vs.* PIS 2 group (P=0.024). Finally, increased CD8 expression levels were detected in the extratumoral region of positive PIS 3 biopsies as compared to PIS 2 (P=0.017).

CONCLUSIONS: Peritumoral inflammation assessed by the PIS in prostate biopsy cores is associated with different patterns of immune cells infiltration in prostate biopsy cores. Subsets of CD8+ T cytotoxic and CD4+ T helper lymphocytes, which have opposite roles in the immune response, are represented in greater number in neoplastic and benign prostates, respectively. The more inflamed is the prostate, the higher is the amount of CD8+ cells. The immune microenvironment of prostate cancer deserves to be further explored as a promising prognostic and immunotherapy biomarker.

SC24
Micro-ultrasound guided prostate biopsies: results from a single high-volume center

M. Aljoulani, D. Maffei, V. Fasulo, P.P. Avolio, F. De Carne, S. Moretto, P. Arena, N. Frego, F. Dagnino, G. Chiarelli, M. Lazzeri, A. Saita, R. Hurle, G. Lughezzani, G. Guazzoni, N.M. Buffi, P. Casale (Rozzano, Milan)

BACKGROUND: While mpMRI has progressively gained an important role in the prostate cancer (PCa) diagnostic pathway, its widespread use in clinical practice is still limited by cost-effectiveness considerations. Micro-ultrasound (micro-US) is a new imaging modality with resolution down to 70 μm. This study reports on our clinical experience after introducing micro-US into our prostate biopsy clinic.

METHODS: Data on 1053 consecutive patients imaged with the ExactVu micro-US system (Exact Imaging, Markham, ON, USA) between October 2017 and October 2022 were prospectively collected. All patients were scheduled for prostate biopsy due to clinical suspicion of PCa. The PRI-MUS protocol (Exact Imaging) was used to locate targets on micro-US. Lesions with a PRI-MUS Score ≥3 were targeted. Patients were also subjected to systematic prostatic biopsies. The presence of overall PCa and of clinically significant PCa (defined as a Gleason Score ≥7; csPCa) was determined and the diagnostic performance of micro-US was assessed. Logistic regression models (LRMs) were fitted to test the predictors of csPCa.

RESULTS: Mean age was 66.22 (SD 18.31) years, median total PSA was 9.0 (IQR 6.8-15) ng/mL and median prostate volume was 50.0 mL (IQR 35.0-70.0). Overall, 404/1053 (38.4%) patients were in the repeat biopsy setting, with 150 (14.2%) patients on active surveillance. Micro-US detected prostate lesions with a PRI-MUS Score of 3, 4 and 5 in respectively 111 (10.5%), 463 (44.0%) and 214 (20.3%) patients, while in 255 (24.2%) individuals micro-US did not identify any target. Overall PCa and csPCa detection rates were 84.1% (467) and 87% (340), respectively. Micro-US provided high sensitivity, with 87% (340/391) of csPCa patients having at least one PRI-MUS Score ≥3 lesion. Similarly, NPV was 82% with 205/250 patients with no micro-US targets receiving a benign or insignificant PCa diagnosis (after systematic and MRI-target biopsy). Conversely, PPV and specificity were lower (43.8% and 29.5%), likely due to over-targeting. The ratio between csPCa and overall PCa diagnosed increased with increasing PRIMUS Score (61.9%, 66% and 91.2% for PRIMUS 3, 4 and 5 lesions). At multivariable LRMs, after adjusting for several confounders, patients with a PRI-MUS 4 or 5 lesion had respectively a 2.27 (95% CI: 1.31-3.90; P=0.003) and 5.58 (95% CI: 2.93-11.02; P<0.001) higher risk of harboring csPca compared to those with a micro-US PRI-MUS <3 pattern. Besides increasing PRI-MUS Score, age (OR: 1.068; 95% CI: 1.042-1.094; P<0.001), prostate volume (OR 0.984; 95% CI: 0.977-0.991; P<0.001), total PSA (OR: 1.048; 95% CI: 1.011-1.086; P<0.001), and initial biopsy setting (OR: 2.478; 95% CI: 1.679-3.657; P<0.001) achieved the independent predictor status.

CONCLUSIONS: Micro-US is a promising new imaging modality showing high sensitivity to detect csPCa. In addition, the system appears to be capable of reliably excluding the presence of csPCa in the great majority of patients.

SC25
Lesions' location in prostate cancer: agreement between multiparametric magnetic resonance, targeted, cognitive and systematic biopsy, and radical prostectomy specimens

M. Pacini, P. Greco, E. Sollazzi, A. Perotti, G. Macrì, F. Claps, A. Zucchi, F. Gregori (Pisa)

BACKGROUND: Multiparametric magnetic resonance (mpMRI) brought significant progress in clinical staging and diagnosis of prostate cancer (PCa), improving the effects of prostate biopsy (PB). There is still a lack of concordance between the results obtained from mpMRI, PB and the final surgical specimen (SS). In fact, offering only a targeted biopsy leads to a missed diagnosis of approximately 9% of clinically significant prostate cancer (CSPC). On the other hand, performing a cognitive+systematic PB guarantees a greater agreement between presurgery and SS histology. The aim of this study was to evaluate localization agreement between mpMRI lesions and histology obtained by targeted PB, cognitive+systematic PB and radical prostatectomy SS.

METHODS: Clinical and pathological data were retrospectively collected from 112 patients. All of them were diagnosed with CSPC after mpMRI and PB; furthermore, between 2019 and 2022, they were treated with robotic assisted laparoscopic radical prostatectomy (RALP). All patients had at least one PIRADS V2³3 at mpMRI and raised PSA levels with a subsequent PB. Sixty-one patients (54.46%%) received targeted biopsies (TB) (3 or 4 targeted cores + 6 systematic specimens). Fifty-one patients (45.53%) received both cognitive and systematic (C+S) biopsies (3 or 4 cognitive cores + 16 systematic specimens). C+S biopsies were conducted according to the following template: right base, left base, parasagittal right, parasagittal left, right lateral mid, left lateral mid, right apex, left apex. The same template to localize mpMRI lesions and disease locations in SS was employed. For each patient we evaluated how many areas of the above-mentioned template resulted as a PIRADS V2³3 at mpMRI or positive for CSPC at PB compared to the SS histology. After that, a mean of the areas identified by each method was made.

RESULTS: Compared to results obtained from pathological analysis of prostate macrosections after RALP, mpMRI was able to point out about 51% of CSPC areas. Whereas TB detected 62% of the areas if compared to SS. The best results were obtained by C+S biopsy: it identified about 82% of CSPC areas. The differences between mpMRI and TB as compared to C+S biopsy in locating CSPC areas was statistically significant.

CONCLUSIONS: PCa diagnosis by mpMRI and TB showed low levels of concordance, showing a substantial discrepancy between the methods used for clinical and pathological tumor identification and characterization, respectful to the definitive SS analysis obtained from the whole prostate gland after RALP. The comparison between cognitive/systematic and TB showed significant differences in terms pointing out CSPC areas. Nowadays, the methods used for early diagnosis and staging of PCa seem to be inefficient and inaccurate. Either tumor upgrading or upstaging frequently found at SS pathological analysis may be interpreted if based on the limitations above described. Other methods for PCa early diagnosis such as novel biomarkers or different criteria for PB are mandatory to improve the current clinical standards.

SC26
Use of PSA density for risk stratification of PIRADS 3 lesions in prostate biopsy

S. Soldano, M. Zingarelli, A.P. Lorusso, S. Forte, G.V. Palella, G. Papapicco, D.F. Colatorti, A.M. Capurso, G. Lippolis, L. Rella, F. Falsetti, U. Carbonara, G. Lucarelli, P. Ditonno (Bari)

BACKGROUND: Multiparametric prostate MRI and PIRADS Score have improved the diagnosis of prostate cancer (PCa); however, the additive use of PSA density (PSAd) in PIRADS 3 lesions to better select patients at risk of malignancy requires further studies. The aim of this study was to evaluate if PSA density can provide complementary insights into prostate cancer diagnostic in PIRADS 3 lesions.

METHODS: A retrospective analysis was performed on patients with PIRADS 3 lesions who underwent systematic and MRI-transperineal ultrasound fusion guided biopsy between 2017 and 2022. Total PSA and prostate volume calculated with MRI were used for PSAd estimation. The localization of the PIRADS 3 lesions was categorized in peripheral (PZ) and transitional zone (TZ). We used logistic regression with regression method to simulate a model to differentiate malignant and benign prostatic biopsy. A P value <0.05 was considered statistically significant. The receiver operating characteristic (ROC) curve was used to evaluate the performance of PSA density in predicting prostate cancer in patients with PIRADS 3 lesions. The χ^2 test was used to assess a statistically significance difference between the different groups.

RESULTS: One hundred sixty-eight men were included in this study: 87 (52%) PIRADS 3 lesions were located in the PZ and 81 (48%) in TZ. PCa was diagnosed in 32 PZ (37%) and 19 TZ (23%), respectively. At multivariate analysis high PSAd value was the only predictive factor for positive biopsy in patients with PIRADS 3 lesions of the peripheral zone (P=0.0017). PSAd cutoff value predictive of Pca was calculated using AUC in ROC analysis. (cut-off value =0.135; AUC=0.617, 95% CI: 0.54-0.691, P<0.0167). PIRADS 3 lesions localized in PZ were more likely to be positive (22/41, 53,7 %) compared to lesions in the TZ (8/32, 25%) for PSA density values ≥ 0,135 (P=0.0142).

CONCLUSIONS: The use of PSAd in patients with PIRADS 3 lesions of the peripheral zone provide an additional tool to increase the diagnostic accuracy of PCa.

SC27
Diabetes and prostate cancer: clinical characterization at diagnosis from a large cohort of patients from PROST IT 2

M. Gacci, R. Nicoletti, F. Sessa, C. De Nunzio, A. Porreca, S.M. Magrini, V. Mirone, A. Tubaro, S. Maggi, M. Noale, S. Serni (Florence)

BACKGROUND: The is a clear association between patients with type 2 diabetes and an increased risk of common cancers. However, the relationship between DM and Prostate Cancer (PCa) seems to be more complex and remains unclear and controversial. The aim of our study is to investigate the prevalence of type 2 diabetes mellitus (T2DM) at prostate cancer diagnosis and its association with cancer severity and prostate-specific antigen (PSA) levels in a sample of Italian patients enrolled within the National Research Council (CNR) Prostate cancer monitoring project in Italy (Pros-IT CNR). Secondly, to describe the quality of life at diagnosis of patients with and without diabetes mellitus.

METHODS: We queried Tìthe PROST-IT2 database to identify patients with T2DM, Demographic characteristics, anamnestic data (weight, height, smoking status), pharmacological treatments, self-reported T2DM, initial cancer diagnosis, clinical staging, and quality of life measures were evaluated at baseline and after follow-up. Characteristics of patients at prostate cancer diagnosis were compared according to the presence of T2DM.

RESULTS: A total of 263 (15.5%) Pros-IT CNR participants reported T2DM. As compared with patients without T2DM, Patients with T2DM were significantly older (mean age 70.6±6.1 *vs.* 68.5±7.6 years), obese (BMI≥30 kg/m^2; 25.3% *vs.* 13.7%), less smokers (10.7% *vs.* 14.5%), worst clinical T-staging at diagnosis (T3 or T4 for 16.2% of patients *vs.* 10.8% in the group without diabetes) and had more frequently a high D'Amico risk (44.5% *vs.* 34.7%). Patients with T2DM obtained significantly lower quality of life scores at diagnosis (P<0.05) in relation to sexual function of the UCLA-PCI, and to physical component of the SF-12. At multivariable logistic regression model with outcome prostate cancer, T2DM patients had a 58% higher risk of having a high D'Amico risk at diagnosis (OR=1.58, 95% CI (1.07-2.33). A nonsignificant difference in PSA was found for T2DM patients, with a change in PSA geometric mean of 3.2% (95% CI -7.5, 15.2). A nonsignificant reduction in PSA was detected also for overweight (25≤BMI<30 kg/m^2) and obesity (BMI≥30 kg/m2).

CONCLUSIONS: Diabetic patients with prostate cancer would appear to have a more unfavorable disease to diagnose. However, further studies are needed to confirm our findings.

SC28
Diet quality and prostate cancer, is there any association? results from a case-control study in Mediterranean population

A. Lo Giudice, M.G. Asmundo, O. Maugeri, G.I. Russo, S. Cimino (Catania)

BACKGROUND: The aim of this study was to investigate in a specific Mediterranean population of Sicily (Southern Italy)

the role of quality diet, assessed with a specific tool in prostate cancer incidence, also considering other factors (*i.e.*, age, genetics, and lifestyle habits).

METHODS: A population-based case-control study on the association between prostate cancer and dietary factors was conducted from January 2015 to December 2022 in a single institution of the municipality of Catania (Southern Italy). One hundred eighteen histopathologically-diagnosed PCa cases were collected. A total of 237 controls were selected from a sample of 2044 individuals included in a cohort study: individuals were randomly selected among the same reference population and were matched by age, BMI, and smoking status with cases. Demographics data (including age and educational level) and lifestyle characteristics (including physical activity, smoking, and drinking habits) were collected. Dietary data were collected by using two food frequency questionnaires (FFQs). The Diet Quality Index International (DQI-I) has been used to assess the quality of diet in patients. Diet quality scores were tested for normality distribution with the Kolmogorov-Smirnov Test, and it followed a slightly asymmetric normal distribution due to extreme values of the upper side. Mann-Whitney U test and Kruskal-Wallis Test were used to compare differences in intakes between groups, as appropriate. Association between diet quality scores was calculated through logistic regression analysis.

RESULTS: The univariate logistic regression analysis showed that high scores in quality diet adherence where negatively associated with PCa (OR=0.38, 95% CI: 0.22-0.67); the multivariate logistic regression analysis adjusted for potential confounding factors (including age, energy intake, weight status, smoking status, alcohol consumption, physical activity level), and for adherence to the Mediterranean diet, confirmed the univariate logistic regression results (OR=0.25, 95% CI: 0.10-0.59). Regarding advanced PCa cases, the univariate logistic regression analysis showed that high scores in quality diet adherence where negatively associated with advanced PCa (OR=0.11 95% CI: 0.01-0.87), despite there is no significant association in the multivariate analysis adjusted for potential confounding factors (including age, energy intake, weight status, smoking status, alcohol consumption, physical activity level) and adherence to the Mediterranean diet (OR=0.29, 95% CI: 0.03-3.10).

CONCLUSIONS: Our results showed a protective function of high-quality diet for prostate cancer. These results should be considered when counseling patients and, also, should represent a starting point for further research to establish a causal relationship and to better understand the mechanisms behind this association. Patients may benefit from incorporating more plant-based food, whole grains, and lean protein sources into their diets as a means of reducing their risk.

SC29
The role of PSA doubling time thresholds in predicting clinical recurrence after biochemical recurrence in surgically treated prostate cancer patients: a stage-by-stage analysis

L. Nocera, G. Gandaglia, A. Stabile, V. Cucchiara, E. Mazzone, G. Sorce, F. Pellegrino, S. Scuderi, F. Barletta, D. Robesti, R. Leni, M. De Angelis, A. Pellegrino, M. Longoni, P. Scilipoti, L. Quarta, P. Zaurito, A. Gallina, N. Fossati, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Not all prostate cancer (PCa) patients experiencing biochemical recurrence (BCR) after radical prostatectomy (RP) ultimately develop clinical recurrence (CR). According to the EAU Guidelines, the risk of CR should be estimated using PSA doubling time (PSA-DT) in addition to ISUP grade group to categorize patients in BCR risk groups (low- *vs.* high-risk). However, the proposed 12-month cutoff has never been validated in stage-by-stage analyses.

METHODS: Overall, 795 PCa patients treated with RP between 1995 and 2021 who exhibited at least one PSA≥0.1 ng/mL during follow-up were identified. Patients were stratified according to pathological status (T2N0 *vs.* T3-4N0 *vs.* N1). CR was defined as the onset of metastases after BCR. The two first detectable PSA values were available for all patients. Multivariable Cox regression models examined the impact of PSA-DT on CR after adjusting for pT stage, ISUP Grade Group, margins, and adjuvant therapies. In the N1 subgroup, additional adjustment for the number of positive nodes was performed. The C-Index identified the PSA-DT cutoff with highest accuracy after stratifying patients according to pathological status.

RESULTS: Overall, 299 (38%), 242 (30%) and 254 (32%) patients had pT2, pT3-4 and pN1. Median follow-up was 104 months. A total of 243 patients experienced CR. The 10-year CR-free survival rate was 68.4%. Pathologic T stage, ISUP Grade Group, positive margins, and adjuvant therapies were predictors of CR (all P<0.05). The PSA-DT cutoff associated with the highest accuracy in predicting CR was 13 months for pT2 (C-Index: 75%). When pT2 patients were stratified

according to this cut- off, the 10-year CR-free survival rates were 96 *vs*. 82% for a PSA-DT above *vs*. below the threshold. In pT3-4, the PSA-DT associated with the highest accuracy was 20 months (C-Index: 66%). When pT3-4 individuals were stratified according to this cutoff, the 10-year CR-free survival rates were 83.4 *vs*. 62.6%. In patients with pN1, the PSA-DT associated with the highest accuracy was 8 months (C-Index: 68%). When pN1 patients were stratified according to this cutoff, the 10-year CR- free survival rates were 61 *vs*. 32%.

CONCLUSIONS: In defining high-risk patients, EAU Guidelines omit pathologic T stage, which is however an independent predictor of CR. The proposed PSA-DT threshold showed high predictive accuracy only in pT2 diseases. Conversely, PSA-DT cutoffs are characterized by a low discrimination in men with more aggressive pathologic features.

SC30
Prostatic inflammation impact on PSA values and prostate cancer diagnosis: implication for prostate cancer screening

S.M. Bruno, A. Ninivaggi, F. Guzzi, U.G. Falagario, N. D'Altilia, M. Recchia, V. Mancini, O. Selvaggio, F. Sanguedolce, C. Bettocchi, G.M. Busetto, L. Cormio, G. Carrieri (Foggia)

BACKGROUND: The association between PSA and prostate cancer (PCa) diagnosis is well established. However, several other benign conditions are known to have an impact on PSA levels. With the recent introduction of MRI and more accurate assessment of prostate volume, PSA density is becoming an increasingly used parameter to assess the need of prostate biopsy. The aim of this study was to assess the impact of prostatic inflammation on clinical parameters currently used for the diagnosis of PCa.

METHODS: This is a prospective single-center observational study evaluating the role of intraprostatic inflammation in prostate cancer screening and treatment. From March 2014 to December 2019, patients with PSA≥4 ng/mL and/or positive digito-rectal examination (DRE) and scheduled for prostate biopsy were enrolled. Men receiving 5 alfa-reductase inhibitors (5-ARIs), or who had previously undergone invasive treatment for BPH, or with dwelling urethral catheters and man with PSA>20 ng/ mL were excluded. The study protocol was approved by the ethics committee of the University of Foggia (Foggia, Italy). Prostatic inflammation (PI) was graded using the validated Irani Scores. Multivariable binary logistic regression analysis was used to assess predictors of csPCa (Gleason Score ≥3+4) and prostatic inflammation (Irani Score >1).

RESULTS: A total of 1988 patients were included. Any PCa and csPCa rates were 47% and 24% respectively. In the group without csPCa, patients with prostatic inflammation had an higher PSA (6.0 *vs*. 5.0 ng/mL; P=0.0003), higher prostate volume (58 *vs*. 52 cc; P<0.0001), were more likely to have a previous negative biopsy (29% *vs*. 21%; P=0.0005) and a negative DRE (70% *vs*. 65%; P=0.023) but no difference in PSA density (0.1 *vs*. 0.11; P=0.2). Conversely in the group with csPCa, patients with prostatic inflammation had a higher prostate volume (43 *vs*. 40 cc; P=0.007), but no difference in the other clinical parameters. At multivariable analysis adjusting for age, biopsy history, DRE and prostate volume, PSA density emerged as a strong predictor of csPCA (OR per 0.1 increase: 1.78; CI: 1.56-2.04; P<0.001) but was not associated with prostatic inflammation (OR per 0.1 increase: 1.07; CI: 0.96-1.19; P=0.201).

CONCLUSIONS: PSA density rather than PSA, should be used to evaluate patients at risk of prostate cancer who may need additional testing or prostate biopsy. This readily available parameter can potentially identify men who do not have PCa but have an elevated PSA secondary to benign conditions.

SMART (SC31-SC38)

Luts/benign prostatic hyperplasia 1

SC31
Holmium laser enucleation of the prostate is associated with complications and sequelae even in the hands of an experienced surgeon: results from a prospective series

SC32
Robotic-assisted simple prostatectomy *vs.* holmium laser enucleation: comparison of perioperative and early functional outcomes in a single Italian center

SC33
Aquablation treatment for benign prostatic hyperplasia (BPH): evaluation of lower urinary tract symptoms (LUTS) category (filling *versus* voiding phase) prevalence rates

SC34
Our single center functional and endoscopic results on Aquablation in BPH related LUTS: a two-year experience

SC35
Impact of treatment of BPH-related LUTS with second generation temporary implantable nitinol device (ITIND) on serum PSA: results from a multicenter prospective study (MT-06-study)

SC36
New minimally invasive techniques *versus* TURP for middle volume (30-80 mL) prostates: a prospective randomized study

SC37
Efficacy of prostatic artery embolization: a single center study of a sexual health preserving procedure

SC38
Prostatic artery embolization in patients with indwelling bladder catheter

SC31
Holmium laser enucleation of the prostate is associated with complications and sequelae even in the hands of an experienced surgeon: results from a prospective series

P. Capogrosso, F. Montorsi, G. Fallara, E. Ventimiglia, E. Pozzi, F. Belladelli, L. Candela, F. Pellegrino, F. Dehò, A. Salonia, A. Briganti (Varese)

BACKGROUND: Holmium laser enucleation of the prostate (HoLEP) is considered a challenging procedure. However, whether long surgical experience can improve peri- and postoperative outcomes is still unknown. We thus aimed at assessing results and complications after HoLEP performed by a highly experienced surgeon.

METHODS: This is a single-institutional prospective study (NCT03583034) performed at a tertiary referral center including 243 consecutive patients with lower urinary tract symptoms (LUTS) due to benign prostatic enlargement (BPE) treated with HoLEP by a single highly experienced surgeon (>1600 cases performed before first patient enrolment). Patients were assessed using validated questionnaires, PSA measurements and uroflowmetry at baseline and several follow-up dates. Intra- and postoperative complications were recorded and graded according to Clavien-Dindo (CD) classification. The Kaplan-Meier analysis estimated urinary continence (UC) (defined as no pad) and erectile function (EF) recovery rates. Logistic regression models assessed predictors of postoperative complications.

RESULTS: At presentation, median (IQR) prostate volume (PV) was 87 cc (60-115) with 146(59.8%) patients having a PV>80 cc and 78(32.1%) having an indwelling urethral catheter at baseline. At 3-month follow-up, 219(90.1%) patients had a peak flow rate >20 mL/s, and 182(74.9%) had a null residual urine volume. Improvement in subjective symptoms was significant already at 1-month, and it was maintained until 12-month after surgery; indeed, among fully continent patients, 130(77%) 182(75%) and 226(93%) reported an IPSS<11 at 1, 3 and 12 months after surgery, respectively. UC recovery was slow with estimated rates of 68% (62-74%) at 1-month and 94% (91-97%) at 12-month post-HoLEP. Increased PV (HR 0.95; 95% CI: 0.91-0.99), incontinence at baseline (HR 0.45; 95% CI: 0.27-0.73) and a higher baseline IPSS (HR 0.97; 95% CI: 0.94-0.99) were predictors of worse UC recovery rates (all P<0.04). The EF recovery rates were 53% (46-61%) at 1-month and 85% (77-90%) at 12-month post-HoLEP. Postoperative complications were reported in 36(14.8%) patients during hospital stay (CD-2: 14[5.8%]; CD-3: 1[0.4%]), in 34(14%) within one-month postdischarge (CD-2: 17[6.9%]; CD-3: 1[0.4%]) and in 10(4.1%) at later follow-up (CD-2: 3[1.2%]; CD-3: 6[2.4%]). Severe complications ($CD^3 2$) were more common in patients with indwelling catheter at baseline (OR: 5.05; P=0.006).

CONCLUSIONS: A highly experienced surgeon is commonly referred complex cases of LUTS due to BPE. Although HoLEP remains an effective procedure, it is not devoid of complications and sequelae even in the hands of a surgeon with more than 1600 procedures completed.

SC32
Robotic-assisted simple prostatectomy *vs.* holmium laser enucleation: comparison of perioperative and early functional outcomes in a single Italian center

T. Ceccato, E. Bovolenta, G. Reitano, G. Randazzo, F. Carletti, G. Betto, G.M. Balta, F. Zattoni, F. Dal Moro (Padua)

BACKGROUND: Robotic-assisted simple prostatectomy (RASP) and holmium laser enucleation of the prostate (HoLEP) represent two surgical treatments for large benign prostatic hyperplasia, however their perioperative outcome has been poorly compared so far. The aim of the study was to compare perioperative and early functional outcomes of these two techniques.

METHODS: Seventy-seven consecutive patients treated with RASP (N.=27) or HoLEP (N.=50) has been collected. Both cohorts were compared for different clinical characteristics and perioperative outcomes in terms of perioperative complications (Clavien-Dindo) and low urinary tract symptoms (IPSS Score). Uni and multivariate logistic regression analysis were performed to evaluate predictors of IPSS>7 at 3 months.

RESULTS: All preoperative demographic variables were comparable between the two groups although the prostatic volume was higher for RASP 170 (130-201) compared to HoLEP 69 (57-80), P<0.01. No differences between the two groups were found in terms of perioperative blood transfusion, Length of hospital stay and Clavien-Dindo at 30 days (P>0.05). IPSS at 3 months was significantly lower after RASP 4 (3-5) compared to HoLEP 7 (6-10), P<0.01, although time to catheter removal was longer for the robotic surgery compared to the endoscopic procedure. Only one patient in each group had a Clavien >2. At univariate analysis RASP showed an improved IPSS >7 at 3 months, compared with HoLEP (OR: 5.30, 95% CI 1.60-17.60, P<0.01). At multivariate analysis the only independent predictor of IPSS>7 was Charlson Comorbidity Index (CCI) >2. (OR: 4.88, 95% CI 1.00-23.86, P=0.05).

CONCLUSIONS: RASP is a safety procedure with improved functional outcomes compared to HoLEP even with higher prostatic volumes. Preoperative assessment of comorbidities is important to predict patients at risk of worse postsurgical IPSS Score.

SC33
Aquablation treatment for benign prostatic hyperplasia (BPH): evaluation of lower urinary tract symptoms (LUTS) category (filling *versus* voiding phase) prevalence rates

S. De Cillis, D. Amparore, E. Checcucci, G. Volpi, M. Manfredi, F. Piramide, A. Piana, M. Sica, D. Zamengo, A. Quarà, E. Cisero, G. Busacca, C. Marco, M. Ortenzi, D. Cidda, L. Ferrando, G. Trapella, A. Turcan, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: The aim of this study was to assess our first clinical experience with Aquablation (PROCEPT BioRobotics, Redwood City, CA, USA) in terms of perioperative and 1-year minctional outcomes, with focus on postoperative LUTS.

METHODS: From October 2018 to July 2021, a patient referred to our center with BPH-related LUTS, International Prostate Symptom Score (IPSS) ≥10, maximum urinary] ow rate (Q_{max}) ≤12 mL/ s, and prostate volume <80 mL, and was enrolled in this prospective study to undergo Aquablation. Demographics, perioperative data, and complications (according to the Clavien-Dindo system) were collected. Functional outcomes were assessed at 1, 3, 6, and 12 months with IPSS. Type of LUTS were classified on the bases of IPSS single questions answers in filling phase LUTS and voiding phase LUTS. For the porpoise of the study, no medications (alpha-blockers [AB], 5-androgen receptor inhibitors [5-ARI], anticholinergic [AC], beta3-agonists [B3A]) were prescribed to the patients after the Aquablation procedure to correctly assess the presence of postoperative LUTS.

RESULTS: Sixty patients were enrolled in the study. The mean (SD) patient age was 64.9 (7.3) years, prostate volume was 63.5 (16.8) mL, Q_{max} was 8.4 (2.6) mL/s, median (IQR) IPSS was 23 (19-26), and IPSS QoL Score was 5 (4–5). 55 patients (91.6%) were previously AB or 5-ARI for BPH, no patients reported preoperative therapy with anticholinergic AC or beta3-agonists B3A drugs. Analyzing the IPSS symptom category there was a reversal of symptom category prevalence rates between baseline and 3 months after surgery (P value = 0.003). Most patients preoperatively complained of emptying phase symptoms, whereas at 1- and 3-months follow-up, filling phase symptoms showed to be predominant in almost two third of study population. 27 out of 38 (71%) patients with a prevalence of filling phase symptoms at 3 months reported a de novo onset of these symptoms after surgery. The difference in prevalence between symptom categories flattens out at longer time points, not reaching significance at 6- and 12-month follow-up.

CONCLUSIONS: LUTS of the filling phase showed to be more prevalent than voiding phase ones in the first 3 months following Aquablation procedure for the treatment BPH-related LUTS but showed a self-limited fashion.

SC34
Our single center functional and endoscopic results on Aquablation in BPH related LUTS: a two-year experience

S.T. De Cillis, D. Amparore, E. Checcucci, G. Volpi, A. Piana, F. Piramide, M. Sica, M. Burgio, D. Zamengo, J. Meziere, A. Quarà, E. Cisero, G. Busacca, C. Gatti, A. Sterrantino, M. Ortenzi, A.G. Mesterca, M. Manfredi, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: The aim of this study was to report our first clinical experience with Aquablation (PROCEPT BioRobotics, Redwood City, CA, USA) with perioperative, endoscopic, and functional results up to the two-year follow-up.

METHODS: In this prospective study, patients undergoing Aquablation at our center with BPH-related LUTS, International Prostate Symptom Score (IPSS) ≥10, prostate volume <80 mL and maximum urination rate (Q_{max}) ≤12 mL/s were enrolled. Patients underwent surgery from October 2018 to October 2020. Exclusion criteria were: prostatic calcifications, prostate cancer diagnosis, previous prostate surgery, indwelling catheter, urethral stenosis and bladder stones. Demographics, perioperative data, and complications (according to Clavien-Dindo system) were collected. Functional outcomes were assessed at 1, 3, 6, 12 and 24 months with uroflowmetry, evaluation of postvoid residue (PVR), IPSS, Sexual Health Inventory for Men (SHIM) and Male Sexual Health Questionnaire for ejaculatory dysfunction (MSHQ-EjD). In addition, the patients underwent cystoscopy at 3 and 12 months after the surgical procedure. During the cystoscopy, the quality of the ablation at cystoscopy was rated according to a Likert Scale (1 = poor; 5 = excellent). Moreover, the preservation of the *veru montanum*, the presence of residual fluffy tissue or mucous aaps and the ureteral orifices as well as the presence of scar tissue at the level of the bladder trigone were evaluated.

RESULTS: Fifty-six patients were enrolled in the study. Preoperative median Q_{max}, IPSS, QoL Score and mean PVR were respectively 8 (2,4) mL/s, 22 (16-28), 4 (3-5) and 76 (9.8) mL. The median ablation time was 5.12 (2.13) min. The median catheterization time and hospital stay were 3 (3-4) and 4 (4-5) days, respectively. We recorded 10 postoperative complications (17.8%), of which 3 were classified as Clavien-Dindo grade >2 (5.3%), namely 1 (1.7%) acute urinary retention after catheter removal and 2 (3.5%) anemia requiring transfusion. At 3-month follow-up, cystoscopy was shown in 15/56 (26.7%) patients' non-obstruent mucosal flap, but no damage to the *veru montanum*, no residual fluffy tissue, ureteral orifices or bladder trigone were recorded. The median quality of the ablation was 3 (3-4). All these findings were confirmed at 12-months cystoscopy. The median IPSS Urinary Symptom Score was 4 (2-6) after 1 month and further improved to 2 (1-4) two year after surgery. Concurrently, the median IPSS QoL Score and mean PVR reached 0 (0-1) and 18.9 mL (22.7) at 24 months. The mean Q_{max} was 19.7 (9.3), 18.1 (3.1), 18.2 (6.2), 17.5 (6.1) and 18.1 (6.6) mL/s at 1, 3, 6, 12 and 24 months, respectively. No patient developed postoperative erectile dysfunction, while 3 (5,4%) reported loss of anterograde ejaculation.

CONCLUSIONS: Endoscopic and functional results demonstrate that Aquablation is a safe, feasible and effective procedure for the treatment of BPH-related LUTS up to 2-year follow-up.

SC35
Impact of treatment of BPH-related LUTS with second generation temporary implantable nitinol device (ITIND) on serum PSA: results from a multicenter prospective study (MT-06-study)

S. De Cillis, A. Daniele, E. Checcucci, J. Meziere, F. Piramide, A. Piana, G. Volpi, M. Sica, M. Schönthaler, G. Robert, F. Cantiello, F.G. Sancha, M. Beverini, S. Parodi, C. Terrone, C. De Nunzio, G. Muellhaupt, N.B. Delongchamps, E. Della Negra, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: Several studies have evaluated the safety and efficacy of the second-generation temporary implantable nitinol device (iTIND; Medi-Tate Ltd®, Hadera, Israel) in the treatment of benign prostatic hyperplasia (BPH)- related lower urinary tract symptoms (LUTS) with good results in term of symptoms relief and flow improvement. The aim of the study was to demonstrate the impact of iTIND on prostate-specific antigen (PSA) serum in the MT-06 study population.

METHODS: From June 2018 to September 2019 patients with IPSS≥10, Q_{max}<12 mL/s, prostate volume (PV) <120 mL were enrolled in this single-arm, prospective multicenter study and underwent iTIND implantation for the treatment of BPH-

related LUTS. Patients included in the study had previously passed prostate cancer screening and none of the included patients had a history of treated or untreated prostate cancer. Moreover, they were not washed out of BPH medication. PSA serum was assessed at baseline and at 1, 3, and 12 months postoperatively. The results were presented as means and interquartile range (IQR). The means of continuous variables were compared to the baseline by using the paired Student's *t*-test. Pearson's correlation coefficient was used to examine the association between the PSA baseline and the PSA at 3-month follow-up after the iTIND implantation. A P value <0.05 was considered to indicate statistical significance. SAS® (Cary, NC, USA), version 9.4 for Windows (Microsoft Corp., Redmond, WA, USA) was used for all statistical analyses.

RESULTS: One hundred forty patients who underwent successful iTIND implantation in 12 different centers around Europe and Australia had baseline PSA serum assessed and were included in this analysis. The mean age was 61.16 years (IQR 54.33-68.89), with mean prostate volume of 37.27 mL (IQR 26.00-45.00 mL) and mean baseline PSA serum of 1.81 ng/mL (IQR 0.72-2.40 ng/mL). All patients had an uneventful placement and removal of the iTIND. Postimplantation PSA serum showed a peak of 4 weeks after surgery, reaching a mean of 3.00 ng/mL (IQR 1.03-3.46 ng/mL). This result is consistent with the iTIND mechanism of action, which – by producing remodeling of the prostatic urethra – produces local inflammation from ischemic necrosis. Subsequently, the PSA serum decreased to a mean of 2.09 ng/mL (IQR 0.87-2.47 ng/mL), 1.90 ng/mL (IQR 0.64-2.81 ng/mL) at 3, and 12 months, respectively (P values were all >0.05, respectively compared to baseline). Change in PSA levels from baseline showed a linear correlation throughout the follow-up, with a Pearson's correlation coefficient at 3-month follow-up of R=0.944 (P>0.0001).

CONCLUSIONS: Implantation of iTIND for treatment of BPH-related symptoms showed to have only a transient impact on PSA serum levels, increasing levels of PSA one month after surgery but reaching levels comparable to baseline at longer follow-up intervals. It suggests that the iTIND procedure is likely not to affect PSA monitoring in patients undergoing screening for prostate cancer or being on active surveillance protocols who would receive treatment for symptomatic BPH.

SC36
New minimally invasive techniques *versus* TURP for middle volume (30-80 mL) prostates: a prospective randomized study

O.A. Rera, A. Fuschi, A.L. Pastore, Y. Al Salhi, A. Martoccia, P.P. Suraci, S. Silvio, F.M. Valenzi, A. Antonioni, D. Graziani, M.B. Sequi, G. Martino, G. Candita, F. Gianfrancesco, C. De Nunzio, R. Lombardo, A. Cicione, A. Carbone (Latina)

BACKGROUND: Today as recommended by European Association of Urology (EAU) and American Urological Association (AUA) guidelines, transurethral resection of prostate (TURP) is still considered the gold standard therapy for mid volume prostate glands (30-80 mL). In the last years, other minimally invasive endoscopic approaches have been proposed and introduced with the aim to reduce the morbidity related to TURP, such as: convective water vapor energy (Rezum, Boston Scientific, Marlborough, MA, USA) and heat free water-jet ablation (Aquablation; PROCEPT BioRobotics, Redwood City, CA, USA). The aim of this prospective randomized study was to compare the perioperative and functional outcomes between gold standard surgery (TURP) and these two new minimally invasive approaches (Rezum and Aquablation).

METHODS: Two hundred fifty-two patients with non-neurogenic Lower Urinary Tract Symptoms (LUTS) secondary to benign prostatic obstruction (prostatic volume 30-80 mL), non-responders to medical therapy for at least 6 months, were prospectively enrolled and randomized for the three surgical approaches between January 2021 and September 2022. Preoperatively and 6 months after surgery patients were studied by: uroflowmetry with postvoid residual, International Prostatic Symptoms Score, Male Sexual Health Questionnaire, and International Index of Erectile Function. All patients were also investigated by urodynamics.

RESULTS: Two hundred fifty-two patients with mean age of 64.6 years old were included in the study. Patients were prospectively randomized to the following treatment groups: 61 subjects underwent Rezum (group A), 92 patients Aquablation (group B), and 99 patients bipolar TURP (group C). Postoperative IPSS resulted lower in patients underwent TURP and AQUABEAM (2 and 2, respectively) than Rezum (7; P<0.001). Both quality of life and sexual satisfaction evaluated through postoperative MSHQ reported a higher improvement after Rezum and Aquablation than after TURP. Postoperative IIEF5 mean scores significantly increased in groups A and B (25 and 24, respectively) than in group C (15, P<0.001). The antegrade ejaculation was spared in all Rezum and Aquablation subjects, whereas all patients in the TURP group reported retrograde ejaculation. At postoperative urodynamics we observed a significant increase of the flowmetry parameters (Q_{max} and Q_{ave}) as well as the Pdet values after all procedures. Particularly, the TURP group reported mean flowmetry parameters significantly better when compared to Aquabeam and Rezum groups (mean Q_{max}-Q_{ave} 19.1-10.3, 17.7-9.2, and 16.3-8.4 mL/sec, respectively P<0.005). Postoperative bladder catheterization time was longer after Rezum (7 days) than after TURP (5 days) and Aquablation (2 days).

CONCLUSIONS: This prospective randomized study is the first to compare new endoscopic approaches to gold standard surgery in the treatment of non-neurogenic LUTS secondary to BPH for prostate volumes 30-80 mL. Our results confirm that Rezum and Aquablation are safe and effective. Postoperative outcomes are better in new approaches in terms of sexual function and overall satisfaction, especially related to the preservation of the antegrade ejaculation.

SC37
Efficacy of prostatic artery embolization: a single center study of a sexual health preserving procedure

C. Morreale, F. Zorzi, C. Costi, G. Rossin, S. Sartori, M. Rizzo, C. Trombetta, G. Liguori (Trieste)

BACKGROUND: The aim of this study was to evaluate the efficacy of prostatic artery embolization (PAE) in improving functional urine voiding parameters and lower urinary tract symptoms without affecting the sexual sphere in patients affected by benign prostatic hyperplasia. The secondary endpoints had to determine if any preprocedural factors could predict treatment failure.

METHODS: Clinical records of 69 patients who underwent

successfully PAE for symptomatic BPH were collected and retrospectively evaluated. Age, Charlson Comorbidity Index, and the number of patients with indwelling urinary catheters due to acute urinary retention were recorded. Procedural complications were assessed according to Clavien Dindo's classification. To objectify voiding symptoms, cervical-urethral obstruction grade and sexual function, datas about the International Prostate Symptoms Score (IPSS), Quality of Life Score (QoL), maximum flow at uroflowmetry (Q_{max}), postvoid residual urine volume (PVR), prostate volume (PV) and IIEF Score were registered before the treatment and at a 6-month follow-up. Each parameter was evaluated at the six-month follow-up. Treatment failure was defined as the completion of a BPH surgical operation at the 1-year follow-up. Logistic regression was performed to evaluate if any of the pretreatment scores could predict the failure of PAE in univariate and multivariate analysis.

RESULTS: Only 2 patients reported a grade-1 Clavien Dindo complication. At the procedure, the mean age was 74.6 (±7.4 SD) years, and the mean Charlson Comorbidity Score was 4.75 (±2.17). Twenty-eight patients had indwelling catheter at the time of the procedure. The mean pretreatment IPSS Score was 16.99 (±5.98), QoL 2.88 (±1.26), Q_{max} 10.9 mL/sec (±6.0), PVR 140.0 (±122.4) mL, PV 97.5 (±62.52) mL, IIEF Score 14.6 (±5.2). Forty-nine patients were receiving combination therapy. At the 6-month follow-up, 25 patients successfully removed the urinary catheter (P<0.001). The mean IPSS Score was 9.21 (±6.22) (P<0.001), QoL 1.77 (P<0.001), Q_{max} 13.25 (± 6.1) mL/sec, PVR was 80.3 (±94.5) mL (P<0.001), and PV was 63.0 (±31.0) mL (P<0.001). No statistical difference was found in the sexual sphere: mean IIEF Score at six-month follow-up was 15.8 (±4.8) (P>0.05). Logistic regression did not show any relationship between age at the procedure, pretreatment IPSS, Q_{max}, PVR, PV in univariate and multivariate analysis (P>0.1).

CONCLUSIONS: PAE is an effective and safe procedure for the treatment of BPH symptoms without affecting sexual function. Additional data are needed to determine predictors factors of procedure failure.

SC38
Prostatic artery embolization in patients with indwelling bladder catheter

D. Campobasso, S. Secco, G. Guarino, S. Maggiorelli, P. Brambillasca, A. De Cinque, I. Paladini, A. Andreone, F. Morelli, A. Olivero, M. Favali, A. Zagnoli, P. Dell'Oglio, S. Ferretti, G. Di Chiacchio, A. Galfano, F. Ziglioli, A. Patera, M. Slawitz, G. Di Marco, S. Puliatti, S. Micali, A. Bocciardi, A.G. Rampoldi, U.V. Maestroni (Parma)

BACKGROUND: Urinary retention (UR) correlates with BPO and is associated with a decline of overall quality of life and an increased morbidity (urinary tract infections, hematuria). In the last few years, prostate artery embolization (PAE) has been developed by interventional radiologist as a minimally invasive procedure to treat BPO-related LUTS. We evaluated the safety and efficacy of PAE in the management of UR secondary to BPO in patients unfit for surgery from three centers.

METHODS: We retrospectively reviewed data on patients with indwelling bladder catheter secondary to BPO and unfit for surgery due to comorbidities who underwent PAE in three Italian urological centers. Considered data were age, Charlson Comorbidity Index (CCI), prostate volume, indwelling urethral catheter time, complications, hospital stay, and catheterization time. The aim of the procedure was to remove bladder catheter and maintain the patients free from urinary catheter. Patients were divided into two groups based on success (group A) or unsuccess (group B) after 1 year since the procedure.

RESULTS: Seventy-four patients with bladder catheter having PAE were considered. No PAE failure occurred for tortuosity or atherosclerotic vessels in our series. After 1 year 49 patients (66.2%) are catheter-free. No differences in terms of age (75.3 *vs.* 78.7), CCI (6 *vs.* 6.6), prostate volume (94,7 *vs.* 94.7), hospital stay (1.9 *vs.* 3,9 days), catheterization time after the procedure (17.2 *vs.* 20.8 days) and complications rate (11.2 *vs.* 8.3%) were found between the two groups. One patient developed postembolization partial penile necrosis, and two penile skin ischemia which were managed conservatively (Clavien II). Four patients developed urinary tract infection after the procedure (Clavien II). Patients in group B had a longer history of indwelling bladder catheter than in Group A (9.7 *vs.* 6.2 months, P=0.018).

CONCLUSIONS: PAE is a minimally invasive surgical treatment for BPO performed by interventional radiologist not requiring anesthesiology assistance. Due to its safety profile, elderly and fragile patients should be considered for PAE. In our experience, PAE is a safe alternative treatment for BPO in patients with indwelling bladder catheter. In our series indwelling urethral catheter time is correlated with the success of the procedure. Patient's selection and counseling is crucial for an effective outcome.

SMART (SC39-SC43)

Adrenal Pathology

SC39
Minimally invasive approach for the treatment of primary adrenocortical carcinoma (ACC): a junior ERUS/YAU robotic study
SC40
High-volume centers experience in minimally invasive adrenalectomy for the treatment of adrenal metastasis: perioperative and survival outcomes
SC41
Minimally invasive approach in the management of solid adrenal metastases: a large retrospective analysis from a single institutional experience
SC42
Robot-assisted adrenalectomy: perioperative results of two high-volume centers
SC43
Management of the incidental adrenal mass, continued surveillance *versus* surgical excision: analysis of US claims data on contemporary socio-demographic predictors and perioperative outcomes

SC39
Minimally invasive approach for the treatment of primary adrenocortical carcinoma (ACC): a junior ERUS/YAU robotic study

F. Piramide, F. Di Maida, D. Amparore, P. Dell'Oglio, C.A. Bravi, G. Busacca, I. Andras, M. Paciotti, A. Piro, E. Balestrazzi, M. Peraire Lores, F. Turri, C. Fiori, G. De Naeyer, R. De Groote, A. Minervini, A. Mottrie, F. Porpiglia, A. Larcher (Orbassano, Turin)

BACKGROUND: Adreno cortical carcinoma (ACC) is a high aggressive disease and its treatment rely on a complete surgical resection. Despite minimally invasive approaches are considered the gold standard for the treatment of benign adrenal masses, their role in case of ACC is still debated. The aim of this multicenter study was to assess perioperative outcomes of minimally invasive adrenalectomy for primary ACC.

METHODS: Data from four European tertiary centers were retrieved from their prospectively maintained database. Specifically, demographic, intraoperative, postoperative, and pathological variables of patients underwent minimally invasive adrenalectomy in case of ACC were analyzed. All the procedures were performed by experienced laparoscopic and robotic surgeons after completion of their learning curve. Descriptive statistics included mean, standard deviation, medians, and interquartile ranges, as well as frequencies and proportions for continuous and categorical variables, respectively. Overall and recurrence-free survival were assessed using Kaplan Maier curves.

RESULTS: 30 patients were included in the study. Median age, BMI and lesion size were 55 (IQR 47-65) years, 25.3 (IQR 23.5-28.65) and 32 (IQR 20-48) mm, respectively. The 50% (15/30) of procedures were performed robotically. Median tumor size was 6 (IQR 4-9.5) cm. Mean operative time and blood loss were 117 (+45.8) minutes and 145 (+125). Only 1 intraoperative complication was recorded. Overall and major postoperative complications rate were 11.1% and 3.3%. Positive surgical margins rate was 3.3%. Median recurrence free survival time was 45 months, whilst overall survival did not reach it.

CONCLUSIONS: Our multicenter experience showed that minimally invasive approaches for ACC tumors are safe and feasible and with good oncological results if the principle of oncologic surgery are respected. Further studies are needed to confirm the generalizability of these findings.

SC40
High-volume centers experience in minimally invasive adrenalectomy for the treatment of adrenal metastasis: perioperative and survival outcomes

F. Piramide, D. Amparore, C.A. Bravi, G. Busacca, M. Paciotti, A. Piro, E. Balestrazzi, M. Peraire Lores, G. Sorce, C. Collà Ruvolo, S. Rebuffo, M. Ticonosco, N. Frego, C. Fiori, G. De Naeyer, R. De Groote, A. Mottrie, F. Porpiglia (Orbassano, Turin)

BACKGROUND: Minimally invasive approaches are considered the gold standard for the treatment of benign adrenal masses, but their role in case of malignant masses, either in case of primitive or metastatic disease, is still debated. The aim of this multicenter study was to assess perioperative outcomes of minimally invasive adrenalectomy for secondary adrenal metastasis.

METHODS: Data from two European tertiary centers were retrieved from their prospectively maintained database. Specifically, demographic, intraoperative, postoperative, and pathological variables of patients underwent either laparoscopic or robotic adrenalectomy for adrenal metastasis were analyzed. All the procedures were performed by experienced laparoscopic and robotic surgeons after completion of their learning curve. Descriptive statistics included medians and interquartile ranges, as well as frequencies and proportions for continuous and categorical variables, respectively. Overall and recurrence-free survival were assessed using Kaplan Maier curves.

RESULTS: Ninety-six patients were included in the study. Mean age, BMI and tumor size were 64.1 (+14) years, 24.4 (+2.23) and 3.9 (+2) cm, respectively. The 30% (28/96) of procedures were performed robotically. Mean operative time and blood loss were 96.6 (+39) minutes and 101 (+128) mL, respectively. No intraoperative complications were recorded. Overall and major (Clavien- Dindo >2) postoperative complications rate was 14.5% and 3.1%, respectively. The vast majority of patients (N.=57, 52%) harbored non-small-cell lung carcinoma (NSCLC) and renal cell carcinoma (N.=13, 13.5%). Positive surgical margins rate was 5.3%. Median overall and recurrence free survival were 34 and 27 months, respectively.

CONCLUSIONS: Our multicenter experience showed that minimally invasive approaches for secondary adrenal tumors are safe and feasible. Further studies are needed to confirm the generalizability of these promising findings.

SC41
Minimally invasive approach in the management of solid adrenal metastases: a large retrospective analysis from a single institutional experience

F. Piramide, D. Amparore, E. Checcucci, S. De Cillis, A. Piana, G. Cattaneo, G. Volpi, M. Sica, M. Burgio, D. Zamengo, A. Quarà, G. Busacca, M. Colombo, F. Pini, A. Giordano, A.G. Mesterca, D. Garino, M. Manfredi, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: The aim of the study was to test differences in survival rates between minimally invasive and open adrenalectomy for solid tumor metastases.

METHODS: Descriptive statistics included medians and interquartile ranges, as well as frequencies and proportions for continuous and categorical variables, respectively. The statistical significance of differences in medians and proportions was evaluated with the Kruskal-Wallis Test and χ^2 test. Kaplan Meier methodology was used to test differences in overall survival (OS) and recurrence-free survival (RFS) rates.

RESULTS: We retrospectively analyzed 66 adrenal metastasectomies from our prospectively maintained database (2001-2021). Of those 51 (77.2%) and 15 (22.7%) were treated with minimally invasive and open adrenalectomy, respectively. Most patients (N.=39, 59%) harbored non-small-cell lung carcinoma (NSCLC) and adrenal car-

cinoma (N.=12, 18.2%) as the primary tumor. Relative to open surgery, minimally invasive adrenalectomy patients harbored usually <2 adrenal metastases (P=0.02) and of smaller size (3.6 *vs.* 5.3, P=0.02). At adrenal pathology, adrenal metastases were more often from NSCLC (62.1%) and adrenal carcinoma (22.7%). No differences in terms of surgical margins, intra and postoperative complications were recorded according to type of adrenalectomy. Kaplan-Meier derived OS rates were 62% (median survival 45 mo) *vs.* 53% (median survival 23 mo) and no differences were observed according to the site of primary tumor (P=0.51) and in terms of RFS.

CONCLUSIONS: Adrenal metastases originated more often from NSCLC and adrenal carcinoma. Minimally invasive adrenalectomy patients showed a longer OS than open adrenalectomy individuals, as minimally invasive approach could have been attempted more common in less advanced disease. Further studies are needed to validate our results.

SC42
Robot-assisted adrenalectomy: perioperative results of two high-volume centers

S. Rebuffo, F. Piramide, D. Amparore, C. Bravi, G. Busacca, M. Paciotti, A. Piro, G. Sorce, M. Ticonosco, N. Frego, B. Eleonora, L.M. Peraire, C. Collà Ruvolo, E. Checcucci, C. Fiori, G. De Naeyer, R. De Groote, A. Mottrie, F. Porpiglia (Aalst)

BACKGROUND: During the last few years, robotic surgery has been introduced in a lot of different settings with good perioperative results. In the treatment of adrenal masses its role is still debated. The aim of this multicenter study was to assess perioperative outcomes of robot-assisted adrenalectomy.

METHODS: Data from two European tertiary centers were retrieved from their prospectively maintained database. Specifically, demographic, intraoperative, postoperative, and pathological variables of patients underwent robotic adrenalectomy for adrenal masses. All the procedures were performed by experienced robotic surgeons after completion of their learning curve. Descriptive statistics included medians and interquartile ranges, as well as frequencies and proportions for continuous and categorical variables, respectively.

RESULTS: A total of 93 patients underwent robotic adrenalectomy were included in the study. Median age, BMI and Charlson's Comorbidity Index were 61 (IQR 49.8-71.25) years, 26 (IQR 24.2-29) and 2 (IQR 0-3) mm, respectively. Median tumor size was 4.65 (IQR 3-6.8) mm. Median operative time and blood loss were 90 (IQR 70-119.25) minutes and 150 (IQR 100-200) mL, respectively. Only 1 (1.07%) intraoperative complication was recorded. Overall and major postoperative complications rate were 11% and 2.2%, respectively. Length of stay was 3 (IQR 2-4). The most majority of patients (N.=57, 61%) harbored benign adrenal adenoma, following by adrenocortical carcinoma (N.=14, 15%), Pheochromocytoma (N.=13, 13.9%) and secondary metastasis (N.=9, 9.6%).

CONCLUSIONS: Our multicenter experience showed that robotic adrenalectomy is safe and feasible with good perioperative results and low morbidity. Further studies are needed to confirm the generalizability of these findings.

SC43
Management of the incidental adrenal mass, continued surveillance *versus* surgical excision: analysis of US claims data on contemporary socio-demographic predictors and perioperative outcomes

D. Carino, C.M. Scornajenghi, V. Asero, P. Dipinto, E. De Berardinis, A. Sciarra, S. Basran, M.L. Eisenberg, B.I. Chung, F. Del Giudice (Roma)

BACKGROUND: Incidentally diagnosed adrenal masses represent an entity that can result in either long term follow-up, surgical excision, or both. Understanding when and which adrenal masses are ultimately excised surgically is not well understood. We sought to understand the ultimate fate of these incidentalomas using a large population-based dataset.

METHODS: The primary outcome of the study was determining the trend in adoption of surveillance *vs.* surgical excision according to socio-demographic, economic, and pathologic indices, and also provider specialty. Secondary outcomes were the assessment of perioperative complications, operative time, surgical approach, hospital stay, and provider specialty (general surgery *vs.* urology) among the cohort that underwent excision.

RESULTS: Out of a total of N.=91,560 adrenal masses, ultimately N.=3375 (3.83%) of these underwent surgical excision. In the surgical excision cohort, the incidence of aldosteronoma, functional adenoma/Cushing's disease, and adrenocortical carcinoma was higher than in the surveillance cohort. Those patients who were older, female, and with higher Charlson Comorbidity Indexes (CCI) were less likely to undergo surgical resection. Factors that predicted for an increased probability of resection included obtaining more CT/MRI scans as well as general surgeons as primary physician providers. Over the study period, the vast majority of surgeries were performed by surgeons other than urologists (12.9%) and open and laparoscopic approaches dominated, with the robotic-assisted approach accounting for a minority of the surgical cases (23.9%). The minimally invasive surgery (MIS) approach independently predicted for both lower rates of complications and shorter hospital stay.

CONCLUSIONS: In the US, adrenal incidentalomas are more likely to undergo surveillance rather than surgical resection. In our study, surgery is mainly offered for functional or malignant disease and the receipt of surgery can vary by physician specialty. A MIS approach independently predicted for both lower rates of complications and shorter hospital stay.

SMART (SC44-SC55)

Basic Research

SC44
Altmetrics of urology journals: where do we stand?

SC45
Artificial intelligence in urology: impact and limitations of CHATGTP in the management of uro-oncological diseases

SC46
Does gender affect scientific activity in Italian urology residency?

SC47
The association between testosterone and psychological well-being: findings from a real-life cross-sectional study

SC48
MUC1 expression is associated with metabolic reprogramming and modulates the immunoflogosis through complement system activation in renal cell carcinoma

SC49
Clinical utility of bioelectrical impedance phase angle in predicting postoperative outcomes in patients undergoing major urological surgery

SC50
Metabolic determinants of nuclear grade in clear cell renal cell carcinoma

SC51
A miniaturized endoscopic camera to measure energy spread during bipolar cauterizing in robot assisted radical prostatectomy

SC52
Apical anatomy and nerve distribution: a microscopical study on fresh prostate specimens

SC53
A novel urogeriatric pathway to screen elderly patients for frailty: preliminary experience from an academic referral center

SC54
G protein-coupled receptor kinase 2 as novel biomarker of bladder cancer progression: a pilot study

SC55
Robotic-assisted ureteroplasty with buccal mucosa graft for the management of complex ureteral strictures

SC44
Altmetrics of urology journals: where do we stand?

G. Tema, C. De Nunzio, A. Nacchia, C. Gravina, J. Stira, B. Turchi, L. Rovesti, C. Leonardo, S. Salciccia, A. Carbone, F. Del Giudice, R. Lombardo, A. Franco, G. Tema, D. Fiasconaro, A. Cicione, A. Tubaro (Rome)

BACKGROUND: Recently new metrics have been introduced in journal evaluation. The aim of our study was to evaluate the Altmetrics of European Urology, European Urology Focus, *Journal of Urology* and prostate cancer and prostatic diseases.

METHODS: Scopus database was used to analyze different metrics of European Urology, European Urology Focus, Journal of Urology and Prostate cancer and prostatic diseases. All the articles published between 2016 and 2019 were recorded. Citation field index, total view, captures, usage, mentions, citation index, tweets, interactions, and field-weighted citation impact. Open access articles were compared to non-open access articles and different journals were compared between them.

RESULTS: Overall, 1984 articles were recorded. European Urology published 479 articles, European Urology Focus 252 articles, Journal of Urology 1006 articles and Prostate Cancer and Prostatic Diseases 212 articles. Overall, 634/1984 (32%) were published as open access manuscripts, these manuscripts presented a higher citation field weighted, higher total views, higher captures, and a higher usage while no differences were recorded in terms of mentions, citation index, tweets and interactions when compared to non-open access articles. When comparing different journals, no clear relationship between impact factor and Altmetrics was recorded. However European Urology presented higher indexes and Altmetrics when compared to the other journals ($P<0.05$).

CONCLUSIONS: The principal urological journals present different metrics which should be considered by the authors. Although the open access articles present higher citations and views, their So-Me impact is similar to non-open access journals. Overall impact factor poorly correlates with So-Me metrics.

SC45
Artificial intelligence in urology: impact and limitations of CHATGTP in the management of uro-oncological diseases

G. La Bombarda, F. Zattoni, G. Novara, A. Morlacco, G. Betto, F. Dal Moro (Padua)

BACKGROUND: ChatGPT(OpenAI, San Francisco, CA, USA) is a language model that uses vast amounts of data to generate human-like responses to various topics. The aim of this study was to investigate whether ChatGPT can provide accurate and quality medical advice for three common urological conditions: prostate cancer, bladder cancer, and renal cell carcinoma.

METHODS: We selected 45 clinical cases on these conditions from the online platform Mirrors of Medicine (CS), where cases are constructed by a multidisciplinary and international expert panel, and compared answers provided by ChatGPT to expert urologists' responses. Scenarios included medical history, symptoms, and histological findings. We evaluated the quality, accuracy (timely response [TR]) of responses and assessed the limitations and robustness of ChatGPT. The CS were proposed to ChatGPT without any options to solve the case. We scored ChatGPT's responses from 0 to 5 (poor 0-2; moderate 3-4; good 5) based on its ability to identify the clinical condition (consistency with the clinical topic CT), (TR), completeness (COML), comprehensibility (CPR). Results were compared to the ones available on CS. The range of responses provided for each CS was then proposed to Chat GPT to evaluate its capability to recognize the most appropriate answers.

RESULTS: The median time for ChatGPT to reply was 5 seconds. The median correct answers given to CS from the urologists was 76% (64-83.5%). ChatGPT was able to provide 1-2, 3-4 and 5 possible solutions to CS in respectively 17%, 35.6% and 2.2%. In 44% of CS, ChatGPT could not provide any solution in 17%. ChatGPT's TR was moderate to good (score 4, IQR 3-5), and the CPR and COML of its responses were moderate to good (score 4, IQR 3-5). A median of 1 (IQR 0-2) corresponding answer between ChatGPT and the available answer proposed by CS was found. When answer options of the CS were proposed, ChatGPT's CT increased from 76% to 84%. COML and CPR of ChatGPT's answers were comparable (score 4, IQR 4-5), and the median of corresponding answers was 2 (IQR 1-3).

CONCLUSIONS: ChatGPT is a fast, easy to consult, and intelligible model for common and non-complex urological conditions. Its responses are accurate, complete, and can provide multiple solutions. However, ChatGPT is limited in providing physical examination, decision-making cutoffs, and treatment decisions. Healthcare providers should use their clinical judgment along with ChatGPT's responses, and it should not be relied on as the sole source of medical advice.

SC46
Does gender affect scientific activity in Italian urology residency?

F. Esperto, G. D'Addurno, N. Deanesi, F. Prata, A. Testa, F. Prata, G. Raso, A. Iannuzzi, A. Ragusa, A. Minore, V.G. Crimi, A. Travino, F. Tedesco, L. Cacciatore, P. Callè, S. Basile, P. Tuzzolo, A. Civitella, R. Papalia, R.M. Scarpa (Rome)

BACKGROUND: Among the stages of training of a doctor, certainly residency is one of the most important ones. Scientific activity and study are as important as surgical training. In our country, urology has always been considered a purely male branch, but the number of female residents in urology in Italy has increased about 300% in recent years. We wondered if gender affects the number of publications and if there is difference between female residents and male residents.

METHODS: We performed a PubMed search of 116 female and of 501 male urology residents in Italy to evaluate their scientific productivity. We therefore carried out a Mann-Whitney U Test to compare the number of publications by female residents and the number of publications by male residents. We divided then residents into categories: male and female residents who published less than 5 articles, residents who published more than 5 articles and residents with no publications and we analyzed the data with Pearson's χ^2 test.

RESULTS: We found a total of 616 articles, of which 500 published by male urology residents and 116 by female resi-

dents. Regarding female urology residents, out of 116, 74 have been founded from the PubMed dataset (63.5%). The mean of articles of female residents was 2.89, with standard deviation of 5.58. 50.6% have at least 3 or more publications indexed in PubMed. The remaining have just one or 2 publications indexed. The mean of articles of male urology residents was 3.52, with standard deviation of 7.14. 28% published 3 articles or more and the remaining have 1 or 2 publications. Comparing the data with Mann-Whitney U Test we found no statistical differences between male and female (P=0.343). Dividing residents into groups, we found that 84 male residents (16.77%) and 18 female residents (15.52%) have more than 5 articles. Applying Pearson's χ^2 test, we did not find differences between male and female residents (P=0.07). Forty-six female residents (36.20%) and 84 male residents (32.93%) have not been founded by the PubMed dataset. Applying Pearson's χ^2 test, we did not find differences between male and female residents again (P=1.8).

CONCLUSIONS: Even if urology may be more challenging for women who have to often fight against a gender prejudice, we did not find differences about scientific activity between male and female residents. Unfortunately, it was not possible to have a complete list of Italian urology residents. Training from an academic point of view in Italy depends on the specialty school attended very much. We believe that the importance of "female" research activity is a point on which our country should invest.

SC47

The association between testosterone and psychological well-being: findings from a real-life cross-sectional study

F. Belladelli, E. Pozzi, G. Fallara, S. Cilio, C. Corsini, F. Lanzaro, L. Candela, A. Bertini, M. Raffo, F. Negri, L. Cella, M. Fantin, D. Cannoletta, L. Boeri, P. Capogrosso, A. d'Arma, F. Montorsi, A. Salonia (Milan)

BACKGROUND: Late-onset hypogonadism (LOH) may be associated with symptoms suggestive for mood deflection up to clinical depression. The aim of this study was to investigate the association between total testosterone (tT) levels and psychological well-being in a cohort of men without symptoms of hypogonadism defined as more specific according to EAU Guidelines.

METHODS: Complete demographic and laboratory data from 820 consecutive men homogeneously assessed were analyzed. Socio- demographic data and hormonal levels were investigated in all patients. Health-significant comorbidities were scored with the Charlson Comorbidity Index (CCI). All men completed the International Index of Erectile Function (IIEF) and International Prostate Symptom Score (IPSS). Likewise, all men completed the Beck Depression Inventory (BDI) at baseline; symptoms suggestive of psychological distress were considered for BDI scores >11. Hypogonadism was defined for tT levels <3ng/mL. Descriptive statistics and linear/logistic regression models tested the association between tT and BDI scores.

RESULTS: Median (IQR) age was 52 (42-63) years and BMI was 24.6 (22.9-26.9) kg/m2. Of all, 301 (37%) and 127 (15%) men were active smokers and presented with CCI≥1, respectively. Median tT level was 4.9 ng/mL (3.9-6.2). Of all, 226 (27.6%) men depicted normal scores both at IIEF and IPSS, along with normal tT levels. Of 226, 157 (69.5%) presented with BDI scores suggestive for psychological distress. Men with higher BDI scores presented with lower tT levels (4.7 *vs.* 4.9, P=0.043). All other variables did not differ between groups. At multivariable linear regression analysis, tT was associated with BDI scores (β: -0.24, P=0.015), after accounting for age, BMI, CCI, and smoking status. At multivariable logistic regression analysis, tT was not identified as an independent predictor of BDI scores suggestive for psychological distress (OR: 0.98, P=0.853), after accounting for age, BMI, CCI, and smoking status.

CONCLUSIONS: In men not presenting with symptoms and signs defined as more specific for hypogonadism higher tT levels emerged to be associated with less probable psychological distress, despite circulating tT per se was not independently associated with more severe depressive symptoms.

SC48

MUC1 expression is associated with metabolic reprogramming and modulates the immunoflogosis through complement system activation in renal cell carcinoma

F. Lasorsa, M. Rutigliano, M. Milella, N.A. di Meo, C. Ardito, M. Battaglia, P. Ditonno, G. Lucarelli (Bari)

BACKGROUND: The aim of this study was to evaluate the metabolomic and transcriptomic profile of human ccRCC, according to *Mucin 1* (*MUC1*) expression. Moreover, we analyzed the role of MUC1 in sustaining ccRCC aggressiveness, and the prognostic value of its soluble form CA15-3 in 428 patients with ccRCC. In addition, we evaluated the immunoflogosis and the role of complement system activation on tumor site.

METHODS: Untargeted metabolomic analysis was performed using LC-MS and GC-MS. MUC1 expression was evaluated by immunohistochemistry (IHC) on normal and pathological tissues, stratifying samples in tumor with high (*MUC1H*), *versus* low *MUC1* expression (*MUC1L*). The role of *MUC1* in sustaining ccRCC cell proliferation, migration and chemoresistance was studied by *in-vitro* assays. To study the relative changes in gene expression in *MUC1H versus MUC1L* ccRCC, gene expression data from GSE15641 dataset were downloaded and stratified according to *MUC1* expression. Gene set enrichment analysis (GSEA) was performed. Complement system activation and immune cell infiltrate was evaluated by IHC and immunofluorescence.

RESULTS: Integrated multi-omics analysis showed that *MUC1*-expressing ccRCC is characterized by metabolic reprogramming involving glucose and lipid metabolism. Primary cancer cells treated with a small interfering RNA (siMUC1) migrated and proliferated at a slower rate than untreated cancer cells. After cisplatin treatment, the death rate of cancer cells treated with siMUC1 was significantly greater than that of untreated cells. Kaplan-Meier curves showed significant differences in CSS and PFS among patients with high *versus* low levels of CA15-3. At multivariate analysis, CA 15-3 was an independent adverse prognostic factor for CSS and PFS. GSEA showed that *MUC1H* ccRCC featured multiple enriched gene sets depicting angiogenesis and complement system activation. PTX3 tissue expression was significantly higher in *MUC1H* ccRCC. C1q deposition, and

the expression of CD59, C3aR and C5aR were extensively present in *MUC1H* ccRCC and co-localized with *PTX3*. Finally, *MUC1* was associated with an increased number of infiltrating mast cells, M2-macrophage, and IDO1+ cells, and a reduced number of CD8+ T cells and reduced PD-L1 expression.

CONCLUSIONS: *MUC1*-expressing ccRCC is characterized by a particular metabolic reprogramming. The inhibition of *MUC1* decreased cell motility and viability, and improved cisplatin susceptibility. Moreover, *MUC1* can modulate the immunoflogosis in the ccRCC microenvironment, by activating the classical pathway of complement system and regulating the immune infiltrate promoting an immune-silent microenvironment.

SC49
Clinical utility of bioelectrical impedance phase angle in predicting postoperative outcomes in patients undergoing major urological surgery

L. Di Marco, M. Rizzo, L. Paulitti, R. Danuso, G. Liguori (Trieste)

BACKGROUND: The first aim of this study was to investigate if phase angle (PA) measured by bioelectrical impedance analysis (BIA) could be used as a predictor of complications after major urologic surgery in oncological patients. Secondary aim is to evaluate the correlations between preoperative PA and days of hospitalization (DOH).

METHODS: We prospectively enrolled in the study 144 patients who underwent 77 radical prostatectomy (4 open and 73 robotic) for prostate cancer, 35 radical or partial nephrectomy (19 robot-assisted and 16 open) for kidney cancer and 31 radical cystectomies (open) for bladder cancer at the Department of Urology of the University of Trieste (Trieste, Italy). The nutritional status of the patients was evaluated using BIA. P value equal or lower than 0.05, 95% CI not encompassing 1 for OR, 0.5 for ROC curve values were considered statistically significant. The analyses described above and those of linear regression and logistic regression were performed using SPSS 21.0 software (SPSS Inc., Chicago, IL, USA).

RESULTS: The median BMI was 26.1 kg/m² and the median abdominal circumference was 99 cm. Median preoperative phase angle was 4.9° while median postoperative phase angle was 4,5°. There were 51 patients with postoperative complication, according to Clavien-Dindo classification, 8 of these were major complications (Clavien-Dindo 3-4-5) and 43 of these were minor complications (Clavien-Dindo 1-2). There is no standard cutoff value for PA, thus ROC curve (Curve 1A) analysis was used: The cutoff values of phase angle were 4,45° for the whole size simple and also for open surgery. There is a strong association between preoperative PA and risk of complications in all type of surgery, with a discriminating value identified by the Youden Index of 4.45°. Patients with a preoperative phase angle PA<4.45° have a 4.16-time increased risk of postoperative complications. There is a strong association between preoperative PA and risk of complications in open surgery, with a discriminating value identified by the Youden Index of 4.45°. Patients with a preoperative phase angle PA<4.45° have a 4.74-time increased risk of postoperative complications. We have noted an inverse correlation: as the preoperative PA increases, the duration of hospitalization (DOH) decreases. In particular, in nephrectomies preoperative PA predicts DOH.

CONCLUSIONS: Many previous studies have shown that PA is an independent prognostic indicator of malnutrition, frailty, and postoperative complications. Our findings consistently highlight the role of phase angle as an independent predictor of complications after major urological surgery. Patients having a combination of low PA were 4 times more likely to increase postoperative complication. The implementation of nutritional parameters will play a key role in the future and will likely help in better tailoring treatment strategies and balancing the advantages and the risk of upfront surgical efforts.

SC50
Metabolic determinants of nuclear grade in clear cell renal cell carcinoma

F. Lasorsa, M. Rutigliano, M. Milella, M. Battaglia, P. Ditonno, G. Lucarelli (Bari)

BACKGROUND: Nuclear grade is a morphological parameter of clear cell renal cell carcinoma (ccRCC) and an independent predictor of cancer-specific survival. The aim of this study was to identify grade-dependent metabolic signatures and corresponding gene expression changes that connect the variations in cancer metabolism with the nuclear grade.

METHODS: Clear cell RCC samples were collected from patients who underwent radical or partial nephrectomy and stratified according to nuclear grade: N.=20 low grade (LG: G1-G2) and N.=20 high grade (HG: G3-4). Untargeted metabolomic analysis was performed using LC-MS and GC-MS. To study the relative changes in gene expression in HG *versus* LG ccRCC, gene expression data from 3 different datasets were downloaded and stratified according to nuclear grade. Gene set enrichment analysis (GSEA) was performed. Oil Red O (ORO) and Periodic Acid-Schiff (PAS) staining were conducted to evaluate lipids and glycogen accumulation in cell vacuoles.

RESULTS: Integrated multi-omics analysis showed that HG tumors were characterized by metabolic reprogramming involving glucose and pentose phosphate pathway. In particular, we found that the Warburg effect in association with changes in Krebs cycle intermediates and related metabolites, were relatively more prominent in HG ccRCC compared to LG tumors. Additional alterations included proteo-metabolic reprogramming in urea cycle, modulation of glutathione metabolism with accumulation of the reduced form of glutathione (GSH) in HG tumors, and progressively increased levels of carnitine derivatives in a grade-dependent manner. Lipid metabolism evaluation showed an increased accumulation of short and medium chain fatty acids in LG *versus* HG ccRCC, and these findings were confirmed by ORO staining in tissue samples. GSEA showed that HG ccRCC featured multiple enriched gene sets depicting amino sugar and nucleotide metabolism, glycosaminoglycan biosynthesis, and reduced fatty acid metabolism.

CONCLUSIONS: ccRCC is characterized by a particular grade-dependent metabolic reprogramming. Given that many of these metabolic pathways and associated molecular alterations are grade-specific, they could represent potential therapeutic targets, especially in HG tumors.

SC51
A miniaturized endoscopic camera to measure energy spread during bipolar cauterizing in robot assisted radical prostatectomy

S. siracusano, D. Scutelnic, G. De Rossi, N. Piccinelli, A.B. Porcaro, R. Muradore, C. Daffara (Sulmona, L'Aquila)

BACKGROUND: Robot assisted laparoscopy (RAL) is the gold standard for nerve-sparing prostatectomy. In this setting cauterizing hemostasis is employed although its use is still debated for tissue damage. We manufactured a miniaturized endoscopic thermal camera to measure thermal spread be used during RAL. The aim of this proposal is to present the characteristics of this device with an Italian and European patent, highlighting the current challenges in designing thermal endoscopes to facilitate the detection of potential thermal stress for the tissues surrounding the cauterized area and fusing the data coming from the endoscopes operating in the visible range of the spectrum.

METHODS: We used sensors for measuring the thermal spread. They are microbolometers operating in a region of the spectrum between 7 to 14 mm, not visible at the naked eye. For designing the thermal endoscope, we used off-the-shelf ultra- compact microbolometers cores of the FLIR Lepton® series (Teledyne FLIR LLC, Wilsonville, OR, USA). These devices can be integrated in printed circuit board (PCB) designed specifically for the application. In this study we designed elongated PCBs that can be fit inside a trocar with a diameter of 15 mm. We prototyped different configurations placing the camera in front of the trocar and in one side of it. Finally, we tested the effectiveness of the various configurations using a custom phantom with 15-mm trocar entrances.

RESULTS: We were able to produce different prototypes of thermal endoscopes. All the endoscopes met the dimensional requirements of the standard trocars used nowadays in RAL. The testing using the phantom highlighted the importance of fusing the data coming from the thermal endoscope (consisting of video representing temperature gradients on the tissue) with the data of the standard endoscope operating in the visible range of the spectrum.

CONCLUSIONS: The miniaturization of thermal sensors allows the construction of thermal endoscopes able to make the surgeon aware of thermal stresses caused to the tissues during RAL. The fusion of the visible and thermal data is pivotal for the correct use of the information provided by thermal endoscopes.

SC52
Apical anatomy and nerve distribution: a microscopical study on fresh prostate specimens

L. Sarchi, M.C. Sighinolfi, S. Assumma, T. Calcagnile, E. Panio, E. Pozzi, M. Sangalli, C. Pescia, C. Cigala, A. Moro, A. Cimadamore, M. Barabino, G. Bozzini, M. Maggioni, A. Gregori, G. Bianchi, S. Micali, B. Rocco (Milan)

BACKGROUND: The anatomy of the prostate apex has been so long evaluated during decades, with studies focusing on both macroscopical shape and microscopical features. The anatomical study by Eichelberg *et al*. (Eur Urol, 2007) firstly described the nerve distribution along the prostatic capsule and found a non-negligible number of nerves on the ventral part of the prostate. The evidence arose surgical implications, with Authors suggesting a high incision for nerve sparing on the anterior part of the prostate. Up to now, anatomical microscopical studies have been carried out on specimens undergoing previous formalin-fixation and paraffin-embedding. The aim of the study was to evaluate apical microscopical anatomy on the fresh specimen by using *ex-vivo* fluorescence confocal microscopy.

METHODS: This is a prospective descriptive analysis of nerve distribution around the un-stained prostate apex. A total of 11 slides were retrieved from 9 patients who underwent non-nerve-sparing robotic radical prostatectomy. 1-mm sections were transversely cut from the prostate apex. Each slide was stained in Acridine Orange for 30 seconds and then analyzed with fluorescence confocal microscopy (Vivascope; Mavig, Munich, Germany). Similar to Eichelberg study, slides were divided into sectors and an anterior aspect, a mid-lateral and a postero-lateral one was evaluated on each side. The primary endpoint is to evaluate the number of nerves around the apex inside each aspect. Two pathologists, an expert, and a trainee (AC and CP), evaluated all slides; every single nerve and ganglion in the apical circumference and in the periprostatic tissue was counted.

RESULTS: Overall, a total of 81 nerves were detected around the apical circumference. The majority (72%) was located in the postero-lateral aspect of prostatic apex (58); the lateral part accounts for 22% of the nerves (18) whereas the least amount (6%, 5 nerves) was located in the anterior apex. There was an adequate level of agreement between pathologists (K value 0.75) as far as nerve count was concerned. The presence of a segmental pseudocapsule – composed by muscular and connective tissue - was evident in 4 out of 11 slices.

CONCLUSIONS: To the best of our knowledge, this is the first description of nerve anatomy at the apical site on the fresh prostate specimen. Compared to Eichelberg's study, we detected a smaller number of nerves in the anterior and mid-lateral aspect of the prostate apex. Despite the current small case series, a tentative explanation to our finding could be the absence of shrinkage induced by formalin-fixation. Further studies are encouraged to get insights on nerve distribution on the fresh specimen, with perspectives on surgical approaches to apical dissection.

SC53
A novel urogeriatric pathway to screen elderly patients for frailty: preliminary experience from an academic referral center

A. Mariotti, D. Stracci, M.L. Gallo, A. Pecoraro, R. Mariottini, N. Firenzuoli, L. Mazzola, C. Caneschi, S. Serni, G. Rivasi, G.D. Testa, R. Campi (Florence)

BACKGROUND: Uro-oncological surgery is often performed in older patients. This age group is heterogeneous and constantly growing. Moreover, many elderly patients present with frailty syndrome, resulting in increased risk of long hospitalization (LOH), poor treatment outcomes and even death. As a result, EAU Guidelines have already recommended geriatric assessment to uro-oncological elderly patients (prostate cancer [Pca] and bladder cancer [BCa]); however, literature is not clear on which patients could benefit from geriatric assessment. In this study, we described our preli-

minary experience with a multi-specialty pathway to screen elderly patients for frailty, to improve their perioperative care.

METHODS: After Ethical Committee approval, we prospectively collected data from elderly (≥75 years) uro-oncological patients undergoing surgery from May to September 2022. After standard preoperative assessment (medical history, physical examination, urologic and anesthesiologic evaluation), all patients underwent preoperative Comprehensive Geriatric Assessment performed by experienced geriatricians. Patients were classified according to the G8-Score as frail (≤14) *vs.* not-frail (>14).

RESULTS: In our cohort of patients who underwent surgery for PCa, renal cell cancer (RCC) and BCa during the period January 2019 October 2022, 9%, 25% and 46% of patients, respectively were elderly. 39 patients ≥75 years were included (69% BCa, of which 61% non-muscle invasive; 8% PCa and 20% RCC). Hypertension (50%) and diabetes (28%) resulted to be most frequent comorbidities, followed by ipovisus (20%), dementia (15.4%), CKD (15%), BPCO (10%), ischemic cardiopathy (10%) and ipoacusia (8%). 7 patients (18%) took anticoagulant drugs, 11 (28%) took antiplatelets drugs and only 1 (2.5%) took both. Median LOH varied from 1 day in BCa to 9 days in RCC. Clavien-Dindo ≥3 occurred in 3 cases: 1 death (2.5%) and 2 sepsis (5%). G-8 Score was ≤14 in 20 cases, therefore 51% of patients were classified as frail. Comparing these two groups it was observed that frail patients were older (mean age 82.6 *vs.* 78.3, P<0.001); had worse functional status (median Barthel Index 95 *vs.* 100, P=0.008); had worse physical performance (median SPPB Score 9.5 *vs.* 12, P<0.001); had worse nutritional status (median BMI 24 *vs.* 26, P=0.004, percentage of sarcopenia 13 *vs.* 3, P=0.002; median MNA short 11 *vs.* 14, P<0.001) and had worse cognitive results (median MMSE 27 *vs.* 30, P=0.029).

CONCLUSIONS: Frailty is common in urological elderly patients. Despite geriatric assessment is a time-consuming tool, it seems to be promising in predicting poor outcomes and complications and it may indicate the need for preoperative intervention. Further research is needed to assess the impact of frailty on intra- and postoperative outcomes, so to optimize treatment decision making and improve perioperative care.

SC54
G protein-coupled receptor kinase 2 as novel biomarker of bladder cancer progression: a pilot study

L. Napolitano, J. Gambardella, A. Fiordelisi, M. Ciccarelli, G.M. Fusco, L. Cirillo, R. La Rocca, V. Mirone, D. Sorriento, G. Iaccarino (Naples)

BACKGROUND: The aim of this study was to evaluate the potential involvement of GRK2 in bladder cancer (BCa) onset and progression and its role as potential biomarker of BCa staging.

METHODS: We conducted a pilot study enrolled patients underwent transurethral resection of bladder tumor (TURBT) at University of Naples Federico II (Naples, Italy) between September 2022 and February 2023. Bladder samples were obtained from 15 patients. Patients who had previously undergone radiotherapy or systemic chemotherapy for any reason and patients in whom the study procedure could have impaired final pathology were excluded from this study. Patients were divided into three groups (group 1, group 2, and group 3): benign tumor, non-muscle-invasive bladder cancers (NMIBCs) and muscle-invasive bladder cancers (MIBCs) respectively. A western blot analysis was performed. All data were presented as mean±SEM. We performed ANOVA with a Bonferroni *post-hoc* test to compare the different parameters between the different groups. A significance level of P<0.05 was assumed for all statistical evaluations. Statistics were computed with GraphPad Prism v. 9.0 software (San Diego, CA, USA).

RESULTS: Mean age ranged between 69 to 74 years: 3 patients were female, and 12 were male; 5 patients had benign tumor, 5 had non- muscle-invasive bladder cancers (NMIBCs) and 5 had muscle-invasive bladder cancers (MIBCs). The western blot analysis showed a marked and progressive increase of GRK2 protein levels related to tumor staging. We also found a progressive activation of NFkb according to BCa stage and increase of proinflammatory cytokines (IFNγ, IL1β, TNFα).

CONCLUSIONS: Our preliminary data suggest that GRK2 promotes BCa progression and mediated NFKb signaling activation suggesting this a potential therapeutic target to attenuate BCa related inflammation and tumor progression.

SC55
Robotic-assisted ureteroplasty with buccal mucosa graft for the management of complex ureteral strictures

R. Orlando, G. Pettenuzzo, A. Veccia, A. Antonelli (Verona)

BACKGROUND: Strictures of the proximal ureter may occur from iatrogenic injury or impacted kidney stones. Surgical management of proximal and middle ureteral strictures that are not susceptible to excision and anastomosis is challenging. Although a buccal mucosa graft is commonly used during urethroplasty replacement, its use in ureteroplasty is limited. The aim of this study was to present the step-by-step of a robotic-assisted ureteroplasty with buccal mucosa grafting (BMG) of a 41-year-old woman with a long right proximal ureteral stricture secondary to previous ureteroscopies.

METHODS: A healthy 41-year-old woman underwent open right ureteral resection with right uretero-ureteral anastomosis in 2021 for impacted right proximal ureteral stones, presented with right lumbar pain. Urinary ultrasound and computed tomography showed right hydronephrosis. Therefore, a right nephrostomy was positioned. Pyelography revealed a long right proximal ureteral stenosis (about 5 cm). Sequential renal scintigraphy showed reduced effective renal plasma flow on the right compared to the left (23% *versus* 77%). The patient was submitted to a robotic-assisted laparoscopic ureteroplasty with BMG.

RESULTS: The patient was placed in modified lateral position with port placement similar to the right pyeloplasty. Intraoperative flexible ureteroscopy was used to define the distal extent of the stricture. The ureteroscope was advanced until the stricture, and transilluminance of light from the ureteroscope was seen from the robotic camera using Firefly (Intuitive Surgical, Inc., Sunnyvale, CA, USA). After inci-

sion of the anterior aspect of the stenotic ureteral segment, BMG was prepared; a patch 2 cm in width and equal to the measured length was harvested. The graft was minimally defatted and brought in the abdomen through one of the ports. The graft was then sutured with 4-0 PDS as an onlay graft with the mucosal side facing toward the lumen of the ureter. Ureteroscopy was used to confirm stenosis resolution, followed by stent placement. Finally, an omental flap was harvested and fixed to the psoas fascia beneath the ureter, and then wrapped over the reconstructed ureter. The omental flap was also tacked to the side of the BMG with a suture to promote blood supply. The operation time was 238 minutes. Blood loss was minimum and there was no perioperative complication. As a postoperative complication, the patient developed a septic shock, that required intensive care unit admission.

CONCLUSIONS: This technique offers the possibility of resolving long proximal ureteral strictures precluding the need for more extensive and morbid surgeries, with low morbidity and good results.

SMART (SC56-SC69)

Luts/benign prostatic hyperplasia 2

SC56
Ultrasound-guided Soractelite™ transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience

SC57
Transperineal interstitial laser ablation (TPLA) of the prostate for patients with benign prostatic obstruction: short- and mid-term functional, sexual and safety outcomes

SC58
Transperineal interstitial laser ablation (TPLA) of the prostate for comorbid patients with benign prostatic obstruction: short- and mid-term functional and safety outcomes from a single center experience

SC59
Transperineal laser ablation (TPLA) and convective water vapor ablation (Rezum) for minimally invasive treatment of BPH: preliminary 3-month results from a single institutional experience of a randomized controlled trial

SC60
Is water vapor thermal therapy safe and feasible in elderly men? The Italian experience

SC61
Perioperative and short-term functional outcomes comparison between HoLEP and robot-assisted simple prostatectomy for large prostate >150 cc

SC62
Robot-assisted simple prostatectomy (RASP) with HUGO™ RAS system: comparative analysis with da Vinci robotic system in a high-volume center

SC63
Initial experience of robot-assisted simple prostatectomy with HUGO™ RAS system: step-by-step description of two different techniques

SC64
Minimally invasive robot-assisted simple prostatectomy with laparoscopic in-pouch morcellation compared to conventional minimally invasive prostatectomy

SC65
Robot-assisted simple prostatectomy *versus* holmium laser enucleation for the treatment of benign prostatic hyperplasia in large (>100 mL) prostates: updated comparative analysis from a high-volume center

SC66
Transperineal laser ablation of the prostate for the surgical treatment of lower urinary tract symptoms in very high-risk patients: six-month follow-up from a cohort of "extreme" patients

SC67
Rezum *vs.* TURP for the treatment of benign prostatic obstruction: a multicenter propensity-score matched pair "Tetrafecta" analysis (URAN Collaborative Group)

SC68
A comparison of the efficiency and safety profile between two morcellators for laser enucleation of the prostate: Piranha *versus* Cyber Blade devices

SC69
BPH3 trifecta for robotic assisted simple prostatectomy (RASP) *vs.* BPH6: a novel outcomes comparison metric

SC56
Ultrasound-guided Soractelite™ transperineal laser ablation (TPLA) of the prostate for the treatment of symptomatic benign prostatic hyperplasia (BPH): a prospective single-center experience

G. Di Lascio, A. Laganà, A. De Carolis, A. Di Blasi, A. Tufano (Tivoli, Rome)

BACKGROUND: The aim of this study was to evaluate the efficacy and safety of ultrasound-guided transperineal laser ablation (TPLA) in patients with symptomatic BPH.

METHODS: Inclusion criteria were: 1) patients with BPH with several comorbidities; 2) patients with a desire to spare anterograde ejaculation; and 3) patients intolerant of or poorly compliant to medical therapy, with no indication for surgery. Exclusion criteria were: 1) acute and chronic prostatitis; 2) prior prostatic abscess; 3) prostate volume >85 mL; and 4) all patients with PSA>4.0 ng/mL without a negative MRI scan or negative biopsy for prostate cancer. From January 2020 to March 2023, 90 prospectively enrolled patients underwent TPLA with a 1064-nm continuous-wave diode laser (EchoLaser; Elesta SpA, Calenzano, Florence, Italy). Primary endpoints were the change in IPSS, QoL, Q_{max}, PVR and prostate volume at 3 ,12 months and 24 months. TPLA procedure involves the coagulative necrosis of prostate tissue; this is achieved by laser illumination delivered by up to two laser fibers per prostatic lobe that are inserted transperineally under US guidance.

RESULTS: A total of 90 patients aged 74.3±11.0 years with symptomatic BPH underwent TPLA. At 3-month follow-up, IPSS was significantly improved from 20.8±7.4 to 11.0±6.6 (P<0.001), QoL significantly improved from 4.7±1.4 to 1.5±1.2 (P<0.001) and Q_{max} increased numerically from 8.6±3.5 mL/s to 13.2±5.7 mL/s (P=0.083). PVR was significantly reduced from 124.8±115.4 mL to 43.6±53.6 mL (P<0.001), and prostate volume significantly decreased from 63.6±29.7 mL to 45.6±21.8 mL (P=0.003). Of the 27 patients who were receiving alpha-blockers at baseline, 15 (55.6%) discontinued this therapy at 3-month follow-up. Of the six patients who were taking a 5-ARI preoperatively, three (50%) discontinued this therapy. At 12-month follow-up, IPSS was significantly improved from 20.8±7.4 to 8.4±5.9 (P<0.001), QoL from 4.7±1.4 to 1.2±0.8 (P<0.001), and Q_{max} significantly increased from 8.6±3.5 mL/s to 16.2±4.3 mL/s (P=0.014). PVR was significantly reduced from 124.8±115.4 mL to 40.6±53.6 mL (P=0.003), and prostate volume decreased from 63.6±29.7 mL to 42.8±14.2 mL (P=0.071). At 24-month follow-up, IPSS was improved from 20.8±7.4 to 8.0±6.9 (P<0.001), QoL from 4.7±1.4 to 1.3±0.9 (P<0.001), and Q_{max} significantly increased from 8.6±3.5 mL/s to 18.2±4.8 mL/s (P=0.011). PVR was significantly reduced from 124.8±115.4 mL to 38.1±55.6 mL (P=0.003), and prostate volume decreased from 63.6±29.7 mL to 39.8±12.2 mL (P=0.071). At 24-month follow-up all patients had discontinued medical therapy.

CONCLUSIONS: In conclusion, TPLA represents an effective and safe treatment for symptomatic BPH, providing clinically significant benefits on prostate volume, bladder function and QoL.

SC57
Transperineal interstitial laser ablation (TPLA) of the prostate for patients with benign prostatic obstruction: short- and mid-term functional, sexual and safety outcomes

M. Lo Re, P. Polverino, M. Saladino, C. Bisegna, A. Pecoraro, L. Moscardi, G.R. Resta, R. Mariottini, A. Rivetti, R. Nicoletti, V. Li Marzi, G. Siena, A. Cocci, M. Gacci, A. Minervini, S. Serni, R. Campi, F. Sessa (Florence)

BACKGROUND: Among new minimally invasive surgical techniques for benign prostatic obstruction (BPO transperineal interstitial laser ablation of the prostatic adenoma (TPLA) has showed promising preliminary results in terms of functional and sexual outcomes. Moreover, potential advantages result in its feasibility in an outpatient setting without general anesthesia. In this abstract we presented functional, sexual and safety outcomes of a single-center cohort after TPLA for LUTS due to BPO.

METHODS: We prospectively analyzed data from patients undergoing TPLA for LUTS due to BPO between September 2021 and February 2022, in men with prostate volume ranging from 30 to 100 mL and moderate to severe LUTS (IPSS ≥8) and reach at least 12 months of follow-up. TPLA was performed in an outpatient setting, under local anesthesia and low-dose oral benzodiazepine administration, using Soracte Lite-EchoLaserX4 (Elesta SpA, Calenzano, Florence, Italy). Functional and sexual outcomes were evaluated through validated questionnaires (IPSS, IIEF-5, MSHQ-SF 3 items) and uroflowmetry parameters (Q_{max}, PVR) at 1-, 3- and 12 months.

RESULTS: We selected 34 patients with a mean prostate volume of 55.67 mL (±20.6); moreover, 4 (11.34 %) patients had indwelling catheter before TPLA; mean preoperative IPSS and IIEF 5 were 21.91 (±6.25) and 14.3 (±7.30), respectively; mean Q_{max} and PVR were 8.9 (±2.88) and 148 (±116); all patients, except one, were discharged on the same day. Mean catheterization time was 10.24 days (±15.38). An improvement in functional questionnaires as well as at postoperative flowmetry were recorded with a mean IPSS of 18.94 (±7.90), 14.79 (±7.03) and 17 (±7.01) at 1, 3 and 12 months, respectively. Mean Q_{max} and PVR were 11.55 (±5.46) and 70 (±79), 11.72 (±5.87) and 81 (±76.77), 12.5 (SD 5.82) and 81.21 (±90.14) at 1, 3 and 12 months, respectively. One patient needed re-catheterization after procedure. Sexual and ejaculatory functions were preserved in all patients at all time points. No postoperative Clavien-Dindo ≥2 complication was recorded.

CONCLUSIONS: In our experience, TPLA seems to be a safe procedure with no need for general anesthesia, efficacy in short and mid-term symptoms relief and urodynamic parameters improvement ensuring the preservation of ejaculatory function.

SC58
Transperineal interstitial laser ablation (TPLA) of the prostate for comorbid patients with benign prostatic obstruction: short- and mid-term functional and safety outcomes from a single center experience

P. Polverino, M. Lo Re, M. Saladino, C. Bisegna, A. Pecoraro, L. Moscardi, G.R. Resta, R. Mariottini, A. Rivetti, R. Nicoletti, L. Mazzola, P. Spatafora, V. Li Marzi, M. Gacci, G. Siena, A. Cocci, A. Minervini, S. Serni, R. Campi, F. Sessa (Florence)

BACKGROUND: Nowadays, despite the technological progress they have undergone in recent decades, standard

surgical techniques for benign prostatic obstruction (BPO) are still not devoid of side effects, requiring general or spinal anesthesia and hospitalization. Recently, several ultra-minimally invasive surgical techniques ensuring good functional results and a high safety profile were developed, often not requiring general anesthesia and/or hospitalization. Among these, transperineal interstitial laser ablation (TPLA) of prostate adenoma has showed promising results in preliminary series. Our work aims to evaluate functional and safety outcomes in comorbid patients undergoing TPLA for LUTS due to BPO.

METHODS: We prospectively collected data from consecutive patients undergoing TPLA at our institution between April 2021 and February 2023. Inclusion criteria were moderate to severe LUTS (International Prostatic Symptoms Score ≥8); a prostate volume ranging from 30 to 100mL and an ASA Score of 3. In case of indwelling catheter an invasive urodynamic evaluation was performed preoperatively to exclude bladder impaired contractility. Procedures were performed in an outpatient setting using local anesthesia and mild oral benzodiazepine administration, using EchoLaser™ multisource diode laser generator (Elesta SpA, Calenzano, Florence, Italy). Data regarding functional outcomes evaluated by validated questionnaires (IPSS and QoL) and uroflowmetry parameters, as well as patient management (catheterization, medications, complications) were recorded pre- and postoperatively at 1-, 3-months and last follow-up (LF-UP) for descriptive analyses.

RESULTS: Overall, 22 patients were enrolled with a median age of 76.5 (IQR 67.3-81.3). Median follow-up time was 12 months (IQR 6.5-15). Median prostate volume was 52.5 mL (IQR 38.3-72.5); median preoperative IPSS and QoL were 21 (IQR 15-26.5) and 4 (IQR 3-5), respectively; median preoperative Q_{max} and PVR were 8 (IQR 5.9-9.6) and 110 (IQR 92.5-132.5), respectively. 4 patients had an indwelling catheter before the procedure. All patients were discharged on the same day as the procedure. Median catheterization time was 7 days (IQR 0). Median IPSS and QoL were 13.5 (IQR 9.5-22.8) and 2 (IQR 1-4), 13 (IQR 10-20.5) and 2 (IQR 1 – 3.5), 16 (IQR 11.8-22) and 3 (IQR 1-3.3) at 1-, 3-months and LF-UP, respectively. Median Q_{max} and PVR were 9.1 (IQR 6.4-11) and 44 (IQR 12.5-67.5), 9.1 (IQR 8.1-9.7) and 67.8 (IQR 25-115), 10 (IQR 8.3-11.5) and 90 (IQR 30-100) at 1-, 3-months and LF-UP, respectively. 2 (9%) patients failed to remove the catheter (both with an indwelling catheter before the procedure). No Clavien-Dindo Grade ≥2 postoperative complications were recorded.

CONCLUSIONS: In our preliminary experience, TPLA appears to be a safe and feasible minimally invasive option for LUTS due to BPO in comorbid and frail patients, showing promising functional and safety outcomes. Larger series are needed to confirm these results.

SC59

Transperineal laser ablation (TPLA) and convective water vapor ablation (Rezum) for minimally invasive treatment of BPH: preliminary 3-month results from a single institutional experience of a randomized controlled trial

M. Pacini, E. Sollazzi, M. Giada, A. Perotti, P. Greco, R. Bartoletti, A. Zucchi, R. Rago (Pisa)

BACKGROUND: Minimally invasive techniques are becoming increasingly important treatment options for benign prostate hyperplasia (BPH). We evaluated the safety and efficacy of transperineal laser ablation (TPLA) and convective water vapor ablation (Rezum; Boston Scientific, Marlborough, MA, USA) in patients with BPH at 3-month follow-up.

METHODS: From February and December 2022, 74 patients were randomized for underwent TPLA (41 patients) or Rezum (33 patients). The median adenoma volume was 59.8 cc (25-200) in the TPLA group and 33 cc (10-60) in the Rezum group. Ten patients in TPLA group (24.4%) and 3 patients in Rezum group (9.1%) were catheter carriers before the procedure. The primary outcomes were the improvement in urodynamic parameters (Q_{max}, Q_{med} and PVR) and LUTS relief, assessed using the IPSS Questionnaire. The secondary outcomes were the preservation of sexual function, assessed with the IEEF-5, ejaculation, and rates of postoperative complications.

RESULTS: At 3 months, the median postoperative Q_{max} improved by +57.4% after the Rezum procedure and +57.9% after TPLA, the median postoperative Q_{med} improved by +68.2% after Rezum and +54% after TPLA, while the median PVR decreased by –56% after Rezum and -63.1% after TPLA. At the same time point, median IPSS improved by 42.7% after TPLA and 34.6% after Rezum, while IIEF-5 had not a statistically significant improvement in sexually active patients in both groups. Transient complications consisted of one patient with prostatic abscess after the TPLA procedure. Ejaculatory function was preserved in all sexually active patients. Seven out of 74 patients underwent TURP after minimally invasive treatment, not for procedural failure or complications, but for patient's will, except for the patient with prostatic abscess.

CONCLUSIONS: Both TPLA and Rezum are feasible and safe in the treatment of BPH in well selected patients, providing significant clinical results at 3 months. Longer follow-up and larger population are needed to confirm these findings, to assess the superiority of one a technique over the other and mostly which treatment would be best suited for each patient.

SC60

Is water vapor thermal therapy safe and feasible in elderly men? The Italian experience

A. Minore, S. Morselli, F. Franzoso, D. Maruzzi, F. Varvello, S. Toso, G. Ferrari, G. Siena, E. Conti, R. Papalia, R.M. Scarpa, L. Cindolo (Rome)

BACKGROUND: In recent years, water vapor thermal therapy (WVTT) has spread as one of the most innovative minimally invasive surgical treatment (MIST) in bladder outlet obstruction treatment due to benign prostate enlargement. Together with satisfying and seemingly lasting outcomes, its safety and feasibility have been largely proved in young men, nevertheless nobody has still proved these features in the elderly population (men older than 75 years old). The aim of this study was to compare WVTT safety profile between elderly *versus* younger men.

METHODS: Data on men who underwent WTT in several Italian centers has been collected prospectively since 2020. Inclusion criteria were full data set, including operative time, number of injections, intraoperative complications, intraoperative and postoperative complications, reinterventions rate. Patients were grouped according to age in elderly and non-elderly. A descriptive statistical analysis and a comparison between groups was carried out with Mann-Whitney U-Test

and χ^2 test, accordingly. Statistical significance was set with P<0.05.

RESULTS: Patients included which respected inclusion criteria were 426, of whom 60 were elderly (14.8%). Cohorts of non-elderly *vs.* elderly differed for age 63 (57-67) *vs.* 78 (76-82) years (P<0.001) and ASA Score 2 (1-2) *vs.* 2 (2-2) (P<0.001), while PSA 2.5 (1.4-3.9) *vs.* 2.8 (1.8-4.0) ng/mL and prostate volume 60 (45-80) *vs.* 64 (48-88) mL were comparable (P>0.05). Elderly patients were more likely to be in antiplatelets or anticoagulants therapy (45% *vs.* 9.6) P<0.001. Regarding safety profile, operative time was similar, 11 minutes for both groups (P=0.535), and so total number of injections 7 for non-elderly *vs.* 8 for elderly (P=0.314). We found no intraoperative complications in elderly and only one in younger men (P=0.678), while clot retentions occurred in 2 elderly *vs.* 5 younger men (P=0.239). Only one blood transfusion occurred in the elderly group (P=0.014). No differences between groups occurred in terms of length of stay, postoperative AUR and reintervention rate, while catheterization time was longer in the elderly men.

CONCLUSIONS: WVTT might be safely performed in elderly patients with similar safety profile in terms of intraoperative and postoperative complication rate to younger patients. Further studies might confirm these results.

SC61
Perioperative and short-term functional outcomes comparison between HoLEP and robot-assisted simple prostatectomy for large prostate >150 cc

G. Cochetti, M. Roupret, A. Paladini, T. Seisen, C. Vaessen, U. Pinar, S. Ciarletti, A. Tancredi, A. Vitale, R. La Mura, E. Chartier-Kastler, E. Mearini (Perugia)

BACKGROUND: Holmium laser enucleation of prostate (HoLEP) and open simple prostatectomy (OSP) are recommended treatments for large benign prostate hyperplasia (BPH). Robot-assisted simple prostatectomy (RASP) seems comparable to OSP in terms of efficacy and safety, providing similar improvements in Q_{max} and IPSS, but with advantages of minimally invasive technique. Further studies are necessary to evaluate the role of HoLEP as treatment for extremely large prostate. The aim of this study was to compare these techniques in terms of perioperative data and short-term functional outcomes in patients with prostate larger than 150 cc.

METHODS: From January 2016 to December 2022, data from 78 patients with prostate volume >150 cc who underwent HoLEP or RASP were retrospectively analyzed. Overall, 38 patients underwent HoLEP and 40 underwent RASP. Operative time (OT), blood loss, evaluated as difference between preoperative and postoperative hemoglobin level (ΔHb), length of catheterization (LOC), length of stay (LOS), International Prostatic Symptoms Score (IPSS) , Quality of Life (QoL) Index, maximum flow rate (Q_{max}), PSA, intra- and postoperative complications classified according to Intraoperative Adverse Incident Classification (EAUiaiC) and Clavien-Dindo classification, urgency and urinary continence were analyzed at 30 and 90 days after surgery. A χ^2 test and Student's *t*-test were used for statistical analysis. Statistical significance was set at P<0.05.

RESULTS: The groups were comparable in terms of age, BMI, preoperative IPSS and QoL Index. The mean prostate volume (PV) was similar (HoLEP 166.1+/-23.1 *vs.* 187.52+/-25.67 cc, P=0.1). LOC (2.3+/-1.3 *vs.* 3.8+/-1.3 days, P<0.05) and LOS (2.7+/-1.6 *vs.* 4.7+/-1.2 days; P<0.05) were significantly shorter for HoLEP group. No differences were observed in postoperative ΔHb, QoL, IPSS, PSA, urgency, and urinary continence at 30 and 90 days after surgery. Otherwise, OT of RASP was significantly shorter than HoLEP (109.4+/-20.5 *vs.* 145.8+/-38.6 min; P<0.05). No Q_{max} difference was observed at 1 and 3 months. No intraoperative complication occurred, and only minor postoperative complications were observed without significant differences (10% for HoLEP *vs.* 15% for RASP; P=0.6).

CONCLUSIONS: Compared to RASP, HoLEP shows advantages in reducing LOC and LOS. OT is higher in HoLEP group considering even morcellation time. HoLEP and RASP are both safe and effective enucleative techniques. Probably, RASP could be more useful for patients with larger BPH and multiple vesical lithiasis or large diverticulum. HoLEP is a safety alternative treatment in patients with large PV who had previous pelvic surgery or contraindication for robotic approach.

SC62
Robot-assisted simple prostatectomy (RASP) with HUGO™ RAS system: comparative analysis with da Vinci robotic system in a high-volume center

E. Balestrazzi, A. Mottaran, C.A. Bravi, M. Paciotti, M. Peraire Lores, A. Piro, M. Ticonosco, N. Frego, F. Piramide, C. Collà Ruvolo, S. Rebuffo, G. Sorce, R. De Groote, G. De Naeyer, A. Mottrie (Melle, Cuneo)

BACKGROUND: Recently, HUGO™ RAS S (Medtronic, Minneapolis, MN, USA) was introduced into the market next to the already known da Vinci robotic system (Intuitive Surgical, Inc., Sunnyvale, CA, USA). This allowed lowering the costs of robotic surgery and offering the possibility to expand indications for the robotic approach also for urological benign pathologies. The aim of our study was to compare the outcomes of robot-assisted simple prostatectomy (RASP) performed with HUGO™ RAS with a similar set of patients undergoing the procedure with the da Vinci robotic system.

METHODS: We collected data of 40 patients underwent RASP between May 2021 and February 2023 at OLV Hospital (Aalst, Belgium). All procedures were performed by experienced robotic surgeons. We collected data about patient's preoperative characteristics, operative time, intra- and postoperative complications, clashing of instruments or technical errors of the two robotic system and patient's postoperative outcomes.

RESULTS: Overall, 20 patients underwent RASP with HUGO™ RAS and 20 patients with da Vinci robotic system. Baseline characteristics – including age, BMI, CCI, ASA Score, use of antiaggregant/anticoagulant therapy, presence of transurethral and suprapubic catheter– did not differ between the two groups (all P>0.05). The median preoperative prostate volume did not differ between HUGO™ RAS and da Vinci group (206 cc *vs.* 198 cc, P=0.2); functional preoperative parameters – Q_{max} and postvoidal residue (PVR) – did not differ between the two groups (all P>0.05). The total operative time (165 *vs.* 132 minutes, P>0.05) was similar between the two groups. No intraoperative complications occurred,

and there was no need for open conversion or additional port placement. One robotic HUGO™ RAS monopolar curved shears had to be replaced during the surgery, however no further instrument clashing or technical errors occurred in the groups. Complication rates were similar in both groups (rate of all Clavien-Dindo complications: 15% *vs.* 25%; P=0.2). The median catheterization time (1 day *vs.* 1 day) and length of stay (4 days *vs.* 4 days) did not differ between the groups (all P>0.05). On final pathology, median prostate weight was similar between the groups (120 gr *vs.* 103 gr; P=0.2). At the first follow-up after surgery, no differences were found regarding Q_{max} and PVR between men underwent RASP with HUGO™ RAS and with da Vinci system (all P>0.05).

CONCLUSIONS: Our study provided similar intra-operative and postoperative outcomes of RASP performed with HUGO™ RAS and da Vinci robotic system. These results allowed to consider HUGO™ RAS as a good new tool for urological robotic surgical procedures.

SC63
Initial experience of robot-assisted simple prostatectomy with HUGO™ RAS system: step-by-step description of two different techniques

A. Piro, F. Piramide, E. Balestrazzi, M. Paciotti, C.A. Bravi, M. Peraire Lores, G. Sorce, M. Ticonosco, N. Frego, S. Rebuffo, C. Collà Ruvolo, A. Inferrera, G. G. De Nayer, R. De Groote, F. Greco, A. Mottrie (Modena)

BACKGROUND: Robot-assisted simple prostatectomy (RASP) is a minimally invasive alternative to open simple prostatectomy and has demonstrated equal early functional and better perioperative outcomes. RASP is a very attractive option for large glands, especially with concomitant bladder diverticula and stones. There are only a few clinical data on non-oncological procedures performed with the new HUGO™ robot-assisted surgery (RAS) system (Medtronic, Minneapolis, MN, USA). In this study, we reported the first large series of RASP performed with this new robotic platform.

METHODS: This study is a step-by-step description of two different surgical techniques for RASP (anterior and posterior approach) performed by two experienced robotic surgeons. We analyzed the data of 20 consecutive patients who underwent RASP at OLV Hospital (Aalst, Belgium) between February 2022 and March 2023. Patients baseline characteristics, perioperative outcomes, pathological outcomes, and one-month functional outcomes were reported. All data are reported using the median (interquartile range [IQR]) and frequencies (proportions), as appropriate.

RESULTS: The median (IQR) age and Body Mass Index were 72 (67-76) years, 28.5 (25-30.6) kg/m^2, respectively. Median preoperative PSA level was 7.7 (5-13.4) ng/mL. On the preoperative uroflowmetry, the median Q_{max} and postvoid residual (PVR) were 9.7 (6-11.8) mL/s and 95 (11.3-334) cc. Before the surgery a total of 11 (55%) patients had an episode of acute urinary retention (AUR), and 8 (40%) men had an indwelling bladder catheter (N.=5) and suprapubic (N.=3) bladder catheter, respectively. Four patients had a concomitant bladder stone, and two men had a bladder diverticulum. Three out of four patients (75%, N.=15) underwent previous unsuccessful pharmacological treatments. No intraoperative complication occurred, and there was no need for conversion and/or additional ports placement. Median operative and console time were 165 (121-180) and 125 (101-148) minutes, respectively. Median estimated blood loss was 400 (313-875) mL. No drainage was placed and 80% of the patients removed the urethral catheter on the first postoperative day. Median length of stay was 3 (3-4) days. After surgery, 3 (15%) patients had a postoperative complication. On final pathology, the median prostate volume was 120 (101-154) gr, and 1 patient was diagnosed with an International Society of Urological Pathology (ISUP) GG 1 prostatic carcinoma. On the postoperative uroflowmetry, the median Q_{max} and PVR were 16 (12.9-26.2) mL/s and 15 (0-34) cc), respectively.

CONCLUSIONS: This series represents the first report of surgical outcomes of RASP executed with the novel HUGO RAS System. Awaiting further comparative evidence with long-term follow-up, these preliminary results are comparable to those described in the literature for RASP performed with other robotic systems, suggesting that HUGO RAS has multiple potential applications, and it ensures optimal outcomes also in non-oncological procedures.

SC64
Minimally invasive robot-assisted simple prostatectomy with laparoscopic in-pouch morcellation compared to conventional minimally invasive prostatectomy

C. Zaccaro, A. Alberti, R. Nicoletti, E. Dibilio, G.R. Resta, D. Subirà, I. Lopez-Díez, J.P. Ascensios-Vargas, R. Campi, S. Serni, M. Gacci, I. Moncada-Iribarren (Madrid)

BACKGROUND: Robot-assisted simple prostatectomy (RASP) is a good treatment alternative for men with BPH, presenting advantages over the standard open procedure, but been limited by the need of laparotomy at the end of the procedure to remove the adenoma. In this study we compared the perioperative and mid-term results between two techniques of prostate adenoma removal after RASP: mini-laparotomy *vs.* laparoscopic bag morcellation.

METHODS: Data were collected from all consecutive patients who underwent RASP, from January 2018 to July 2022, at a single center. Preoperative assessment, specimen extraction modality, surgical time and length of hospital stay were collected; complications according to Clavien-Dindo (CD) classification were recorded. Postoperative follow-up included physical examination, IPSS, the Part II "Satisfaction with symptoms" and the Surgical Satisfaction Questionnaire (SSQ-8). For laparoscopic bag morcellation, MorSafe® Tissue Isolator (Balmer Médical SA, Concise, Switzerland) was used as the specimen collection bag and Versator® (Balmer Médical SA) as the tissue morcellation system.

RESULTS: Overall, 69 consecutive patients underwent RASP; in 48 patients a mini-laparotomic approach was used (group A), while 21 had laparoscopic morcellation for specimen extraction (group B). Operative times were similar for the two techniques, both considering console time and specimen removal. Time spent for laparoscopic morcellation decreased as procedures were repeated and experience increased. Length of stay and adenoma characteristics showed no significant differences between the two groups. No statistically significant differences between group A and B were found for either IPSS at one month or complications. In group A, however, there was one case of wound infection and one laparocele that required surgical correction. In group B, a higher degree of satisfac-

tion was found, with a statistically significant difference, in itching related to surgical scars, probably correlated with the smaller extent of the wound itself. On the other hand, no significant differences were found considering pain, discomfort, numbness, paresthesia, and scar-related problems, although a higher degree of satisfaction was found in group B overall. A higher degree of satisfaction was also found in group B in the responses to the SSQ-8. A statistically significant difference emerged in the answer to question 6 "How satisfied are you with the outcome of the surgery?"

CONCLUSIONS: Laparoscopic in-pouch morcellation of prostate adenoma after simple robotic prostatectomy is technically feasible and competitive in terms of operative time, providing better results in terms of overall satisfaction than the mini-laparotomic approach and less discomfort in relation to scar symptoms. Further studies are needed to consolidate the evidence.

SC65
Robot-assisted simple prostatectomy *versus* holmium laser enucleation for the treatment of benign prostatic hyperplasia in large (>100 mL) prostates: updated comparative analysis from a high-volume center

A. Mottaran, E. Balestrazzi, C.A. Bravi, L. Nocera, M. Paciotti, A. Piro, M. Peraire Lores, L. Sarchi, F. Piramide, R. De Groote, G. De Naeyer, P. Schatteman, A. Mottrie (Belgium)

BACKGROUND: In patients with large benign prostatic hyperplasia (BPH), both holmium laser enucleation of prostate (HoLEP) and robot-assisted simple prostatectomy (RASP) are possible treatment options. While both techniques have advantages and disadvantages, comparative evidence on perioperative outcomes of these operations for the treatment of large prostates (>100 mL) is still limited. Therefore, our aim was to update our comparative analysis of HoLEP *vs.* RASP for the treatment of BPH in patients with large (>100 mL) prostate volumes.

METHODS: We analyzed data of 339 patients with symptomatic BPH due to large (>100 mL) prostates glands who underwent RASP (N.=130, 35%) and Holep (N.=239, 65%) at OLV Hospital, Aalst (Belgium) between 2011 and 2021. Preoperative data collected included age, Body Mass Index (BMI), Charlson Comorbidity Index (CCI), prostate volume, uroflowmetry and the International Prostate Symptoms Scores (IPSS) questionnaire. Perioperative outcomes included operative time (OT), catheterization time (CV time) and length of stay (LOS). Perioperative complications were reported according to the Clavien- Dindo classification. Functional parameters were assessed postoperatively 3 months after surgery. We compared preoperative characteristics, operative time, and peri- and postoperative outcomes between the groups.

RESULTS. Baseline characteristics – including age, BMI, preoperative IPSS Score, preoperative maximum flow and postvoidal residue (PVR) – did not differ between patients receiving RASP *vs.* HoLEP (all P>0.05). As compared to HoLEP, patients treated with RASP had higher CCI scores (CCI≥2: 64% *vs.* 76%, P=0.001) and bigger prostates at preoperative imaging (median: 159 (115, 200) mL *vs.* 120 (110, 140) mL; P<0.001). Median OT (100 min *vs.* 120 min), catheterization time (2 *vs.* 3 days) and LOS (2 *vs.* 4 days) were slightly shorter in the HoLEP group (all P<0.001). On final pathology, median prostate weight was similar between the groups (100 gr *vs.* 105 gr; P=0.4). Complication rates were similar in both groups (rate of all Clavien- Dindo complications: 23% *vs.* 22%; P=0.2). At 3-month follow-up, both groups showed an improvement of maximum flow rate (+12 *vs.* +13.3 mL/s; P=0.4), a reduction of PVR (-93 *vs.* -75 mL; P=0.9) and IPSS Score (-16 *vs.* -12; P=0.2); transitory urge incontinence rates were higher in the HoLEP *vs.* RASP group (25% *vs.* 9%; P<0.001).

CONCLUSIONS: Our study provided relevant data on perioperative outcomes of RASP and HoLEP and might help clinicians in preoperative counselling for men with large (>100 mL) prostates requiring surgery for BPH. While patients receiving RASP had slightly longer hospital stay, both techniques achieved excellent results in this patient population, and represent valuable treatment option according to physician preferences and expertise.

SC66
Transperineal laser ablation of the prostate for the surgical treatment of lower urinary tract symptoms in very high-risk patients: six-month follow-up from a cohort of "extreme" patients

P. Destefanis, M. Sibona, F. Vitiello, E. Vercelli, G. Montefusco, L. Micai, F. Bracco, C. Mangione, A. Bosio, A. Bisconti, P. Gontero (Turin)

BACKGROUND: Transperineal laser ablation of the prostate (TPLA) has been proposed as a minimally invasive surgical technique for the treatment of Lower Urinary Tract Symptoms (LUTS). Initial results were promising in standard benign prostatic hyperplasia (BPH) patients. However, this technique appeared also suitable for application in elderly and comorbid patients. Preliminary results from our prospective cohort of elderly and very comorbid patients demonstrated a high safety profile and suggested efficacy in treating LUTS. The aim of our study was to show 6-month follow-up (FU) results from the same cohort.

METHODS: Local ethics committee approval was obtained (N.=00161/2020). From 10/2020 to 06/2022, BPH patients meeting the study's criteria were prospectively enrolled. Inclusion criteria: 1) ongoing anticoagulant or double antiplatelet therapies or severe non-pharmacological coagulopathies (*i.e.,* low platelet syndromes) or American Society of Anesthesiologists (ASA) Score >3 together with 2) moderate to severe LUTS (IPSS>8 and IPSS Bother Score ≥3) or indwelling catheter. All procedures were performed under local anesthesia with the SoracteLite® system (Elesta s.r.l., Calenzano, Italy), composed of a transrectal ultrasound-guided, multifiber interstitial diode laser (Echolaser®) and a treatment planning platform named Echolaser Smart Interface (ESI). Baseline, 3 and 6-month FU data were recorded.

RESULTS: Forty patients were enrolled in the study. Median (IQR) age was 80 (72.5-84) years; 23/40 (57.5%) patients were chronic CV carriers. Median Charlson Comorbidity Index was 6 (5-7). Median prostate volume was 38 (30.5-73) cc. A TPLA procedure was performed correctly in all patients, without intraoperative complications. The median number of fibers used per patient was 2.4 (2.4±0.77). Median energy delivered to the prostate and laser time were 7498 (7498±4658) Joules and 15 (15±6.3) minutes. Median operation time was 43 (43±13) min. We reported 21 compli-

cations (52%): according to Clavien-Dindo classification, 13 grade I (32.5%), 5 grade II (12.5%): only 1 grade III (2.5%; endoscopic re-intervention for hematuria) and no grade IV-V; none was long-term. Two patients deceased within 3 months from surgery, due to unrelated causes. After 3 months, median IPSS Score decreased from 25 (19-30) to 10.5 (7.5-13), P<0.001; 10/40 (25%) patients were persistent CV carriers. After 6 months, median IPSS Score was 8 (6-11.5), P=0.001 and only 10 patients were still CV carriers, meaning that a successful removal of a permanent CV was obtained in 3/4 of cases. Postoperative pressure/flow studies revealed detrusor hypocontractility in 6 out of 7 patients with refractory urinary retention.

CONCLUSIONS: TPLA could be safely proposed for the treatment of LUTS in elderly men with severe comorbidities, thus offering a chance of treatment to patients otherwise deemed not suitable for surgery. Despite an increased risk, severe comorbidities are infrequent, and a successful treatment can be often achieved also in complex patients, such as permanent CV carriers.

SC67

Rezum *vs.* TURP for the treatment of benign prostatic obstruction: a multicenter propensity-score matched pair "Tetrafecta" analysis (URAN Collaborative Group)

A. Cocci, G. Busetto, A. Lo Giudice, F. Sessa, A. Tuccio, G. Siena, M. Pezzoli, G. Cacciamani, F. Castiglione, M. Falcone, M. Ricci, G. Patruno, P. Dell'Oglio, R. Bertolo, M. Carilli, E. Durukan, G.I. Russo (Florence)

BACKGROUND: Benign prostatic hyperplasia (BPH) is a common condition that affects aging men. It is characterized by the enlargement of the prostate gland, leading to lower urinary tract symptoms (LUTS). Two common procedures used to treat BPH are Rezum (Boston Scientific, Marlborough, MA, USA) and TURP. Rezum is a minimally invasive procedure that uses steam to ablate excess prostate tissue. The procedure involves inserting a small device into the urethra and using steam to shrink the prostate tissue. Rezum has been shown to be effective in treating BPH and has a lower risk of complications compared to traditional surgical procedures. The aim of this study is to perform a match-pair comparison between Rezum and TURP by investigating clinical outcomes after 1-year follow-up.

METHODS: We undertook 1:1 matched-pair analysis (age and prostate volume) of 177 consecutive patients treated for benign prostatic obstruction, including 55 Rezum and 55 TURP. Inclusion criteria were as follows: lower urinary tract symptoms or benign prostatic obstruction, IPSS≥12, prostate-specific antigen (PSA) <4 ng/mL, or PSA between 4 and 10 ng/mL but negative prostate biopsy and peak flow <15 mL/s. We evaluated the following variables after 12-month follow-up: peak flow, IIEF-5 and IPSS. The rate of retrograde ejaculation was also recorded. A Tetrafecta positive outcome was defined as the presence of IPSS <8, IIEF-5 >20, peak flow ≥12 mL/s and antegrade ejaculation.

RESULTS: A total of 110 patients, 55 Rezum and 55 TURP, has been included in the final analysis. Median age was 64 years old (IQR: 59.0-68.0), median peak flow was 9.0 (IQR: 6.9-11.6), median IPSS was 23.0 (IQR: 18.0-28.0), median PSA was 1.75 (IQR: 0.9-2.65) and median prostate volume was 54.5 (IQR: 40.0-68.0). We did not observe any statistical significance difference regarding age (P=0.85), prostate volume (P=0.15), IPSS (P=0.75) and peak flow (P=0.11) between groups. After 12-months of follow-up, in Rezum group the median change of peak flow was 5.8 (IQR 3.0-9.3), median change of IPSS was -10 (IQR: -18.0, -6.0) and median change of IIEF-5 was 0.0 (-1.0, 5.0); in TURP group the median change of peak flow was 9.1 (IQR 4.1-13.9) (P<0.01), median change of IPSS was -18 (IQR: -22.0, -11.0)(P<0.01) and median change of IIEF-5 was 2.0 (0.0-3.0) (P=0.19). The rate of retrograde ejaculation was 27.45% (14/55) and 72.55% (37/55) in Rezum and TURP groups, respectively (P=0.01). The rate of Tetrafecta was 11.11% (2/55) and 88.89% (16/55) in Rezum and TURP groups, respectively (P=0.01). At the logistic regression analysis adjusted for prostate volume, TURP was an independent predictor of Tetrafecta (odds ratio: 10.94; 95% CI 2.35-50.83; P<0.01).

CONCLUSIONS: After 1-year of follow-up, TURP demonstrated to be more frequently associated with Tetrafecta outcomes respect to Rezum. This latter, however, has more chance to maintain antegrade ejaculation. These results should be considered during the counselling of patients before surgery.

SC68

A comparison of the efficiency and safety profile between two morcellators for laser enucleation of the prostate: Piranha *versus* Cyber Blade devices

L. Berti, D. Perri, F. Mazzoleni, A. Pacchetti, E. Morini, U. Besana, A. Paulesu, M.C. Sighinolfi, B. Rocco, J.B. Roche, E. Liatsikos, F. Bruyere, G. Bozzini (Busto Arisizio, Varese)

BACKGROUND: Different types of morcellator by different companies are available on the market with different features. However, the type of morcellator which provides the best performance has not been found yet and evidence on the comparison between these tools is still scarce. We performed a comparison between the Wolf® Piranha™ (Richard Wolf GmbH, Knittlingen, Germany) and the Quanta System® Cyber Blade™ instruments (Quanta System S.p.A., Milan, Italy) for the Thulium laser enucleation of the prostate (ThuLEP).

METHODS: 205 patients suffering from lower urinary tract symptoms due to benign prostatic hyperplasia underwent ThuLEP using the Cyber TM laser generator between 2020 and 2022. All surgeries were performed by the same operator. Morcellation was performed with the Piranha morcellator in 100 cases (group A, 48.8%) and the Cyber Blade morcellator in 105 cases (group B, 51.2%). Morcellation time and efficiency were recorded relating instrument performance to prostate volume. Complication rate and device malfunctions were reported to assess safety of these instruments.

RESULTS: Groups were comparable according to preoperative features. Mean prostate volume (PV) was 82.5 mL and 91.9 mL (P=0.21) in Group A and B respectively. Mean morcellation time was 9.7 min and 10.1 min in Group A and B respectively when PV was ≤100 mL, with no statistically significant difference (P=0.34). On the contrary, mean morcellation time was significantly lower in the Cyber Blade group *vs.* the Piranha group when PV was >100 mL (12.7 min *vs.* 10.1 min, P=0.04). Similarly, morcellation efficiency was comparable when PV was ≤100 mL (8.5 g/min *vs.* 9.1 g/min, P=0.08), while it was significantly higher in the Cyber

Blade group when PV was >100 mL (7.0 g/min *vs.* 9.3 g/min, P=0.04). Bladder injury occurred in 3 cases (3.0%) in Group A and 2 cases (1.9%) in Group B. Both morcellators had comparable complication rate (P=0.12). No mechanical problems occurred.

CONCLUSIONS: Performance was similar in terms of morcellation time and efficacy between Piranha and Cyber Blade tools when PV was ≤100 mL, while it was significantly higher with the Cyber Blade morcellator when PV was >100 mL. Both instruments are safe and reliable according to the risk of bladder injury and the occurrence of mechanical problems.

SC69
BPH3 trifecta for robotic assisted simple prostatectomy (RASP) *vs.* BPH6: a novel outcomes comparison metric

A.M. Bove, A. Brassetti, S. D'Annunzio, G. Tuderti, M. Ferriero, U. Anceschi, L. Misuraca, R. Mastroianni, F. Proietti, G. Simone (Rome)

BACKGROUND: BPH6 is a comprehensive metric to assess outcomes after treatment for BPO. However, since the BPH6 includes reduction of <6 points in International Index of Erectile Function (IIEF) and persistence of antegrade ejaculation at Male Sexual Health Questionnaire (MSHQ), only a small percentage of disobstructive procedures can lead to its achievement. We tested our novel BPH3 trifecta, in assessing the disobstructive proficiency of robotic-assisted simple prostatectomy (RASP) according to different techniques.

METHODS: Baseline prostate volume (PV), flowmetry parameters and Validated questionnaires: IIEF, Incontinence Severity Index Score (ISI), International Prostatic Symptoms Score (IPSS), MSHQ, Quality of recovery (QOR), were recorded preoperatively and 12 months postoperatively. RASP was performed according to the urethra-sparing (Madigan) technique and a non- urethra-sparing trans-vescical (Freyer) approach. The 2 cohorts were tested for our novel composite BPH-3 achievement rate as well as for BPH-6 achievement rate. BPH-3 was defined as combination of reduction of ≥30% in IPSS compared to baseline, ISI Score ≤4, and no complication Clavien >1.

RESULTS: One hundred fifty-eight patients underwent RASP (93 Madigan and 65 Freyer). Patients scheduled for Madigan procedure were younger, with lower PV, baseline IPSS Score, overactive symptoms (ISI Score), but higher MSHQ and IIEF Score, when compared to the Freyer population (all P<0.02). At 12-month follow-up, Madigan patients reported a shorter bladder irrigation time and time to catheter removal (both P<0.001). A superiority in postoperative IEEF and MSHQ Score were reported by the Madigan patients as expected (all P<0.001). Postoperative complication incidence was higher in the Madigan cohort, mainly due to UTI (P<0.001). Although there were no differences in postoperative IPSS and Q_{max} between groups, the Madigan cohort presented with higher post void residue (P<0.001). BPH6 achievement was higher in the Madigan cohort (48% *vs.* 28%) (P<0.001), while no difference was found in BPH3 achievement rate.

CONCLUSIONS: Novel BPH3 composite trifecta appears to be more suitable than BPH6 in assessing the proficiency in disobstructive symptoms relief after RASP.

SMART (SC70-SC83)

Andrology 1

SC70
Routinely use of penile dynamic duplex ultrasound for erectile dysfunction diagnosis: retrospective analysis of a single center experience
SC71
Is dynamic penile color Doppler duplex ultrasound a reliable tool to discriminate vasculogenic erectile dysfunction? Potential implications of the diagnostic findings in real-life clinical practice
SC72
Atherogenic index of plasma: the role of lipidic balance on erectile dysfunction
SC73
Comparison between LI-ESWT and alprostadil as second line after robot assisted radical prostatectomy
SC74
Predictive factors for the efficacy of the low intensity extracorporeal shock wave therapy (LI-ESWT) to improve erectile dysfunction: a prospective study
SC75
Major adverse cardiovascular events (MACE) related to phosphodiesterase 5 inhibitors (PDE5I): analysis of real-life data from Eudra-Vigilance (EV) database
SC76
Trends and incidence of reported events associated with penile prosthesis: an analysis of the Food and Drug Administration's manufacturer and user facility device experience database
SC77
Influence of overactive bladder on sexual function of male patients with multiple sclerosis
SC78
A preliminary report on hereditary amyloidogenic transthyretin (ATTR) amyloidosis and the correlation with early onset erectile dysfunction (DE)
SC79
Erectile function recovery among young men with erectile dysfunction on OAD tadalafil 5 mg: findings from a real-life study
SC80
Retrospective comparison of split-thickness skin grafts *versus* full-thickness skin grafts in the surgical repair of adult acquired buried penis (AABP)
SC81
Outcomes of neurological patients treated with penile implants: data from the multicenter prospective registry INSIST-ED
SC82
Cancer survivorship in male patients: the importance of involving the andrologist
SC83
Genital lichen sclerosus: national multicentric survey

SC70

Routinely use of penile dynamic duplex ultrasound for erectile dysfunction diagnosis: retrospective analysis of a single center experience

A. Piasentin, A. Sartorel, S. Sartori, A. Biasatti, A.I. Iachimovsky, L. Braulin, F. Zorzi, M. Rizzo, C. Trombetta, G. Liguori (Trieste)

BACKGROUND: Penile dynamic duplex ultrasound (PDDU) is routinely used to evaluate patients with erectile dysfunction (ED). The aim of the study was to identify if PDDU parameters can influence the management of these patients.

METHODS: We retrospectively analyzed all the PDDUs performed in a single center between January 2020 and September 2022. Ultrasound parameters were collected for each cavernous body. According to EAU guidelines we consider normal peak systolic velocity (PSV) >30 cm/s and Resistance Index (RI) >0.8. Cavernous arteries (CA) ultrasound appearance was described if pathological (intimal thickness and corkscrew aspect). Considering only patients with adequate anamnesis for ED, we split the population in two groups, the one with patients able to penetrate with or without the help of PDE5-i (group A) and the one with impossibility to penetrate (group B).

RESULTS: One hundred forty-eight patients were included in the study. Median (IQR) age was 59 (51-65) years, 61.7 % had a previous cardiovascular event, 22.4% had either insulin-dependent or type II DM, 33% took one drug for hypertension and 15.8% more than one drug. 51 (34.5%) had an ultrasound proved penile plaque. 64.2% of the patients were addressed to the exam by an andrologist, 35.8% by another physician. 96 (63.5%) patients had an adequate anamnesis for ED, while 54 (36.5%) did not. Patients assessed by an andrologist did not have a more accurate anamnesis (P=0.63). Group A included 63 (65.6%) patients and group B 33 (34.4%). No differences according to RI and PSV were found between the two groups (P=0.70 left and P=0.78 right for RI; P=0.689 left and 0.661 right for PSV); a similar dosage of alprostadil was injected to achieve erection (P=0.479); CA ultrasound appearance was similar (P=0.327). No relation to CV or DM-related events was observed during the follow- up (P=0.71 and P=0.66 respectively). We then observed that CA ultrasound appearance was related to lower RI bilaterally (P=0.017 left, P=0.032 right), lower age of the patients (P=0.015), lower PSV (P=0.022 left, P=0.032 right) but seems not to be related to cardiovascular and DM related events during follow-up. CA ultrasound appearance was not related to the presence of fibrotic plaque (P=0.002).

CONCLUSIONS: PDDU is a valuable tool to rule out vasogenic ED, and the ultrasound appearance of the cavernous arteries is related to lower performance at the exam. However, patients with anamnestic ED did not have a pathological exam, reflecting the importance of psychological factors.

SC71

Is dynamic penile color Doppler duplex ultrasound a reliable tool to discriminate vasculogenic erectile dysfunction? Potential implications of the diagnostic findings in real-life clinical practice

G. Fallara, F. Belladelli, E. Pozzi, A. Bertini, F. Lanzaro, L. Candela, S. Cilio, C. Corsini, M. Raffo, F. Negri, L. Cella, M. Fantin, P. Capogrosso, L. Boeri, A. d'Arma, A. Muneer, F. Montorsi, A. Salonia (Milan)

BACKGROUND: The aim of this study was to assess dynamic penile color doppler duplex ultrasound (CDDU) performance in a cohort of patients consecutively investigated for erectile dysfunction (ED) at a single tertiary referral center.

METHODS: Complete sociodemographic and clinical data from the last 272 consecutive patients submitted to CDDU were analyzed. All patients completed the International Index of Erectile Function (IIEF) at baseline. Vasculogenic ED was suspected for IIEF- EF≤16 (moderate ED) and a history of cardiovascular (CV) risk factor or previous CV events. Peak systolic velocity (PSV) at 20 minutes after intracavernous 20 microgram alprostadil injection was measured for both cavernous arteries, and thus segregated according to IIEF-EF groups, age, and CV risk factors. The diagnostic accuracy (Se, Sp and AUC) of CDDU for a PSV threshold equal to 30 cm/s was assessed. Thereof, the probability of vasculogenic ED was plotted according to the number of CV risk factors as stratified for PSV values.

RESULTS: Overall, median (IQR) age was 53 years (42-61). Of all, 170 (62.5%) and 108 (39.7%) patients depicted at least 1 or 2 CV risk factors, respectively. Median IIEF-EF was 12 (6-19), with 120 patients (44.1%) with severe ED, 54 (20%) moderate ED, and 88 (32.4%) mild ED according to Cappelleri's criteria. Of all, 88 (32.4%) had baseline criteria suggestive for a possible vasculogenic ED. Despite median PSV value was significantly lower in severe (39.2 [26.3-50.0]) compared to no ED patients' group (45.5 [31.4, 58.8]) (P=0.006) according to IIEF-EF domains scores, the established 30 cm/s threshold for PSV had a low accuracy (AUC=0.56, Se=33%, SP=82%) in detecting vasculogenic ED. Indeed, 79 (20.0%) patients with vasculogenic ED had normal PSV whilst 26 (9.6%) without vasculogenic ED had abnormal PSV values. The probability of vasculogenic ED increased with the number of CV risk factors and with lower PSV values, being highest for PSV≤15 cm/s.

CONCLUSIONS: The mismatch between a clinical history of CV risk factors and CDDU findings weakens CDDU performance in terms of vascular investigation in patients with ED, thus limiting the application of scientific guidelines. Lower threshold for PSV might increase CDDU accuracy to discriminate vasculogenic ED.

SC72

Atherogenic index of plasma: the role of lipidic balance on erectile dysfunction

L. Napolitano, A. Fraia, F. Di Bello, C. Collà Ruvolo, G. Califano, S. Morra, M. Creta, N. Longo, V. Mirone, N. Longo (Naples)

BACKGROUND: The aim of this study was to describe the role of Atherogenic Index of Plasma (AIP) as predictor of erectile dysfunction (ED) severity and worsening post robot-assisted radical prostatectomy (RARP) in prostate cancer (PCa) patients.

METHODS: The blood panels of 424 consecutive RARP patients at a single tertiary academic referral center, from September 2020 to April 2022, were reviewed. Data from 359 patients with a complete lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides) were

included in the final analysis. Furthermore, two independent multivariable logistic regression models (LRMs) were fitted to predict the ED severity and worsening in non-ED and non-severe ED patients.

RESULTS: Within the overall sample, the median age was 70 (inter quartile range [IQR]:65-74), and the median BMI value of 28.4 (IQR: 26-30.4). The overall median values of AIP, Castelli Risk Score I (CR-I) and Castelli Risk Score II (CR-II) were 0.36 (IQR:0.20- 0.51), 4 (IQR: 3.4-4.7) and 2.7 (IQR: 21.3.3), respectively. Of all, 194 (54%) had received a nerve-sparing procedure. According to the preoperative IIEF-5, 94 (26.2%), 84 (23.4%), 26 (7.2%) and 42(11.7%) were mild, mild-to-moderate, moderate, and severe ED patients, respectively. According to postoperative IIEF-5, 28 (7.8%), 83 (23.1%), 91 (25.3%) and 140/359 (39%) were mild, mild-moderate, moderate, and severe ED patients, respectively. After multivariable LRMs predicting ED severity, age, BMI, and nerve sparing (NS) approach were an independent predictor. After multivariable LRMs predicting ED worsening, only NS approach was an independent predictor.

CONCLUSIONS: AIP did not represent an independent predictor of ED severity and worsening in RARP patients. Moreover, neither CR-I nor CR-II were correlated to ED severity and worsening.

SC73
Comparison between LI-ESWT and alprostadil as second line after robot assisted radical prostatectomy

M. Benedetti, S. Di Bari, A. Mofferdin, G. Stella, S. Gallo, D. De Nicolo, S. Ferretti, S. Puliatti, S. Micali (Modena)

BACKGROUND: Low-intensity extracorporeal shock wave therapy (LI-ESWT) is gaining popularity as an adjunct therapy in the treatment of erectile dysfunction (ED). It is now one of the options for vasculogenic ED in the guidelines, although it has received less attention as a form of postprostatectomy rehabilitation. We intended to compare the association between PDE5 inhibitors and ESWT, with endocavernous Alprostadil therapy in patients who underwent a robot-assisted nerve sparing radical prostatectomy (RALP) after failed first line rehabilitation treatment (oral PDE5 inhibitor).

METHODS: We evaluated 100 patients who underwent RALP and failed rehabilitation for ED with oral PDE5 inhibitor medication, tadalafil 20 mg 3 cp/week. In our center we retrospectively evaluated 100 patients between 2018 and 2021. Fifty patients in group 1 underwent ESWT rehabilitation with PDE5 inhibitor; the other 50 patients (group 2) received alprostadil endocavernosal treatment. Group 1 received 12 cycles of ESWT with 5000 shock waves delivered directly to the perineum and corpora cavernosa. Patients were evaluated using the IIEF 5 Score Questionnaire at T0, before surgery, then at T1, after three months of oral therapy PDE5 intake, then at T2 after other three months in which they alternatively received ESWT or Alprostadil medication.

RESULTS: In our series, one patient did not finish the ESWT cycle. Nobody experienced complications. A *t*-test was used to investigate the values examined. Group 1 registered at T0 a IIEF 5 Score of 22.8±2.7 (14-25), whereas group 2 registered a score of 20.7±4.0. (10-25). At T1, following the oral PDE5 treatment, the scores in both populations decreased to 7.3±5.6 (0-25) and 6.8±3.9 (0-15) respectively. After other 3 months of follow-up at T2, we recorded the following results: 13.0 ±6.8 (5-25) and 11.6±6.7 (0-22), respectively, with a P<0.001.

CONCLUSIONS: Combined ESWT and PDE5 inhibitor therapy demonstrated to have similar results compared to alprostadil endocavernous injection therapy, reducing the invasiveness of the treatment. Prospective, randomized trials are needed to validate this new therapeutic approach.

SC74
Predictive factors for the efficacy of the low intensity extracorporeal shock wave therapy (LI-ESWT) to improve erectile dysfunction: a prospective study

L. Quaresima, D. Fasanella, L. Mariani, W. Giannubilo (Civitanova Marche, Macerata)

BACKGROUND: Low intensity extracorporeal shock wave therapy (LI-ESWT) has been used for some years for the treatment of Erectile Dysfunction (ED): in particular, the EAU guidelines provide it for the treatment of mild ED or for patients who are poorly responsive to oral therapy. Unfortunately, therapy with LI-ESWT, which consists of a cycle of treatments of at least 10 sessions, whose cost is at patient's charge, is burdened by a failure rate that is far from negligible. The purpose of our work is to identify the factors that predispose to the response of LI-ESWT.

METHODS: One hundred five patients with mild to moderate ED were treated from February 2021 to February 2023. All patients were stratified by age, BMI (normal weight, overweight, obese) and comorbidities (smoking, compensated or decompensated diabetes mellitus, compensated or decompensated hypertension) and were evaluated before and 2 weeks after the end of the course of treatment with questionnaire International Index of Erectile Function short version (IIEF-5). The study excluded patients who had previously performed unsuccessful drug therapy. Patients with iatrogenic or post trauma ED were also excluded. The patients underwent a cycle of 10 sessions of focal LI-ESWT with electro-pneumatic device with 1.1 Bar pressure with 4000 strokes per session with 4 Hz frequency.

RESULTS: A total of 92 patients with an average age of 63 years (47-76) and an average pretreatment IIEF 5 of 18/25 (16-21 / 25) met the study criteria. Of these, 82 have completed the treatment cycle and follow-up. Among them, 65% of the patients showed an increase in the questionnaire score: these patients with an average pretreatment IIEF 5 of 19/25, had an average post-treatment IIEF 5 of 22/25. Percentage of patients with a valid erection recovery were 61%. This percentage was lower in the subcategories of obese patients, smokers, in polytherapy, with diabetes not well compensated, with hypertension not well controlled with percentages of 52, 54, 55, 51 and 54% respectively(P<0.05). No association was found with age, overweight, compensated diabetes o hypertension (P<0.05).

CONCLUSIONS: Age, overweight (not obesity), well-controlled diabetes or hypertension do not affect the recovery of a valid erection with the LI-ESWT treatment. On the contrary, smokers or patients with diabetes or poorly controlled hypertension or with obesity show a less than average response to treatment and should be directed towards other therapy.

SC75
Major adverse cardiovascular events (MACE) related to phosphodiesterase 5 inhibitors (PDE5I): analysis of real-life data from Eudra-Vigilance (EV) database

A. Nacchia, L. Sarcinelli, R. Lombardo, A. Franco, L.M. Rovesti, C. Gravina, B. Turchi, J. Stira, A. Guercio, G. Gallo, O.A. Voglino, V. Baldassarri, G. Guarnotta, E. Mancini, A. Cicione, A. Tubaro, C. De Nunzio (Rionero In Vulture, Potenza)

BACKGROUND: Phosphodiesterase 5 inhibitors (PDE5i) are one of the mainstays for erectile dysfunction (DE). The cardiovascular safety is of outmost importance and registry studies suggest these drugs are safe in these terms. The aim of our study was to evaluate real-life data on major adverse cardiovascular events associated with PDE5i based on Eudra-Vigilance (EV) database.

METHODS: Eudra-Vigilance database is the system for managing and analyzing information on suspected adverse reactions to medicines which have been authorized or being studied in clinical trials in the European Economic Area (EEA). Major adverse cardiovascular events (MACE) are defined as myocardial infarction, stroke, revascularization after coronary artery bypass graft (CABG) and heart failure. We recorded the number of MACE for sildenafil, tadalafil, vardenafil, avanafil per age and severity until September 2021. Pooled relative risk (PRR) was used to compare data between drugs.

RESULTS: Overall, the number of MACE reported were for PDE5i 642 events. MACE was less than 3% of total AEs in all classes of drugs. Most reported MACE were for Sildenafil and Tadalafil (respectively 296 events and 173 events of Myocardial Infarction, 11 events and 17 events for Stroke, both 4 for revascularization after CABG and 60 events and 27 events for heart failure). No MACE was reported for avanafil. Most of the reported MACE for drugs were present in the range of age between 65 and 85 years old with a total of 308 events (48%). No significative differences were reported comparing myocardial infarction, stroke, revascularization after CABG and heart failure between drugs (PRR 0.99 0.83-1.20, P>0.05). No significative differences were reported comparing groups for age (PRR: 0.80-1.30, P>0.05)

CONCLUSIONS: MACE related to PDE5i are reported in EV database. Real-life data suggest PDE5i are poorly associated with MACE. According to real life data PDE5i are safe regarding major and serious cardiovascular events.

SC76
Trends and incidence of reported events associated with penile prosthesis: an analysis of the Food and Drug Administration's manufacturer and user facility device experience database

F. Zammitti, C. De Nunzio, A. Nacchia, C. Gravina, G. Gallo, D. Fiasconaro, L. Sarcinelli, N. Ghezzo, A. Guidotti, R. Lombardo, A. Franco, G. Tema, A. Cicione, A. Pastore, A. Sciarra, G. Di Pierro, G. Franco, A. Tubaro (Rome)

BACKGROUND: The aim of this study was to summarize medical device reports (MDRs) between 2012 and 2022 relating to penile prosthesis systems within the Manufacturer and User Facility Device Experience (MAUDE) database maintained by The Food and Drug Administration (FDA).

METHODS: The MAUDE database was analyzed for all MDRs relating to each FDA-approved penile prosthesis for the last ten years. Event descriptions were reviewed and characterized into specific event types. Outcome measures include specific penile prosthesis and reported events as detailed by the MDRs. All data is de-identified and in compliance with the Health Insurance Portability and Accountability Act (HIPAA). No further data was available in the database. Pooled relative risk was used to compare data.

RESULTS: Overall, 1340 reports were retrieved in 10 years, between 2019 and 2021 a higher number of events were reported. Overall, 1240/1340 (92%) were reported as injury while 91/1340 (7%) as malfunction of the prosthesis. The most frequently reported AEs were infections (181/1340:14%), erosion (144/1340:11%), pain (68/1340:5%) and perforation (47/1340: 4%). In terms of manufacturer: 675/1340 (50%) were Boston prosthesis, 198/1340 (15%) were Coloplast and 463/1340 (35%) were AMS. When comparing on disproportional analysis the different manufacturers, Coloplast (Humlebæk, Denmark) presented a higher risk of infection when compared to Boston and AMS (PRR=1.5-2.62; P<0.05). Regarding perforation, pain, Failure to implant and erosion incidence the incidence was comparable between manufacturers.

CONCLUSIONS: Standing to MAUDE database the most frequent complications related to penile prosthesis are infections, erosions, pain, and perforation. As well Coloplast prosthesis seem to be associated with a higher risk of infection.

SC77
Influence of overactive bladder on sexual function of male patients with multiple sclerosis

R. Bientinesi, F. Gavi, D. Fettucciari, S. Coluzzi, F. Marino, C. Gandi, M. Campetella, S. Moretto, V. Nociti, M. Racioppi, E. Sacco (Rome)

BACKGROUND: Overactive bladder (OAB) and sexual dysfunction are common symptoms in patients with multiple sclerosis (MS) having a great impact on their quality of life. The aim of this study was to assess the impact of OAB in MS patients focusing on the quality of sexual health and the quality of their marital relationship.

METHODS: Data of consecutive male patients with diagnosis of MS and in a stable relationship (at least 6 months relationship) that attended our outpatients' clinic between October 2021 and August 2022 were collected. Patients were clinically classified as group A (patients with OAB) or group B (patients without OAB) according to 3-day bladder diary (at least 1 episode/ day). Variables including age, EDSS, prostate volume (PVol), presence of urinary incontinence (UI) and maximum urinary flow rate at uroflowmetry (Q_{max}) with postvoiding residual volume (PVR) were collected. Patients were asked to complete validated questionnaires to assess lower urinary tract symptoms (LUTS) by international consultation on incontinence questionnaire male lower urinary tract symptoms module (ICIQ-MLUTS), erectile function by International Index of Erectile Function (IIEF-5) and quality of marital relationship (DAS). Student's *t*-test and χ^2 were used to assess statistically significant differences between the two groups.

RESULTS: Seventy-four MS patients were included in the present analysis. 33 were included in group A and 41 were

included in Group B. There were no statistically significant differences between the two groups regarding age, prostate volume, Q_{max}, UI rate and PVR (P>0.05). ED was present in 26 (78%) patients in group A in group A (39%) and 13 (32%) in group B (P<0.001). Patients in group A had a lower EDSS scores respect to patients in group B (P<0.006). Patients in group A had worse results regarding LUTS assessed by ICIQ-MLUTS (P<0.02), erectile function assessed by IIEF-5 (P<0.001) and quality of marital relationship assessed by DAS (P<0.05).

CONCLUSIONS: OAB in MS patients is associated with erectile disfunction and poorer quality of marital relationship.

SC78
A preliminary report on hereditary amyloidogenic transthyretin (ATTR) amyloidosis and the correlation with early onset erectile dysfunction (DE)

V. Cantavenera, V. Di Stefano, G. Tulone, C. Minasola, S. Altomare, P. Alonge, F. Brighina, A. Simonato (Palermo)

BACKGROUND: ATTR amyloidosis is a rare disease caused by a mutation in the transthyretin (TTR) gene that causes the accumulation of misconfigured TTR proteins as amyloid fibrils in multiple organs and tissues, with a progressive loss of function. The disease is predominantly seen in males aged >60 years, and typically manifests as cardiac symptoms, as well as signs and symptoms of sensorimotor neuropathy and autonomic neuropathy. One of the most frequently reported symptoms at the onset is erectile dysfunction (ED). The aim of this study was to evaluate the extent of ED between two cohort of patient: the first one manifesting neurological symptom and the other reportedly asymptomatic.

METHODS: Our study was conducted prospectively and retrospectively in a reference center for the diagnosis and treatment of ATTR amyloidosis. We administered the International Index of Erectile Function questionnaire (IIEF-15), as well as the International Prostatic Symptoms Score (IPSS) to two cohort of patients: neurological symptomatic patients and carriers (non-neurologic patients). We considered a value of IIEF-15 inferior to 25 suggestive for ED. An IPSS value greater than 8 was an indicator of moderate to severe lower urinary tract symptoms (LUTS).

RESULTS: From the analysis of the collected data (between August 2022 and October 2022) of 24 patients, it emerges that the onset of mild erectile deficit occurs at an average age of 47 years old in asymptomatic carrier patients. In fact, 60% of carriers complained ED, 89% of them with mild to moderate dysfunction (IIEF 23, IQR [23-27.5]). A moderate to severe erectile disfunction is present in about 89% of patients with advanced disease with neurological manifestation. The presence of LUTS did not differ significantly from the general population.

CONCLUSIONS: Given the apparently early onset of ED in young carrier patients, it is useful, at the time of the anamnestic collection, to investigate possible other symptoms correlated with TTR amyloidosis. A careful specialist evaluation could therefore lead to an early diagnosis of a rare disease. Ultimately, this would determine an alteration of the evolution of the disease, being able to start a targeted therapy aimed at delaying the progression of ATTR.

SC79
Erectile function recovery among young men with erectile dysfunction on OAD tadalafil 5 mg: findings from a real-life study

E. Pozzi, F. Negri, F. Belladelli, G. Fallara, S. Cilio, C. Corsini, A. Bertini, M. Raffo, L. Cella, M. Fantin, F. Lanzaro, L. Candela, P. Capogrosso, L. Boeri, A. d'Arma, F. Montorsi, A. Salonia (Milan)

BACKGROUND: Daily tadalafil 5 mg provides a valuable alternative to on-demand tadalafil for men who prefer spontaneous to scheduled sexual attempts. We investigated the rate and the clinical factors associated with erectile function (EF) recovery after discontinuation of 5 mg tadalafil OaD in a cohort of young men seeking medical help for erectile dysfunction (ED) as their primary complaint.

METHODS: Complete data from 96 consecutive young patients (<50 year) seeking first medical help for ED and prescribed with 5 mg tadalafil OaD were analyzed. All patients were diagnosed with psychogenic ED after a comprehensive clinical evaluation including penile duplex ultrasound and hormonal profile assessment. All completed the International Index of Erectile Function (IIEF) at baseline. The length of treatment varied from a minimum of 1 to 12 months according to clinical judgement. EF recovery was assessed after 2 weeks from treatment discontinuation and defined as IIEF-EF>21 after daily 5 mg tadalafil discontinuation. Patients without EF recovery was classified as tadalafil OaD non-responders. Cox-regression models tested the association between patients' baseline characteristics and the probability of EF recovery after treatment discontinuation. Kaplan-Meier analyses estimated the probability of EF recovery over time.

RESULTS: Overall, median (IQR) age was 39 (32-45) yr. Of all, 82 (85.4%) achieved EF recovery at treatment discontinuation, whilst 14 (14.6%) were identified as non-responders. The median treatment length was 3 (2-11) months. Most common treatment- related adverse effect was headache in 9 (9.4%) patients. Non-responders were older (43 vs. 38, P=0.03), had higher BMI (25.54 vs. 23.6, P=0.04) and depicted lower IIEF-EF scores at baseline (12 vs. 15, P=0.02) than responders. No differences in terms of comorbidities (CC≥1), smoking, alcohol consumption and regular physical exercise were detected. Kaplan Meier estimates of EF recovery at 3, 6 and 12 months, were 43% (95% CI: 41-62), 60% (95% CI: 49-69) and 75% (95% CI: 64-83), respectively. Younger age (HR: 0.95; 95% CI: 0.92-0.99, P=0.01) was associated with EF recovery after adjusting for baseline EF, BMI, smoking and CCI≥1.

CONCLUSIONS: Almost one out of two young ED patients prescribed with tadalafil OaD achieved full EF recovery within 3 months of treatment. Younger patients have higher probability of EF recovery with daily 5 mg tadalafil therapy.

SC80
Retrospective comparison of split-thickness skin grafts *versus* full-thickness skin grafts in the surgical repair of adult acquired buried penis (AABP)

N. Plamadeala, M. Falcone, M. Preto, F. Peretti, L. Cirigliano, I. Ferro, M. Scavone, C. Ceruti, P. Gontero (Turin)

BACKGROUND: The aim of this study was to compare the outcomes between split-thickness skin grafts (STSG) and

full-thickness skin grafts (FTSG) in the surgical correction of acquired adult buried penis (AABP).

METHODS: From 2017 to February 2023, 37 patients who underwent surgical repair for AABP were retrospectively recruited in our department. The surgical complexity of the AABP repairs was classified according to Santucci. There were 21 cases requiring skin grafting performed either with STSG or FTSG. The study's primary endpoint was to compare the outcomes of both groups. The secondary endpoints were surgical, functional and patients' reported outcomes (PROs). Postoperative complications were classified according to Clavien-Dindo. The International Index of Erectile Function (IIEF-15) and the International Prostate Symptoms Score (IPSS) were used to assess patients' erectile and urinary function in pre- and postoperative settings, while PROs were extrapolated from a 6-item *ad-hoc* questionnaire.

RESULTS: Twenty-one patients who required skin grafting were enrolled: FTSG was applied in 9 cases, STSG in 12. No significant difference between the two groups was described for preoperative risk factors and symptoms. The median follow-up was 22 months (IQR 12-39). The mean BMI was 32.2 (IQR 30-35). The most common complaints at presentation were voiding (66.7%) and sexual (42.9%) dysfunction. Of all, 81% underwent a complex repair (≥III): 88.9% of patients from FTSG group and 75% from the STSG group. The overall median operative time was 150 minutes (130-195). No significant differences in general postoperative complications and in BP recurrence were described between the two groups. The overall postoperative complication rate was 33.3% with 2 (9.5%) cases of high-grade (Clavien ≥3) ones: one per group (11.1% in FTSG, 8.3% in STSG). A recurrence of BP occurred in 23.8%. In total 16 patients (76.2%) answered the questionnaires. In both groups, IPSS and IIEF-15 scores were significantly improved after surgery, although starting from worse values for the STSG group (P value <0.05), and the overall satisfaction rate was 81.3%.

CONCLUSIONS: AABP surgical repair is a complex procedure to be performed in referral centers. There are no differences in terms of outcomes between STSG and FTSG use. Further comparative studies with larger series, longer follow-up and specific validated questionnaires are needed to confirm the preliminary results.

SC81
Outcomes of neurological patients treated with penile implants: data from the multicenter prospective registry INSIST-ED

L. Cirigliano, M. Falcone, C. Ceruti, M. Preto, F. Peretti, I. Ferro, N. Plamadeala, M. Scavone, P. Capogrosso, F. Dehò, N. Schifano, E. Pescatori, E. Caraceni, A. Palmieri, P. Gontero (Turin)

BACKGROUND: Neurological disease is among the main causes of erectile dysfunction (ED). Penile prosthesis implant (PPI) may be offered to patients unresponsive to oral and intracavernous therapies. PPI in the neurological population has been historically considered to be at increased risk of complications and infections. The aim of our study was to investigate surgical and functional outcomes of PPI in this population.

METHODS: Patients undergoing PPI were investigated through the INSIST-ED registry, from 2014 to 2022. Data were prospectively recorded by 45 surgeons on a dedicated website (www.registro.andrologiaitaliana.it) and reviewed by a data-manager. Patients affected by neurological disease undergoing PPI for ED were selected. Surgical and functional outcomes were evaluated postoperatively at 3, 6 and 12 months, and annually thereafter. Validated questionnaires (IIEF-5, SEP 2-3, and EDITS) were adopted to assess functional outcomes, while patient reported outcomes were evaluated through an *ad-hoc* non-validated questionnaire.

RESULTS: Thirty-five patients were included with a median age of 49 (IQR: 41-54). Median follow-up was 23 months (IQR: 13-63). The most frequent etiology of ED was spinal cord injury (68.6%). Most surgeons performed a penoscrotal approach (91.4%) and implanted an inflatable device in 32 cases (91.4 %). Two (5.8%) intraoperative complications were reported, and both were successfully managed. Postoperative complications occurred in 4 cases (11.4%): 2 wound dehiscence (Clavien-Dindo G1 and G3a, respectively), 1 prosthesis infection and 1 prosthesis extrusion, both requiring device explantation (Clavien-Dindo G3a). Functional outcomes after 12 months proved to be overall satisfactory. A significant increase was observed in all validated questionnaires and median EDITS was 78 (IQR 66-86). The *ad-hoc* questionnaire showed an overall satisfaction with the procedure of 91.4% and a self-reported satisfaction with penile length in 29 patients (82.9 %).

CONCLUSIONS: In our cohort of neurological patients, PPI proved to be safe and effective in the treatment of ED, without increased risks of complications compared to not neurological patients.

SC82
Cancer survivorship in male patients: the importance of involving the andrologist

S. Cilio, E. Pozzi, F. Belladelli, G. Fallara, L. Candela, A. Bertini, C. Corsini, F. Lanzaro, D. Cannoletta, M. Raffo, F. Negri, L. Cella, M. Fantin, L. Boeri, P. Capogrosso, A. d'Arma, F. Montorsi, A. Salonia (Naples)

BACKGROUND: Male cancer survivors may develop sexual dysfunction (SD) even many years after the recovery from the original disease. An andrological assessment of these patients is not routinely provided in everyday clinical practice. We aimed to evaluate the prevalence and clinical characteristics of cancer survivors among men seeking medical help for SD (any) in the real-life setting of an andrological tertiary-referral center.

METHODS: Complete data from 2841 men consecutively assessed for new-onset SD between 2005 and 2022 were analyzed. All patients were assessed with a comprehensive sexual and medical history, including history of any non-metastatic cancer (*i.e.*, urological cancers, non-urological solid cancers, hematological cancer). All patients were invited to complete the International Index of Erectile Function (IIEF), and the Beck's Depression Index (BDI). The IIEF-Erectile function (IIEF-EF) domain was categorized according to Cappelleri's criteria.

RESULTS: Of all, 237 (8.34%) patients assessed for SD reported a history of non-metastatic cancer, either solid or hematological. Of 237, 118 (49.8%) reported a history of urological cancer, 92 (38.8%) of non-urological solid cancer, and 27 (11.4%) of hematological cancer. Overall, the most frequent complaint was ED (76.4% of patients), followed by Peyronie's disease (PD) (13.9%), low sexual desire/

interest (LSD/I) (13.5%), premature ejaculation (PE) (6.8%), and delayed ejaculation (2.1%). Moreover, the most frequent concurrent complaints were ED and LSD/I reported together by 11.4% of patients, followed by ED and PD reported by 8.4% of patients. Of all, prostate cancer (PCa) survivors accounted for 41.0% of solid cancer survivors and 37.1% of the whole cohort. The most frequent non-urological cancer was colon-rectal cancer (CRC), reported by 10.6% of patients. Men with a history of either PCa or CRC complained more of ED (98 [92.5%] *vs.* 68 [62.4%] men; P=0.001) and had lower rates of normal IIEF-EF scores (1 [0.9%] *vs.* 6 [5.5%] men; P=0.03), with respect to patients with a history of other types of cancers, whom reported higher rates of PE (4 [3.8%] *vs.* 12 [11%] men; P=0.03) and of PD (9 [8.5%] *vs.* 21 [19.3%] men; P=0.007).

CONCLUSIONS: Almost 10% of men seeking first medical help for SD in a tertiary-referral andrology center are cancer survivors. Following the improvement of survivorship rates in male patients, an andrological assessment should always be included over the follow-up of cancer survivors.

SC83
Genital lichen sclerosus: national multicentric survey

L. Di Marco, M. Rizzo, G. Liguori, A. Palmieri, S. Lauretti (Trieste)

BACKGROUND: Genital lichen sclerosus (LS) is a chronic inflammatory disease due to autoimmune events of unknow etiology; LS usually occurs in anogenital region. True prevalence is not known, but seems to affect mostly women (M:F 1:3-10). The aim of this survey was to analyze the quality of diagnostic and therapeutic Italian management of patients affected by genital LS.

METHODS: Using Google forms (Google LLC, Mountain View, CA, USA), we developed a questionnaire composed by 10 items regarding personal and clinical aspects and examinating patients' views of their diagnostic-therapeutic process. The survey was sent by email to all LISCLEA members (780: 564 F/216 M) and it was available for 48 hours.

RESULTS: Two hundred eighty-three (F 79% *vs.* M 18.72%) questionnaires were completed: 82% of patients were between 31 and 70 years old. Only 14% had a diagnosis by 6 months after first symptoms, while 26% declare to have not received a correct diagnosis after 5 years; 48.76% of all diagnosis was made by gynecologists, 30.74% by dermatologists and 4.5% by andro-urologists. Furthermore, 81.96% of patients considers their diagnostic and therapeutic process complex (difficult, quite difficult, very difficult) *vs.* 16.6% simply (simply, quite simply). In addition, 41.9% of patients have no sex because of LS, in 57.3% LS causes anxiety and discomfort in relationships. 71.72% was treated with topical therapy and 5 patients (1.7%) were directed to a specialist. 78.09% thinks doctors' knowledge about LS is inadequate and 63.9% hopes that a better doctors' preparation about LS is mandatory.

CONCLUSIONS: Genital LS is a disease that significantly and negatively impact patients' quality of life. Genital LS causes anxiety, discomfort in sexual behaviors and impossibility to have sex. Late diagnosis is common and quite few patients are directed to specialists. Doctors' awareness and consciousness could lead to early diagnosis and improve genital LS treatment and management.

SMART (SC84-SC98)

Kidney Cancer 6

SC84
Environmental impact of minimally invasive surgery: a retrospective study to compare laparoscopic *versus* robot-assisted radical and partial nephrectomy

SC85
Predictors of early long-term functional outcomes in patients treated with robot-assisted partial nephrectomy: results from a prospectively maintained dataset from a single tertiary referral center

SC86
Development of a novel score (RENSAFE) utilizing pre-/perioperative risk factors to determine the probability of acute kidney injury and renal function decline postsurgery: a multicenter retrospective analysis

SC87
Evaluation of predictive factors for intraoperative complications in laparoscopic renal and adrenal surgery (I-CLARAS): results of a multicenter international study

SC88
Staging of patients with newly diagnosed unfavorable intermediate or high-risk prostate cancer: preliminary results of the all-in-one whole-body MRI protocol

SC89
Development of the NODESAFE scoring system to predict lymph nodes invasion and lymph nodes recurrence in a large international cohort of renal cell carcinoma patients: analysis of the INMARC registry

SC90
Newly proposed TNM staging system for localized renal masses: how could it change decision-making in clinical practice?

SC91
Role of inflammatory markers and Frailty Index as predictors of adverse pathological stage in patients with kidney cancer: a multicenter analysis

SC92
Lawton instrumental activities of daily living scale identifies patients at high-risk of adverse outcomes after kidney surgery for renal cancer: a prospective clinical study

SC93
Generalizability of the MK-6482-004 trial to real-world VHL patients: results from a prospective surveillance study

SC94
Deciphering the relationship between pathogenic variants and clinical phenotype in VHL patients: results from a prospective observational study

SC95
Two-dimensional shear wave elastography: an effective tool in predicting adherent perinephric fat in robot-assisted partial nephrectomy

SC96
Exploring the clinicopathological characteristics and mid-term oncologic outcomes of oncocytic *vs.* non-oncocytic renal tumors: insights to refine current diagnostic algorithms for patients with non-metastatic renal masses

SC97
Active surveillance *vs.* partial nephrectomy in CT1A renal mass: matched-pair analysis of oncological and functional outcomes

SC98
3D virtual models to plan "minimal surgical impact" robotic- assisted partial nephrectomy for the treatment of small renal masses

SC84
Environmental impact of minimally invasive surgery: a retrospective study to compare laparoscopic *versus* robot-assisted radical and partial nephrectomy

M.B. Sequi, A. Fuschi, A.L. Pastore, A. Martoccia, Y. Al Salhi, O.A. Rera, S. Scalzo, F.M. Valenzi, A. Antonioni, G. Candita, D. Graziani, G. Martino, F. Gianfrancesco, G. Tema, C. De Nunzio, S. Nardecchia, A. Carbone (Latina)

BACKGROUND: The aim of this study was to assess and compare the environmental impact and CO_2 emissions between minimally invasive robot-assisted and laparoscopic partial and radical nephrectomy.

METHODS: From November 2020 to December 2022, 55 patients underwent robot-assisted (group A RAPN) and laparoscopic (group B LPN) partial nephrectomies, and 49 patients who robot-assisted (group C RARN) and laparoscopic (group D LRN) radical nephrectomies were retrospectively enrolled. For each patient, we evaluated: age, surgical procedure time, anesthesiologic time, length of stay, days spent in postoperative ICU, need for blood transfusion, pre, and postoperative Hb, open conversion, complications per Cliven-Dindo, and Renal and Padua Score for partial nephrectomies. A Life Cycle Assessment (LCA) was developed to estimate the energy consumption required for the surgical procedures and the hospital stay. A report was made on materials and the amount of CO_2 used. All disposable and reusable materials and instruments were weighed and divided into three main components: metal, plastics, and composite fibers. CO_2 consumption necessary for disposal and decontamination was also evaluated.

RESULTS: Groups A and B underwent RAPN and LPN, respectively, while groups C and D underwent RARN and LRN, respectively. The instrumentation weighed 1669.41 and 1341.45 g in groups A and B, respectively. The instrumentation's CO_2 emissions were higher in group B (9606.62 *vs.* 9041.98 g) due to the use of reusable instruments in group A, most of which came from plastic components (6930.3 group B *vs.* 6143.8 g group A). More energy was required for hospital stay and the OR in group B, resulting in higher CO_2 emissions (44,871.79 *vs.* 34,277.94 g). Total CO_2 emissions were lower in group A (43,319.92 *vs.* 54,478.42 g). Groups C and D underwent RARN and LRN, respectively. The instrumentation in group D outweighed the instrumentation of group C (2284.45 *vs.* 1471.09), with the most significant difference between the groups coming from the plastic components (1696.20 group D *vs.* 1130.20 g group C). The total instrumentation CO_2 emissions in group C were almost half of the emissions of group D (8742.32 *vs.* 17,295.22 g). Both operative time and hospital stay were lower in group C, consequently having lower energy consumption and thus lower CO_2 emissions than group D (33,354.66 *vs.* 35,828.508 g). Total CO_2 emissions were substantially lower in group C than in group D (42,096.98 *vs.* 53,123.73 g).

CONCLUSIONS: Robot-assisted radical nephrectomy generates substantially less CO_2 than laparoscopic radical nephrectomy per procedure due to the use of more reusable surgical supplies and the shorter operative time and hospital stay. Robot-assisted partial nephrectomy, similar to RARN, is a more environmentally friendly surgical procedure, allowing also to reduce operative time and hospital stay in more challenging surgical settings.

SC85
Predictors of early long-term functional outcomes in patients treated with robot-assisted partial nephrectomy: results from a prospectively maintained dataset from a single tertiary referral center

M. Bacchiani, A. Mari, L. Lambertini, E. Massaro, A. Sandulli, R. Mariottini, V. Salamone, A. Cadenar, S. Giudici, A. Grosso, L. Olivera, S. Scelzi, F. Di Maida, G. Vittori, R. Fantechi, L. Masieri, A. Minervini (Florence)

BACKGROUND: The aim of this study was to assess the functional outcomes of patients undergoing robot-assisted partial nephrectomy (RAPN) and to identify factors associated with renal function (RF) loss, including early and long-term outcomes, using a standardized tumor-resection reporting system (Surface Intermediate Base [SIB] Score) in a single tertiary referral center.

METHODS: We conducted a prospective study that included data from 1285 patients who underwent RAPN between January 2017 and March 2021. A clinically significant functional loss was defined as a ≥25% drop from baseline of estimated glomerular filtration rate (eGFR). We used univariable and multivariable logistic regression models to identify predictors of RF loss at the last follow-up.

RESULTS: A total of 985 patients were included, with a median age at surgery of 67.2 (interquartile range [IQR] 58-76) years. The median Charlson Comorbidity Index (CCI) was 1 (IQR 0–2). The median Preoperative Aspects and Dimensions Used for an Anatomical (PADUA) Score was 8 (IQR 7-10). Acute kidney injury (AKI) occurred during the postoperative course in 10 (1.02%) patients. Our analysis included 985 patients with a median age of 67.2 (interquartile range [IQR] 58-76) years. The median Charlson Comorbidity Index (CCI) was 1 (IQR 0-2), and the median clinical tumor dimension was 38 mm. Overall, 22.3% of tumors were classified as cT1b, and 5% were classified as cT2. The median Preoperative Aspects and Dimensions Used for an Anatomical (PADUA) Score was 8 (IQR 7-10). SIB scores of 0-1 were observed in 79% of the cohort. Acute kidney injury (AKI) occurred in 10 (1.02%) patients during the postoperative course. The median ischemia time was 14.5 minutes (IQR 8-21). At the 12th month, 207 (21%) patients showed significant RF loss, followed by 187 (19%) patients at the 24th month, and 158 (16%) patients at the last follow-up (40 [24-60] months). In the multivariable analysis, higher BMI (HR 1.05 (95% CI 1.02-1.08), P=0.002), preoperative eGFR (HR 1.02 (95% CI 1.01-1.03), P<0.001), CCI (HR 1.27 (95% CI 1.11-1.46), P=0.001), and AKI (HR 1.92 (95% CI 1.07-3.46), P=0.028) during the postoperative course were significant predictors of RF loss at the last follow-up.

CONCLUSIONS: Our study reported that higher BMI, lower preoperative eGFR, higher CCI, and AKI during the postoperative course were significant predictors of early long-term RF loss in patients treated with RAPN and having SIB scores 0-1. Interestingly, type of resection and ischemia time did not significantly affect the final functional outcome, while postoperative AKI did. Our findings can help clinicians better identify patients at risk for RF loss and guide decision-making in the management of T1 renal tumors, with a focus on the prevention of postoperative AKI. The comprehensive assessment of patient and tumor characteristics, as well as surgical factors, can provide a more accurate prediction of RF loss, enabling better patient counseling and personalized management strategies.

SC86

Development of a novel score (RENSAFE) utilizing pre-/perioperative risk factors to determine the probability of acute kidney injury and renal function decline postsurgery: a multicenter retrospective analysis

C. Saitta, J. Afari, L. Wang, C. Cerrato, P. Diana, G. Lughezzani, N.M. Buffi, R. Autorino, U. Capitanio, F. Montorsi, A. Antonelli, F. Porpiglia, I. Derweesh (Milan)

BACKGROUND: Emerging literature has called into question the association between surgical techniques for definitive renal mass treatment and the development of acute kidney injury (AKI) and the development of long-term chronic kidney disease (CKD). We sought to create Renal Safety (RENSAFE), a preoperative nomogram which predicts AKI and CKD to guide clinical decision making.

METHODS: We conducted a multicenter retrospective analysis of cT1-T3 renal masses. Primary objective was to develop a predictive model for postoperative AKI (reduction >25% of preoperative eGFR) and CKD (<45 mL/min/1.73m^2) by 48 months with internal validation of the models with bootstrapping. RENSAFE was developed with a stepwise approach with logistic regression. Accuracy was tested with receiver operator characteristics (ROC) curves estimated Area Under the Curve (AUC).

RESULTS: One thousand five hundred seventeen patients met inclusion criteria. Postoperative AKI and CKD occurred in 29.8% (452) and 11.6% (116) of cases, respectively. RENSAFE's multivariable logistic regression model includes gender (OR=1.3, P=0.02), ASA Score (OR=1.3, P<0.003), hypertension (OR=1.5, P<0.002), R.E.N.A.L. Score (OR=1.7, P<0.0001), preoperative eGFR (OR=0.75, P=0.009), and radical nephrectomy (RN) (OR=11.1, P<0.0001) were significant predictors for AKI. Age (OR 1.0, P<0.001), diabetes (OR 2.7, P<0.001), preoperative eGFR (OR 0.47, P<0.002) and RN (OR 2.2, P<0.005) were predictors for development of CKD. RENSAFE showed AUC=0.79 and AUC=0.75 predicting postoperative AKI and CKD, respectively. The use of 6.5-point threshold had a sensitivity of 80.8%, specificity of 61.4%, and a negative predictive value of 88.3% for AKI while 9.5 points for de novo CKD G3b shows sensitivity of 78.6%, specificity of 64.1%, and a negative predictive value of 96.5%.

CONCLUSIONS: We present two nomograms which address prediction of risk of AKI and declining renal function (to a threshold of eGFR<45 mL/min/1.73m^2). RENSAFE's clinical utility is attributed to its point of care modeling, inclusion of RN and PN, and ability to provide counseling urologists with a and cost-effective and easily adoptable model with wide applicability to predict AKI and CKD to guide shared decision making. Further investigation is requisite.

SC87

Evaluation of predictive factors for intraoperative complications in laparoscopic renal and adrenal surgery (I-CLARAS): results of a multicenter international study

A. Territo, P. Verri, G. Di Buono, R. Vella, G. Mantica, V. Falco, V. Hevia Palacios, R. Antelo Antelo, E.R. Jesus, N. Crisan, I. Andras, F. Medas, A. Breda, A. Agrusa (Barcelona)

BACKGROUND: The laparoscopic approach represents the standard of treatment for renal and adrenal diseases and its use is becoming increasingly popular, even outside of referral centers. Although most procedures are routinely performed, they are not devoid of intraoperative complications, whose rate and predictive factors are not established. The aim of this study is to evaluate the rate and type of intraoperative complications and identify predictive factors in patients undergoing laparoscopic renal and adrenal surgery.

METHODS: This study included seven centers from Italy (Palermo, Rome, Ancona, Naples, Turin, Genoa, Cagliari), two from Spain (Madrid, Barcelona), one from Mexico, one from Argentina and one center from Romania (i-CLARAS Study Collaborative Group). Patients who underwent laparoscopic renal and adrenal surgery between April 2017 and March 2022 were included. Bivariate analysis was performed using contingency tables and the χ^2 test for independent samples to compare qualitative variables, the *t*-test, and Mood Test for continuous variables. Multivariate analysis was performed with the logistic regression model to obtain adjusted odds ratios (ORs). The main factors evaluated were the intraoperative and short-term post operative complications and the conversion rates.

RESULTS: Two thousand three hundred seventy-four patients were included. Intraoperative complications were reported in 8.09% of patients undergoing renal surgery, with the most common complications reported being hollow viscus and vascular ones, and in 6.75% patients undergoing adrenal surgery, with the most common complications reported being parenchymatous viscus complications. The presence of invasive features (OR=3.57, P value = 0.0708) and a higher Renal Score (OR=1.279, P value <0.001) resulted associated with a higher incidence of intraoperative complications.

CONCLUSIONS: Multivariate analysis showed that both in adrenal and renal surgery radiological preoperative factors, such as invasive features for adrenalectomy and RENAL Score for nephrectomies, are predictive factors of intraoperative complications. In contrast with existing data, surgeon experience was not associated with a reduction of perioperative complications.

SC88

Staging of patients with newly diagnosed unfavorable intermediate or high-risk prostate cancer: preliminary results of the all-in-one whole-body MRI protocol

S. Nardini, C. Vaccaro, M.L. Piccinelli, M. Fontana, S. Luzzago, F.A. Mistretta, E. Di Trapani, M. Ferro, R. Bianchi, B.A. Jereczek-Fossa, G. Marvaso, G. Petralia, S. Alessi, G. Musi, O. de Cobelli (Milan)

BACKGROUND: The possibility of a one-step staging modality has been raised, wherein multiparametric magnetic resonance imaging (mpMRI) + whole body MRI (WB-MRI) would be used to further assess nodal and metastatic disease status in a single setting.

METHODS: This is a multicentric, prospective, interventional study comparing the accuracy of staging with All-in-One MRI *vs.* standard (CT and BS) staging pathways for unfavorable intermediate and high-risk PCa patients (EAU guidelines). All patients should undergo BS, CT, and WB-MRI within 6 weeks of each other. Radiologists will be

blinded from findings of other imaging tests. Primary outcome is the per-patient sensitivity, specificity, and accuracy for detection of nodal and distant metastases with WB-MRI *vs.* BS+CT. Secondary outcomes are: 1) disease management changes; 2) the rate of equivocal findings; 3) costs, radiation exposure, patient compliance/preference, and side effects; and 4) interobserver variability. All cases will be evaluated into a multidisciplinary team meeting (MDT) that will decide for patient treatment according to WB-MRI *vs.* BS+CT. For non- metastatic patients, the accuracy of WB-MRI *vs.* BS+CT will be evaluated at final pathology and according to PSA values during follow-up. Conversely, for metastatic patients, the accuracy of WB-MRI *vs.* BS+CT will be evaluated according to changes of radiological appearance of metastases after treatment. The study started on 01/01/2022 and will recruit patients for up to 36 months. All patients will be followed for at least one year after treatment. Considering 80% an acceptable level of power, 350 patients would be evaluated.

RESULTS: At the time of this preliminary analysis (April 2023), 55 patients have been enrolled. Of those, two (3.5%) patients refused WB-MRI due to claustrophobia. Of the other 53 patients, 23 (43.5%) showed discordance between BS+CT *vs.* WB-MRI staging. Specifically, compared to BS+CT, 17 (32.5%) and 6 (11%) patients showed, respectively upstaging and downstaging after WB-MRI. Of all patients that experienced upstaging after WB-MRI, 13 (24.5%) switched from cN0M0 to cN1M0. Moreover, five (9.5%) patients switched from cN0M0 to cN0/1M1a. Additionally, four (7.5%) patients switched from cN0M0 to cN0/1M1b. Last, one (2%) patient switched from cN0M1b to cN0M1c. Conversely, of the patients that experienced downgrading, 1 (2%) *vs.* 3 (5.5%) and 1 (2%) switched from cN0M1a to cN0M0 *vs.* from cN0M1b to cN0M0 and from cN0M1b to cN0M1a. After MDT, 16 (30%) patients experienced disease management changes.

CONCLUSIONS: Systemic staging with all-in-one WB MRI in patients with unfavorable intermediate and high-risk PCa results in approximately 40% of changes in disease stage and 30% of treatment changes, relative to BS+CT. These preliminary findings should be confirmed after study completion.

SC89

Development of the NODESAFE scoring system to predict lymph nodes invasion and lymph nodes recurrence in a large international cohort of renal cell carcinoma patients: analysis of the INMARC registry

J. Afari, C. Saitta, V. Master, F. Yasuhisa, I. Derweesh (San Diego, CA)

BACKGROUND: The impact of lymph node positivity in renal cell carcinoma is poorly understood and the role of lymph adenectomy remains controversial. However, patient selection for lymphadenectomy is still a cornerstone of presurgical planning. We sought to develop a preoperative nomogram called NODESAFE (NODE SAFEty) to predict nodal invasion (NI) at final histological report and nodes occurrence at follow-up.

METHODS: We quired the INMARC database for patients affected by solid renal mass confirmed to be RCC at final histological report. NI was defined as adenopathy greater than 10 mm at the CT scan. Multivariable logistic model (MVL) was fitted for the outcome of interest through a stepwise approach. Accuracy was tested with receiver operator characteristic estimated Area Under the Curve (AUC), postestimation goodness of fit test.

RESULTS: A total of 2297 patients met inclusion criteria. The following covariates were found to be highly statically significant in our model: cN (OR 6.5, P<0.001), tumor size (OR 1.7, P<0.003), c-reactive protein (OR 1.8, P<0.05), neutrophile-lymphocyte ratio (OR 1.8, P<0.05) , low enhancement in CT imaging (OR 2.1, P<0.005), hypertension (OR 2.3, P<0.002) and Charlson Comorbidity Index (OR 1.1, P<0.001). AUC was 0.86. Goodness of fit test showed acceptable adaptability of the model (P>0.4). 2.4% threshold shown 81.9 % sensitivity, 72.2 % specificity and 99.1% negative predictive value.

CONCLUSIONS: Combining clinical features, serum biomarkers and radiographic findings, we developed a model capable of predicting with accuracy NI. NODESAFE may refine clinical decision making with respect to the performance of lymphadenectomy at the time of surgery, postsurgical surveillance, and spur consideration for adjuvant therapy.

SC90

Newly proposed TNM staging system for localized renal masses: how could it change decision-making in clinical practice?

C. Riccardo, A. Pecoraro, A. Mariotti, R. Mariottini, N. Firenzuoli, L. Mazzola, E. Dibilio, D. Stracci, G.R. Resta, M.L. Gallo, P. Spatafora, D. Facchiano, F. Sessa, A. Sebastianelli, M. Gacci, S. Serni (Florence)

BACKGROUND: Currently, the TNM scheme is the most universally accepted staging system for patients with cancer. The EAU Guidelines Panel on Renal Cell Carcinoma (RCC) recently proposed a renewal of the TNM Staging System for to comply with current decision-making. The aim of the study was to evaluate how the newly proposed TNM scheme could have reclassified patients who underwent surgery for localized renal masses (LRM) at a kidney cancer Center, and how such reclassification could impact on our contemporary decision-making strategies.

METHODS: After ethical committee approval, we queried our prospectively maintained databases to identify patients with a single LRM (cT1-T2N0M0) who underwent partial (PN) or radical (RN) nephrectomy between January 2017 and September 2022 at a single high-volume academic center. The prognostic value of the current and newly proposed TNM schemes were compared. The proposed changes in the setting of LRMs were: cT1a stage (tumors <3 cm, for whom active surveillance [AS] or focal therapy [FT] can be considered); cT1b stage (tumors 3-7 cm, for whom surgery remains the standard); cT2 stage (tumors >7 cm, for whom FT and AS can jeopardize cancer control).

RESULTS: Overall, 689 patients were included. According to the newly proposed TNM scheme, tumors would have been classified as cT1a in 42.5% of patients (*vs.* 63.4% of current TNM), cT1b in 47.9% (*vs.* 27%), and cT2 in 9.6% (*vs.* cT2a in 7.7% and cT2b in 1.9%). Both the newly proposed and current TNM schemes significantly stratified LRMs regarding tumor nature (solid *vs.* cystic), tumor complexity, proportion of PN, proportion of benign tumors at pathological analysis, ISUP grading, % sarcomatoid de-differentiation and necrosis, median Leibovich Score (for ccRCCs), proportion of RCC-

related deaths or disease recurrence at median follow-up of 30 months (IQR 16-44). Applying the newly proposed TNM scheme, cT1a tumors were mostly solid (90.4%), often of intermediate complexity (median PADUA Score 7), with non-negligible proportion of benign tumors (30%), rather indolent disease features (median Leibovich Score 0; 4.1% necrosis; 0% sarcomatoid de- differentiation; 16.4% ISUP grading 3-4) and no RCC-related death or RCC recurrences at a mid-term follow-up.

CONCLUSIONS: Both the current and the revised TNM schemes correctly risk-stratified patients with LRMs who candidates for surgery are. Yet, the revised scheme allowed to identify a patient cohort (new cT1a stage) with a higher (non-negligible) proportion of benign tumors, less aggressive tumors features, and favorable oncologic outcomes, who may indeed benefit from renal non- surgical interventions and/or renal tumor biopsy. Further studies are needed to evaluate the impact of the newly proposed TNM scheme on patient outcomes using established outcome metrics.

SC91
Role of inflammatory markers and Frailty Index as predictors of adverse pathological stage in patients with kidney cancer: a multicenter analysis

S. D'annunzio, R. Lombardo, G. Guarnotta, L. Sarcinelli, E. Mancini, A.F. Cicione, R.S. Flammia, A. Tufano, C. Leonardo, A. Fuschi, A.L. Pastore, A. Carbone, A. Brasetti, G. Simone, C. Anceschi, G. Tuderti, A. Nacchia, A. Cantiani, S. Signore, A. Tubaro, C. De Nunzio (Rome)

BACKGROUND: The aim of this study was to assess patient frailty and inflammatory state as predictors of adverse pathological outcomes after renal cancer surgery.

METHODS: We performed an analysis of prospectively collected data of consecutive patients undergoing nephrectomy or patrial nephrectomy in 5 primary care Italian urology centers. Charlson Comorbidity Score and Frailty Index was measured using a Simplified Frailty Index (sFI) with a 5-item score including: 1) diabetes mellitus; 2) functional status; 3) chronic obstructive pulmonary disease; 4) congestive cardiac failure; and 5) hypertension, with a maximum 5-item score meaning high level of frailty. Inflammatory status was evaluated with neutrophil/lymphocyte ratio (NLR), monocyte to lymphocyte ratio (MLR), fibrinogen and albumin levels. Binary logistic regression analysis was used to assess the risk of advanced pathological stage.

RESULTS: Two hundred sixty-two patients were enrolled. Overall, 75/262 (29%) presented a sFI Score≥3 and 24/262 (9%) presented advanced disease (≥3a). sFI ≥3 (OR: 2.88; 95% CI: 1.22-6.82; P=0.016), Charlson Comorbidity Index OR=1.24; 95% CI: 1.03-1.51; P=0.024), ASA Score (OR: 3.22; 95% CI: 1.72-6.06; P=0.001), fibrinogen levels (OR: 1.01; 95% CI: 1.00-1.01; P=0.002) and albumin levels (OR=0.80; 95% CI: 0.69-0.93; P=0.003) were predictors of adverse pathological outcomes. NLR and MLR were not predictors of adverse pathological outcomes.

CONCLUSIONS: In patients undergoing surgery for renal cancer, Frailty Index, inflammatory mediators, and comorbidities are predictors of adverse pathological outcomes. Further studies should assess their role in clinical practice and in predictive models.

SC92
Lawton instrumental activities of daily living scale identifies patients at high-risk of adverse outcomes after kidney surgery for renal cancer: a prospective clinical study

G. Baiamonte, G. Rosiello, G. Basile, G. Fallara, C. Re, G. Musso, F. Cei, D. Cignoli, G. Avesani, N. Disabato, G. Villa, M. Boarin, D. Canibus, P.I. Karakiewicz, F. Dehò, N. Suardi, A. Briganti, A. Salonia, F. Montorsi, A. Larcher, U. Capitanio (Milan)

BACKGROUND: Frailty is a clinical syndrome associated with delayed recovery and suboptimal outcomes after surgery. Frailty scales have been suggested for identifying frailty before kidney cancer surgery. In this prospective clinical study, we aimed at assessing the role of Lawton Instrumental Activities of Daily Living (IADL) Scale in predicting surgical outcomes in patients undergoing partial or radical nephrectomy for renal cell carcinoma (RCC).

METHODS: Between January 2021 and June 2022, 98 consecutive patients surgically treated for cT RCC were prospectively enrolled. The IADL Scale was calculated for each patient at hospital admission. Postoperative complications were prospectively collected using Clavien-Dindo classification. Acute kidney injury (AKI) was defined according to the RIFLE criteria. Multivariable logistic and linear regression models tested the association between iADL Score and postoperative complications, as well as length of stay (LOS) and postoperative AKI, after adjusting for age, preoperative eGFR, blood loss and tumor characteristics.

RESULTS: Overall, 98 patients were included. Of these, 21 (21%) had IADL<6. Median age at surgery and clinical size were 62 (interquartile range [IQR]: 53-71) years and 5 (IQR: 3.4-7) cm. Median preoperative eGFR was 70 (IQR: 56-91) mL/min. Finally, median LOS was 5 (IQR: 4-7) days. Overall, the rate of postoperative complications was 13% (5% of major complications defined as Clavien-Dindo >3). Overall, 22 (22%) out of 98 patients experienced postoperative AKI. At MVA, increasing IADL Score predicted lower risk of overall complications [Odds ratio (OR): 0.35, 95% CI 0.22-0.48; P<0.001] and shorter LOS (Relative risk: 0.28, 95% CI 0.19-0.41; P<0.001). Moreover, increasing IADL was independently associated with lower risk of postoperative AKI after surgery (OR: 0.64, 95% CI 0.47-0.88; P<0.01).

CONCLUSIONS: Assessing preoperative IADL Score allows the identification of patients at increased risk of suboptimal outcomes after surgery for kidney cancer. Therefore, frailty assessment allows the stratification of surgical risks and, potentially, the implementation of dedicated management which may help in protecting frail patients from suboptimal outcomes.

SC93
Generalizability of the MK-6482-004 trial to real-world VHL patients: results from a prospective surveillance study

F. Belladelli, C. Re, F. Cei, L. Salerno, S. Cusano, F. Iannace, P. Carrera, M.G. Patricelli, A. Falini, F. De Cobelli, P. Mortini, F. Bandello, R. Lattanzio, M. Falconi, S. Partelli, A. Necchi, D. Raggi, L. Marandino, R. Lucianò, I. Rowe, F. Montorsi, U. Capitanio, A. Larcher, A. Salonia (Milan)

BACKGROUND: The use of MK-6482 (belzutifan) may completely change the treatment of VHL patient with ccRCC,

potentially reducing unnecessary surgeries along with the consequent renal functional impairment. Since no data about the generalizability of the study to real-world VHL patients is available, the aim of this study was to investigate this topic relying on a prospective database of VHL patients enrolled in multidisciplinary surveillance program.

METHODS: Since January 2021, a multidisciplinary program devoted to VHL disease is operational at our institution. All the consenting patients with VHL diagnosis based on pathogenic variant are enrolled into a prospective, observational surveillance study. In our outpatient clinic, each patient receives diagnostic and clinical evaluation by a multidisciplinary team of physicians to cover all the potential areas of interest in VHL disease. The primary outcome of the study was the overall inclusion rate and the inclusion/exclusion criterion-specific rate of patients that would have access to the MK-6482-004 trial. Inclusion criteria were: 1) diagnosis of VHL pathogenic variant; 2) at least one measurable renal cell carcinoma ≥10 mm in diameter; and 3) Eastern Cooperative Oncology Group Performance-Status [ECOG-PS] Score of 0 or 1. Exclusion criteria were renal cell carcinoma requiring immediate surgery and metastatic disease.

RESULTS: Overall, 30 patients were enrolled in our VHL program. The median (IQR) age was 48 (27-62) and the median eGFR was 92 mL/min/1.73m^2. The rate of real-world VHL patient that would have been included in the trial was 23% (N.=7) only. Specifically, 40% (N.=12) of the patients are excluded owing to absence of any measurable renal cell carcinoma ≥10 mm in diameter. 37% (N.=11) of the patients are excluded owing to ECOG-PS higher than 1. 7% (N.=2) patient would have been excluded due to evidence of metastatic disease.

CONCLUSIONS: Despite the ramping enthusiasm generated by the MK-6482-004 trial, the findings of the study appear applicable to a small proportion of real world VHL patients. Larger studies, focusing also on extra-renal VHL lesions are required to better define the role of MK-6482 (belzutifan) for the treatment of VHL patients.

SC94
Deciphering the relationship between pathogenic variants and clinical phenotype in VHL patients: results from a prospective observational study

C. Re, F. Belladelli, F. Cei, L. Salerno, S. Cusano, F. Iannace, G.B. Pipitone, P. Carrera, A. Russo Raucci, M.G. Patricelli, A. Falini, F. De Cobelli, P. Mortini, F. Bandello, R. Lattanzio, M. Falconi, S. Partelli, A. Necchi, L. Marandino, I. Rowe, M. Francesco, C. Umberto, A. Larcher, A. Salonia (Milan)

BACKGROUND: Von Hippel-Lindau disease (VHL) is associated with increased risk of developing multiple tumors in different anatomical districts caused by pathogenic variants in VHL. The aim of the study was to investigate the association between pathogenic variants and clinical phenotype in a cohort of VHL patients enrolled into a prospective observational surveillance study.

METHODS: Thirty-three VHL patients enrolled in our prospective surveillance study since January 2021 were included. All patients received a comprehensive clinical evaluation. The primary outcome of the study was the rate of different anatomical sites involved, defined by at least one VHL- related primary diagnosed before enrolment or during surveillance; the secondary outcome of the study was the total number of VHL-related primaries before enrolment or during surveillance. First, we investigated the risk of any anatomical site involvement according to pathogenic variants defined as partial or complete deletion (DEL) or missense (MISS) and study outcomes. Second, multivariable logistic and linear regression models were used to test the association between pathogenic variants.

RESULTS: Complete data about pathogenic variants were available in 26 patients. 35% of the cases (N.=9) had a DEL and 65%(N.=17) had MISS. At a median age of 46 (95% CI 32 - 55), the rate of different anatomical sites involved was 0, 1, 2, 3, and 4 in 10% (N.=3), 18% (N.=6), 21% (N.=7), 24% (N.=8), and 27% (N.=9). No difference was recorded between patients with DEL relative to MISS with respect to age, gender, and renal function at enrolment. At multivariable Poisson's regression reanalysis accounting for age and gender, patients with MISS had higher risk of having more anatomical sites affected (estimate: 0.85; P=0.03) relative to DEL. Conversely, pathogenic variant was not associated with the total number of lesions (P=0.5).

CONCLUSIONS: For the first time, our study elucidates the relationship between pathogenic variants and clinical phenotype in VHL patients. Patients with MISS had a more aggressive disease with more anatomical sites affected. This information can be used to improve and individualize surveillance and treatment strategies in VHL patients.

SC95
Two-dimensional shear wave elastography: an effective tool in predicting adherent perinephric fat in robot-assisted partial nephrectomy

G. Marchi, F. Ambrosini, F. Chierigo, V. Giasotto, G. Guano, A. Sorrentino, C. Paola, G. Drocchi, G. Carboni, G. Mantica, M. Borghesi, C. Terrone (Genoa)

BACKGROUND: The Mayo Adhesive Probability (MAP) Score predicts the presence of adherent perinephric fat (APF) which may increase the surgical complexity of partial nephrectomy. We evaluated the role of 2D shear-wave elastography (SWE) in predicting APF with the goal to describe a novel model for the preoperative assessment of patients submitted to robot-assisted partial nephrectomy (RAPN).

METHODS: Consecutive patients submitted to RAPN were prospectively enrolled between January 2021 and March 2023. Data were collected regarding patients' characteristics, tumor features (RENAL, PADUA, MAP Score), and operative factors (APF was intraoperatively defined by the surgeon). Perirenal fat stiffness was preoperatively assessed with 2D-SWE. The mean value of three measurements for each patient was recorded. We relied on univariable and multivariable logistic regression models to test whether APF was associated with higher values of SWE, gender, BMI, and MAP Score. The models' predictive ability of APF was evaluated using the Concordance Index (C-Index). Linear regression models investigated the association between APF and operative time (OT).

RESULTS: Overall, 128 consecutive patients were collected of whom 87 (68%) did not have APF and 41 (32%) had APF. No statistically significant differences were reported with regards to age, smoking habit, diabetes, cT stage,

PADUA Score, and RENAL Score (all P>0.05). Patients with APF had a significantly lower median (IQR) renal function (eGFR: 73 [54-85] *vs.* 84 [68-97] mL/min/1.73m^2, P=0.005), and a higher BMI (28.4 [25-31.4] *vs.* 25 [23.1-28] kg/m^2, P<0.001). A significantly higher rate of APF in males (90% *vs.* 10% in females P<0.001) and in patients with a higher median (IQR) SWE (9.2 [8.0, 11.3] *vs.* 6.8 [5.7, 8.8]; P<0.001) was found. In univariable logistic regression models, the SWE (odd ratio [OR]:1.4, 95% confident interval [CI] = 1.16-1.74; P=0.001), male gender (OR: 6.94, 95% CI 2.16-31.2; P=0.003) and BMI (OR 1.19, CI 1.07-1.34; P=0.002) achieved the predictor status for APF. MAP Score and the SWE had a comparable predictive ability of APF (C-Index = 0.78 and C-Index = 0.75, respectively). When retaining both SWE and gender, or SWE and BMI there was no noticeable increase in C-Index (0.79 and 0.78, respectively). The most effective model in predicting APF included SWE, gender, and BMI (C-Index = 0.821). The median (IQR) OT was 160 (130-200) minutes and 180 (176-221) minutes in patients without or with APF, respectively (P=0.02). The linear regression analysis showed that the presence of APF is associated with higher total OT (R squared = 0.03, P=0.03).

CONCLUSIONS: The multivariable model including gender, BMI and SWE highly predicts the presence of APF which impacts the total OT. A larger sample size is needed to validate the model and to create a score that effectively predicts APF.

SC96

Exploring the clinicopathological characteristics and mid-term oncologic outcomes of oncocytic *vs.* non-oncocytic renal tumors: insights to refine current diagnostic algorithms for patients with non-metastatic renal masses

A. Mariotti, N. Firenzuoli, L. Mazzola, R. Mariottini, D. Stracci, M.L. Gallo, R. Nicoletti, A. Alberti, R. Ferretti, F. Solazzi, S. Costagli, F. Sessa, P. Spatafora, M. Gacci, S. Serni, R. Campi (Florence)

BACKGROUND: In the field of renal cell carcinoma (RCC), the recently published fifth edition of the WHO classification of urogenital tumors cautioned against a definite diagnosis of oncocytoma on a needle-core biopsy. This might influence the decision to offer active surveillance for biopsy-proven oncocytoma and may raise concerns on the potential clinical impact of novel imaging methods such as 99mTc-sestamibi SPECT-CT on decision-making for patients with a renal mass who are candidates for surgery. The aim of the study was to explore the pattern of histologic subtypes of RCC during the last years at a referral Academic Institution, comparing the characteristics and mid-term oncologic outcomes of patients with "oncocytic" tumors *vs.* non-oncocytic tumors, as well as with oncocytoma *vs.* chRCC.

METHODS: After ethical committee approval, we queried our prospectively maintained database to identify patients with a single non- metastatic (cT1-4N0-1M0) renal mass treated with partial (PN) or radical (RN) nephrectomy between January 2017 and September 2022 at a single high-volume Academic Institution. Clinic-pathological characteristics and oncological outcomes were compared between patients with oncocytic tumors (oncocytoma, chRCC) *vs.* other tumor hystotype.

RESULTS: Overall, 844 patients were included. During the study period, the proportion of ccRCC, pRCC and chRCC was in the range 44.9%-56.4%, 12.5%- 18.9%, and 6.7%-9.0%, respectively. Patients with oncocytic tumors (N.=57 [33.9%] chRCC; 111 [66.1%] oncocytoma) had lower cT stage, higher proportion of solid renal masses (97.6% *vs.* 85.8%, P=0.002), lower proportion of tumors with necrosis (4.8% *vs.* 16.0%, P<0.001) and sarcomatoid de-differentiation (0.6% *vs.* 3.0%; P=0.07), and lower cT1a-pT3a upstaging (6.5% *vs.* 13.3%, P=0.06). As compared to patients with oncocytoma, patients with chRCC were younger (median age 60 *vs.* 69, P<0.001), had less comorbidities (median CCI 2 *vs.* 3, P<0.001) and harbored larger tumors (median diameter 4.0 *vs.* 3.0, P<0.001) with higher complexity (PADUA Score 6-7 *vs.* 8-9 *vs.* >10: 29.8% *vs.* 52.3%; 43.9% *vs.* 30.6%; 26.3% *vs.* 17.1%, P=0.03). Patients with oncocytic tumors did not experience any RCC-related mortality event or disease recurrence at a median follow-up of 33 months (IQR 16-47).

CONCLUSIONS: In our study, more than one out of five patients undergoing surgery for a non-metastatic renal mass harbored an oncocytic tumor, of which 67% were oncocytomas. Given the clinical and histopathological characteristics of these tumors, as well as their indolent behavior, our data suggest that novel imaging targeting oncocytic neoplasms such as 99mTc-sestamibi SPECT-CT might have a role (in conjunction with renal tumor biopsy) to select those patients who are most likely to benefit from non-surgical interventions.

SC97

Active surveillance *vs.* partial nephrectomy in CT1A renal mass: matched-pair analysis of oncological and functional outcomes

M. Nicolazzini, C. Palumbo, F. Portè, M. Berra, D. Pesce, P. De Angelis, M. Zacchero, A. Volpe (Novara)

BACKGROUND: Partial nephrectomy (PN) is the gold standard in the management of cT1a RCCs. However, non-surgical treatment approaches such as active surveillance (AS) represent a feasible alternative option in selected patients. Oncological and functional outcomes of PN and AS were compared in our cT1a RCCs cohort.

METHODS: All patients with a cT1a RCC treated with either PN or AS at our Center from 2008 to 2022 were included. Descriptive statistics tested for differences in baseline characteristics between the two treatments. Propensity Score 1:1 ratio matched- pair analysis was performed (matching variables were age, clinical size, baseline eGFR, gender, Charlson Comorbility Index (CCI)). After matching, differences in terms of progression (defined as local or distant progression/recurrence in case of PN, and local or distant progression or stage progression/volume doubling time <12 months in case of AS), survival (overall mortality [OM], other cause of mortality [OCM] and cancer specific mortality [CSM]) and functional outcomes were assessed. Kaplan-Meier curves of PFS and *de-novo* CKD III or higher were tested with the Log-Rank Test.

RESULTS: Three hundred seventy-four patients treated with either AS (108, 28.9%) or PN (266, 71.1%) were included. AS patients were significantly older, with higher CCI, smaller renal mass and lower mean baseline eGFR. 156 patients (78 treated with AS *vs.* 78 treated with PN) were matched. After matching, all variables were well balanced

with no statistically significant differences. At pathology 30.7% of the AS masses were benign *vs.* 23.1% of PN masses. At a median follow-up of 48 months, no difference in OM was observed (10.3% in AS *vs.* 6.4% in PN, respectively; P=0.56). No tumor related death occurred during AS, while 1 patient (1.3%) died for RCC after PN. Overall, 23.3% of AS patients progressed *vs.* 1.3% of PN patients (P<0.001). No progression to metastatic disease occurred during AS. At last follow-up, 7.7% of AS patients had a *de-novo* CKD III or higher *vs.* 28.2% of PN patients (P=0.002).

CONCLUSIONS: Although AS correlates with a higher risk of radiological progression than PN, survival outcomes are similar between the two treatment approaches after matching. On the other hand, PN correlates with a higher risk of progression to CKD stage III or higher during follow-up. Hence, patients diagnosed with a small renal mass should receive appropriate counseling on advantages and disadvantages of all treatment options. AS should be considered in their management, especially in comorbid patients at higher risk of developing renal failure.

SC98
3D virtual models to plan "minimal surgical impact" robotic- assisted partial nephrectomy for the treatment of small renal masses

D. Amparore, A. Piana, G. Busacca, S. De Cillis, F. Piramide, E. Checcucci, G. Volpi, P. Verri, M. Sica, J. Meziere, D. Zamengo, M. Manfredi, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: In the current precision surgery era, 3D virtual models have shown a primary role in the assistance of the surgeon during different steps of the urological procedures, from the planning to the intraoperative navigation. The current Literature demonstrated the usefulness of such 3D virtual models in the planning and intraoperative management of highly complex renal masses, but no evidence is available about the potential advantages of their employment to assist the surgeon facing with a small renal mass (SRM). The current study is focused on the use of 3D virtual models for the planning of robotic partial nephrectomy aiming to perform a minimal surgical impact procedure, with a complete restoring of the anatomical environment of the renal lodge at the end of the intervention.

METHODS: In the following study, 2 small renal masses with different surgical complexity are treated with robotic partial nephrectomy aided by 3D virtual models planning. The planning of a minimal surgical impact partial nephrectomy starts with the exposure of the renal surface limited to the peri-tumoral area. Then, the renal pedicle anatomy is considered performing selective clamping whenever possible. ICG injection can be used to assess the exclusion of the peritumoral region from the blood supply. At last, the resection and renal defect repair is planned, and the renal lodge integrity is restored. Moving from the simulation to the intraoperative field, all the planned steps are followed.

RESULTS: From June 2021, forty-eight patients harboring SRM (cT1a) were treated with robot-assisted partial nephrectomy guided by the preoperative planning performed by 3D virtual models. Median PADUA Score of the lesions was 7 (IQR 6-9). Focusing on perioperative variables we underline the high rate of selective clamping or clampless procedures (90%), the high rate of pure enucleation (70%) and the low rate of postoperative overall and major complications (18.7% and 4.2% respectively).

CONCLUSIONS: In conclusion, the assistance of a 3D virtual model to plan the intraoperative strategy of a robotic partial nephrectomy for a small renal mass seems to be useful for the standardization of a minimal impact surgical technique aimed to restore completely the anatomical environment of the renal lodge at the end of the procedure.

SMART (SC99-SC108)

Kidney cancer 1

SC99
New size cutoff proposed BY EAU renal cancer working group better identifies patients who can benefit from local tumor ablation

SC100
Proposal and internal validation of a nomogram for the prediction of local recurrence-free survival after percutaneous ablation for CT1 renal masses

SC101
External validation of Trifecta Score in patients treated with percutaneous thermal ablation for small renal masses

SC102
Progression rates according to a newly proposed CT1A classification in a prospective series of small renal masses treated with active surveillance

SC103
Operative outcomes and risk of disease persistence after microwave ablation of renal masses

SC104
Frailty Index in predicting surgical outcomes after partial nephrectomy in patients with renal cell carcinoma

SC105
Development and internal validation of a nomogram to predict five-year significant CKD upstaging after robot-assisted partial nephrectomy

SC106
Nephrometry adjusted comparison of perioperative and functional outcomes between on clamp *vs.* off-clamp robot-assisted partial nephrectomy

SC107
Resection strategy and technique during robotic partial nephrectomy: not all renal tumors are created equal

SC108
Three-arm off-clamp robot-assisted partial nephrectomy with the HUGO RAS system: introducing a novel technology for advanced robotic renal surgery

SC99

New size cutoff proposed BY EAU renal cancer working group better identifies patients who can benefit from local tumor ablation

P. Piazza, L. Bianchi, S. Luzzago, M. Bandini, A. Mottaran, S. Amirhassankhani, B. De Concilio, A. Celia, C. Serra, A. Cappelli, R. Golfieri, G. Musi, A. Gallina, M. Rizzo, G. Liguori, C. Trombetta, F. De Cobelli, G. Mauri, F. Orsi, U. Capitanio, R. Schiavina, O. De Cobelli, F. Montorsi, E. Brunocilla (Bologna)

BACKGROUND: Recently, the EAU Renal Cancer working group proposed to reduce the cutoff to define cT1a renal tumor from 4 to 3 cm, therefore limiting the use of local tumor ablation (LTA) to these small renal masses. The objective of this study was to evaluate the impact of this new cutoff on oncological outcomes in patients treated with LTA (including radiofrequency ablation [RFA], cryoablation [Cryo], microwave ablation [MW]).

METHODS: We retrospectively evaluated 661 patients treated with LTA (including RFA, Cryo or MW) for small renal masses (≤4 cm) at 5 European tertiary centers. Before LTA a percutaneous biopsy of the renal mass was performed to achieve the histology of the tumor. Patients were stratified according to the new size cutoff in cT1a (<3cm) and cT1b (>3 cm and <4 cm). Differences in categorical and continuous variables were analyzed using the χ^2 test and the Wilcoxon-U Test and reported as proportions and median±interquartile ranges (IQR), respectively. Kaplan-Meier curves were used to investigate 5-year RFS according to the new cT classification. Multivariate Cox's proportional hazard regressions were used to identify predictors of local recurrence. Sub-analyses were performed to investigate these outcomes in the cT1b population.

RESULTS: Overall, 530 (34%) and 131 (42%) patients were reclassified as cT1a and cT1b, respectively. Patients with cT1b lesions harbored more endophytic lesion (52.7% *vs.* 41%, P<0.001). At biopsy, 23.4% and 18.3% of patients had benign or non- diagnostic histologic findings in the cT1a and cT1b group respectively (P<0.001). During a median follow-up of 72 months (IQR: 48-120), 55 (10%) and 27 (21%) patients experienced local recurrence in the cT1a and cT1b group, respectively (P<0.001). The 5-year RFS was 90% for cT1a patients and 78% for cT1b patients, respectively (P<0.001). At multivariable Cox's analysis, clinical size (HR: 1.51; CI: 1.17-1.96; P=0.001), papillary histology (HR: 0.26; CI: 0.09-0.62; P=0.006) and MW ablation (HR: 0.29; CI: 0.12-0.65; P=0.004) were independent predictors of RFS. At sub-analysis clinical size remained the only independent predictor of recurrence (HR: 1.26; CI 1.68-2.35; P=0.04).

CONCLUSIONS: The newly proposed size cutoffs for cT1a renal cancer, better identify which patients could benefit from LTA. LTA should be discouraged in patients with renal masses >3 cm.

SC100

Proposal and internal validation of a nomogram for the prediction of local recurrence-free survival after percutaneous ablation for CT1 renal masses

A. Mottaran, L. Nocera, L. Bianchi, S. Luzzago, M. Bandini, P. Piazza, A. Celia, C. Serra, A. Cappelli, A. De Cinque, F. Modestino, R. Golfieri, G. Musi, A. Gallina, F. De Cobelli, G. Mauri, F. Orsi, U. Capitanio, R. Schiavina, O. De Cobelli, F. Montorsi, E. Brunocilla (Bologna)

BACKGROUND: Despite local tumor ablation (LTA) for the treatment of cT1 renal masses is increasing, the role of the different techniques used in influencing local recurrence is still unclear. The aim of this study was to develop a nomogram predicting local recurrence-free survival after different type of percutaneous LTA for small renal masses.

METHODS: We identified 433 patients who underwent percutaneous LTA with radiofrequency (RFA), cryoablation (Cryo) or microwave (MW) ablation at four tertiary referral centers for cT1 renal masses. All patients received a biopsy of the mass before treatment. Patients', as well as renal masses' characteristics were collected. The primary end point was local recurrence, defined as new focal enhancement in the ablation bed or enlargement of the ablation defect on follow-up imaging. Statistical analyses consisted of two steps. First, a nomogram predicting local recurrence was built relying on multivariate Cox regression analysis. Second, performance characteristics of the nomogram were assessed at a threshold of 60 months and compared to model exclusively based on clinical size and tumor's histology, using Heagerty's C and decision curve analysis (DCA).

RESULTS: Overall, 393 (90.8%) patients had a positive biopsy for renal cancer while 40 (9.2%) patients had an undetermined biopsy. Overall, 172 (39.7%), 123 (28.4%), 138 (31.9%) patients underwent Cryo, MW and RFA, respectively. No differences in terms of age, CCI, BMI, clinical size (cm) and histology at preablative biopsy were recorded among the three groups (all P>0.05). Overall, 53 patients (12.2%) recurred after a median time of 34 (IQR 18-60) months. The nomogram relied on the following variables: tumor size (cm), histology (malignant or undetermined), type of ablative procedure (MW, Cryo or RFA), polar involvement, >50% *vs.* ≤50% exophytic rate, rim location (lateral or medial), sinus involvement and BMI. The newly developed nomogram yielded an Area Under the Curve of 0.82 *vs.* 0.73 for the model based on clinical size and histology. Moreover, the new nomogram also exhibited greater net-benefit across all threshold probabilities at DCA.

CONCLUSIONS: The proposed nomogram to predict local recurrence after different techniques of LTA for renal cancer provides valuable information for both patient's and technique's selection for focal ablation of renal masses.

SC101

External validation of Trifecta Score in patients treated with percutaneous thermal ablation for small renal masses

G. Lucignani, M. Rizzo, A.M. Ierardi, A. Piasentin, E. De Lorenzis, C. Trombetta, G. Liguori, M. Bertolotto, G. Carrafiello, E. Montanari, L. Boeri (Milan)

BACKGROUND: Scoring metrics are important to compare outcomes of different percutaneous treatments for small renal masses (RM). The concept of trifecta (no complications, kidney function preservation and absence of local recurrence) has been recently introduced in percutaneous thermal ablation of RM. In this context, previous studies have shown that cryoablation (CA) and microwave ablation (MWA) have similar outcomes. The aim of this study was to validate the trifecta in CA and MWA and factors associated with treatment success.

METHODS: A retrospective comparative analysis of two cohorts was carried out on 190 consecutive patients with RMs treated using percutaneous CA or MWA. Nephrometry scores described renal mass complexity. Postoperative complications were categorized according to the Clavien-Dindo system. GFR at last follow-up was calculated through the CKD-EPI formula, whereas detection of contrast enhancement during follow-up defined local recurrence. Lastly, trifecta was defined by the combination of no major (Clavien >2) complications, eGFR decline <10% and absence of local recurrence. Descriptive statistics and logistic regression models tested the association between predictors and trifecta achievement. Factors associated with recurrence were compared by the Log-rank test.

RESULTS: Of 190, 62 (32.6%) and 128 (67.8%) patients underwent CA and MWA, respectively. Median (IQR) age and RM diameter were 75 years (66-80) and 2.4 cm (1.8-3.0). The CA group had lower preoperative GFR but also had lower rate of comorbidities (both P=0.01). Other demographics and tumor characteristics were comparable between groups. In the CA and MWA groups, major complications occurred after 1.6% and 4.8% of procedures (P=0.33), whereas an eGFR decline >10% was found in 31.5 % and 38.8% of cases (P=0.40), respectively. Similarly, in the CA and MWA group, at a median follow-up of 21 (8-39) and 24 (9.5-36) months, local recurrence was observed after 8 (8.3%) and 5 (9.3%) cases (P=0.78), trifecta was accomplished after 72 (59.5%) and 32 (59.3%) (P=1.00) procedures, respectively. Of notice, recurrence free survival was comparable among groups (P=0.57). Moreover, trifecta achievement was comparable when stratifying for demographics and tumor characteristics in the whole cohort and in the CA group (P>0.05). Conversely, logistic regression showed a lower OR of trifecta for lesions close to renal collecting system treated by MWA, even when accounting for maximum diameter and preoperative GFR (OR: 0.21; CI: 0.06-0.72; P=0.08). Of notice, this factor was also associated with a significantly lower RFS (P=0.02).

CONCLUSIONS: Both percutaneous CA and MWA of RM can safely accomplish good oncological outcomes while preserving renal function. Approximately six out of ten patients achieved trifecta after each procedure. Patient selection should account for tumor proximity to the collecting system, as this factor seems to impact the outcomes of microwave ablation.

SC102
Progression rates according to a newly proposed CT1A classification in a prospective series of small renal masses treated with active surveillance

M. Nicolazzini, C. Palumbo, S. Cavalli, A. Abdulvagabov, G. Bondonno, P. De Angelis, M. Zacchero, A. Volpe (Novara)

BACKGROUND: Recently, the EAU RCC Guidelines panel proposed a reclassification of cT1a small renal masses (SRMs), lowering the cut- off to 3 cm. For these patients, active surveillance (AS) and ablative therapy may be considered the main treatment options. To validate this, we assessed progression rates according to the new TNM system in a prospective series of AS patients.

METHODS: We included patients treated with AS for SRM from 2008 to 2022, with a minimum follow-up of 6 months and at least 3 radiological imaging studies performed. AS protocol was based on serial imaging every 6 months for 3 years and yearly thereafter. AS for SRMs was indicated in comorbid and elderly patients, patients who refused surgery or with severe renal failure. Patients were divided in 3 groups based on diameter at diagnosis: new-cT1a as group A <2.0 cm, group B ≥2.0 and ≤3 cm, and new-T1b as group C >3 cm. Progression criteria were defined as: maximum diameter >4 cm, volume doubling time (VDT) <12 months, TNM progression, onset of metastatic disease or tumor related symptoms, tumor related death. Progression rates and progression free survival (PFS) among the 3 groups were evaluated with Kaplan-Meier curves.

RESULTS: We included 108 patients, of whom 59 (54.6%) in new cT1a <2 cm (A), 28 (26.0%) in new cT1a ≥2.0 and ≤3 cm (B) and 21 (19.4%) upstaged to new cT1b >3 cm (C). Median age at diagnosis was 68 (IQR 58.5-74), 73.5 (IQR 64-80) and 79 (IQR 76-83) years for group A, B and C, respectively (P<0.001). No other significant differences were reported among the three groups. Overall, 24 (22.2%) SRMs progressed. Causes of progression were: diameter >4 cm in 72 cases (66.7%), VDT <12 months in 32 cases (29.2%) and TNM progression in 4 cases (4.1%). No metastatic progression and no tumor-related death occurred. At a median follow-up of 39 months, 7 SRMs of group A (11.9%), 6 of group B (21.4%) and 11 of group C (52.4%) progressed during follow-up. Progression rates at 3, 5 and 10 years were respectively 5.8%, 25.8% and 25.8% for group A, 24.5% at all timepoints for group B, 32.6%, 48.6% and 84.6% for group C. At log-rank test a significant difference in PFS was found between group A and C (P=0.002), but not between group A and B (P=0.33). Median PFS was >120 months for group A and B and 67 months for group C.

CONCLUSIONS: Our results validated the newly proposed TNM classification, supporting AS as a safe option in the management of SRMs≤3 cm (new cT1a). Indeed, SRMs upstaged to cT1b according to the new classification showed faster growth rates and higher progression rates (almost double than cT1a SRMs). In this population AS should be mainly reserved to frail and comorbid patients with limited life expectancy.

SC103
Operative outcomes and risk of disease persistence after microwave ablation of renal masses

F. Dagnino, P. Diana, A. Uleri, A. Piccolini, G. Garofano, C. Saitta, M. Lazzeri, R. Hurle, A. Saita, G. Lughezzani, V. Pedicini, D. Poretti, P. Casale, N.M. Buffi (Milan)

BACKGROUND: The EAU guidelines consider thermal ablation (TA) as an alternative treatment in case of comorbid and elderly patients bearing small renal masses (SRM) up to 4cm. Recently, the EAU renal cell carcinoma (RCC) guidelines panel proposed a new TNM classification defining T1a lesions up to 3cm. The new treatment indications would suggest managing the new T1a with alternative treatments and leave surgery to be an option to be discussed. The aim of this study is to provide the results of our cohort of patients treated with TA in case of SRM and investigate the risk factors for disease persistence after treatment.

METHODS: This study retrospectively analyzes a single center prospective database of patients diagnosed with cT1 renal masses subjected to microwave ablation (MWA) from 04/2018 to 01/2023. Primary outcomes were safety and feasi-

bility in terms of disease persistence at 2 months post-MWA at CT scan for cT1a/T1b renal masses. Linear and logistic regression analysis were used to find a correlation between disease persistence and patient factors.

RESULTS: Our study included 177 patients (120, 68% males), median (IQR) age was 70 years (59-75). 87 patients (49%) had lesions on right side. 34 patients (19.2%) had a single kidney. The patients presented with 1, 2, and 3 lesions in 159 (90%), 13 (7%), 5 (3%) cases, respectively. Median (IQR) tumor size is 21 (16-30) mm. PADUA risk stratification was low/intermediate/high in 56 (32%)/71 (40%)/50 (28%) of cases. We reported 16 (9%) intraoperative complications (14 bleedings and 2 hematuria requiring ureteral stenting). 35 (20%) complications postoperative on the day of the surgery and 5 (3%) on the first postoperative day. Complications were classified as Clavien-Dindo (CD) 1, 2, 3a, 4a, 5 in 30 (17%), 3 (1.7%), 5 (3%), 1 (0.6%), and 2 (1.2%) cases. Median hemoglobin and GFR drop were -1 (IQR: -0.4 – -1.8) and -2 (IQR: -11 – -0), respectively. We calculated an average and median (IQR) length of hospital stay of 1.64 and 1 (1-2) days respectively. Out of 132 biopsies done, we detected 105 malignant lesions (80%), of which histological examination revealed 64 (61%) RCC. The benign lesions detected with biopsy were 27 (20%). 47 patients were lost in follow-up. CT scan was performed at 60 days postoperative reporting 34/130 (26%) cases of disease persistence (31%, 10%, and 26% in malignant, benign, and undefined lesions). At univariate and multivariate analysis, the lesion size (OR: 2.3; 95% CI: 0.004-0.02; P value 0.002) and number of lesions (OR: 3.2; 95% CI: 0.027-0.378; P value 0.02) resulted independent predictors for disease persistence at 60 days postoperative.

CONCLUSIONS: Our study defines the size, and the number of lesions have a 2.3- and 3.2-folds increased risk of disease persistence after MWA. MWA is a valid option for SRM and the new T1a classification (<3 cm) should improve the clinical outcomes as smaller lesions would be treated.

SC104
Frailty Index in predicting surgical outcomes after partial nephrectomy in patients with renal cell carcinoma

G. Rosiello, C. Re, F. Cei, G. Musso, G. Fallara, F. Belladelli, D. Cignoli, D. Canibus, S.P. Soares Pinto, A. Necchi, L. Marandino, P. Karakiewicz, I. Rowe, G. Villa, M. Boarin, N. Disabato, F. Trevisani, A. Bettiga, A. Briganti, F. Montorsi, A. Salonia, A. Larcher, U. Capitanio (Milan)

BACKGROUND: Partial nephrectomy (PN) is the gold standard treatment for localized renal cell carcinoma (RCC), when technically feasible. However, PN is not devoid of complications. We investigated the role of the National Surgical Quality Improvement Program – Frailty Index (NSQIP-FI) on postoperative outcomes in patients undergoing PN for RCC.

METHODS: We relied on a prospectively maintained database including 1282 patients treated with PN for cT1-2 RCC. The NSQIP-FI Score was used to identify frail patients. Prolonged length of stay (pLOS) was defined as LOS above the median. Venn diagram was used to graphically depict the rate of frailty, Charlson Comorbidity Index (CCI) >2 and age >75. Three separate multivariable logistic regression models (LRM) were built to test the impact of frailty status, CCI and age on postoperative complications and pLOS, respectively, after adjusting for patient and tumor characteristics. Finally, Area Under the Curve (AUC) was calculated after including the NSQIP-FI Score within the postoperative models predicting complications and pLOS.

RESULTS: Of 1282 patients, 220 (17%) were frail according to NSQIP-FI, 391 (30%) had CCI>2 and 134 (10%) were older than 75 years. Median BMI and clinical size were 25 (interquartile range [IQR]: 23-28) kg/m^2 and 3 (IQR: 2.4-3.7) cm. Median LOS was 4 (IQR: 3-5) days. The overall rate of complications was 27%, and 4% with Clavien-Dindo >2. At MVA, after confounders, frailty status represented the strongest predictor of postoperative complications (odds ratio [OR]: 1.45, P<0.01), compared to CCI>2 (OR: 1.28, P=0.01) or age >75 (OR: 1.36, P<0.01). Moreover, when NSQIP-FI was included into the postoperative models predicting complications, the AUC increased from 76 to 82%. The same phenomenon was observed relative to prolonged LOS (AUC from 72 to 79%).

CONCLUSIONS: The rate of frail patients undergoing PN is higher than elderly patients (>75 years). Moreover, the NSQIP-FI does represent the strongest predictor of adverse outcomes after surgery, namely overall complications and pLOS. In consequence, preoperative assessment of NSQIP-FI allows for a better stratification of surgical risks in patients candidate to kidney surgery and for selecting those patients which may deserve a dedicated geriatric assessment.

SC105
Development and internal validation of a nomogram to predict five-year significant CKD upstaging after robot-assisted partial nephrectomy

R.S. Flammia, U. Anceschi, A. Brassetti, M. Ferriero, R. Mastroianni, L. Misuraca, G. Tuderti, A. Tufano, C. Leonardo, E. Bologna, M. Gallucci, F. Porpiglia, D. Amparore, A. Minervini, A. Mari, A.A. Grasso, R. Autorino, D. Eun, A. Larcher, U. Capitanio, G. Simone (Rome)

BACKGROUND: To date, Martini nomogram represents the best attempt to stratify the risk of renal function decline in patients treated with robot-assisted partial nephrectomy (RAPN) for kidney tumor. However, this tool relied on short follow-up and adopted a questionable endpoint such as 25% eGFR reduction. To address this void, we developed a novel nomogram to accurately predict the risk of 5-year CKD upstaging in patients treated with RAPN. Moreover, we aimed at stratifying patients in different risk categories-based nomogram-derived probability.

METHODS: Whitin a multi-institutional database, we identified patients treated with RAPN for localized renal tumor (cT1-2, cN0, cM0). Exclusion criteria was end- stage renal disease. Kaplan-Meier and Cox Regression addressed significant CKD upstaging (sCKD-upstaging), defined as any upstaging to CKD≥3a. The predictive model was built as follow: 1) univariable Cox regression analysis excluded non-significant predictors (P≥0.05); 2) predictors were checked for multicollinearity; and 3) stepwise bidirectional Cox regression analysis identified the best model. Model accuracy was reported as Harrel C-Index. Internal validation (bootstrapping) and calibration were performed. Nomogram predicting 5-year sCKD-upstaging risk was displayed. Regression tree analysis identified potential cutoffs in nomogram-derived probability.

Based on these cutoffs, three risk class were derived and tested with Kaplan-Meier analysys (Log-Rank Test).

RESULTS: Overall, 965 patients were identified. At Kaplan-Meier analysis 5-year sCKD-upstaging free-survival was 69.1% (95% CI 64.8-73.7%). The final model included baseline eGFR, postoperative AKI, WIT, hypertension, age at surgery, solitary kidney status and multiple lesions. Model accurately predicted 5-year sCKD-upstaging (C-Index 83.3%). Two nomogram cutoff (16 and 37%) were identified. Based on this cutoff, the overall cohort was stratified in three risk categories (low <16% *vs.* intermediate 16-37% *vs.* high >37%). Kaplan-Meier analysis depicted a significant reduction in 5-year sCKD-upstaging free survival rates between low *vs.* intermediate *vs.* high-risk (97.0% *vs.* 71.9% *vs.* 32.2%, respectively; P<0.001).

CONCLUSIONS: We developed a novel nomogram that accurately predicted 5-year significant CKD-upstaging. Moreover, we were able to identify three subgroups with substantial difference in risk profiles. If externally validated this nomogram may represent a useful tool to improve patient counselling and management.

SC106
Nephrometry adjusted comparison of perioperative and functional outcomes between on clamp *vs.* off-clamp robot-assisted partial nephrectomy

A. Tufano, R.S. Flammia, A. Brassetti, M. Ferriero, R. Mastroianni, L. Misuraca, G. Tuderti, U. Anceschi, C. Leonardo, E. Bologna, M. Gallucci, P. Francesco, D. Amparore, A. Minervini, A. Mari, A.A. Grasso, I. Derweesh, R. Autorino, D. Eun, A. Larcher, U. Capitanio, G. Simone (Rome)

BACKGROUND: The advantages of off-clamp (off) *vs.* on-clamp (on) robot-assisted partial nephrectomy (RAPN) is debatable due to conflicting results in terms of perioperative and functional outcomes. However, warm ischemia time (WIT) for low complexity renal masses is likely to be <25 minutes. Here, hypothetical benefit of off-RAPN might be diluted. Conversely, for complex renal masses, when prolonged WIT may be anticipated, off-RAPN approach may prove its advantage. We hypothesized that on-RAPN exhibited worse perioperative and functional outcomes relative to off-RAPN especially for more complex renal cases.

METHODS: Whitin a multi-institutional database we identified patients with kidney tumors (cT1-2, cN0, cM0) treated with on-RAPN *vs.* off-RAPN. Exclusion criteria were multiple lesions, solitary kidney, selective clamping. To maximally reduce covariates imbalance, 1:1 Propensity Score Matching (PSM) between on- *vs.* off-RAPN was performed adjusting for important confounders (age, sex, ASA, baseline eGFR, Hypertension, Diabetes, BMI, RENAL). After PSM, logistic regression models addressed trifecta achievement and Cox regression models addressed any upstaging to CKD ≥3a (CKD-upstaging) for on- *vs.* off-RAPN. Trifecta was defined as combination of negative surgical margins, no perioperative Clavien≥3 complications and absence of significant perioperative eGFR decline (>30%). All analysis were repeated after stratification according to RENAL Score <7 *vs.* ≥7.

RESULTS: Overall, 1015 patients were identified between on- *vs.* off-RAPN (37.0 *vs.* 63.0%). After PSM, on-RAPN yielded a higher risk of CKD-upstaging (HR: 1.39; 95% CI: 1.00-1.93; P=0.047). Moreover, on-RAPN reduce the probability of achieving trifecta (OR: 0.37; 95% CI: 0.25- 0.56; P<0.001). In subgroup analysis, on-RAPN yielded a higher risk of CKD-upstaging in more complex (HR 1.83, 95% CI 1.15-2.90, P=0.011), but not les complex cases (HR: 1.31; 95% CI: 0.79-2.17; P=0.3). Similarly, on-RAPN strongly reduce the probability of achieving trifecta in more complex (OR: 0.26; 95% CI: 0.15-0.44; P<0.001), but not in less complex less cases (OR: 0.56; 95% CI: 0.29-1.06; P=0.079).

CONCLUSIONS: In the current study, on-RAPN was associated with worse perioperative and functional outcomes relative to their counterparts in the overall cohort, as well as in more complex, but not in less complex renal masses. In conclusion, a greater detrimental effect of on-RAPN was detected for complex renal masses, for whom a prolonged WIT is required.

SC107
Resection strategy and technique during robotic partial nephrectomy: not all renal tumors are created equal

R. Bertolo, M. Vittori, C. Marani, P. Bove (Rome)

BACKGROUND: An anatomical resection strategy such as enucleation, that follows a relatively avascular dissection plane can facilitate and/or minimize the renorrhaphy, with known benefits. But enucleation is not always feasible, for several reasons. In the study (created in April 2023), two emblematic clinical cases of robotic partial nephrectomy are showed to open a point of reflection about the impact of anatomo-pathological tumor characteristics on the accomplishment of an anatomical resection strategy.

METHODS: The first case presented refers to a 69-year-old gentleman diagnosed with a 5-cm RENAL Score 9 suspicious mass located at the medium third of the right kidney. After accurate counseling, the patient underwent robot-assisted transperitoneal partial nephrectomy. The second case presented refers to a 27-year-old guy diagnosed with a 5-cm RENAL Score 7 mass located at the lower pole of the right kidney. After accurate counseling, the patient underwent robot-assisted transperitoneal partial nephrectomy.

RESULTS: In both the cases an off-clamp approach was chosen. In the first case, a pure enucleation resection technique was pursued (Surface-Intermediate-Base Score = 0). No renorrhaphy was performed at the end of the procedure given the absence of active bleeding. Pathology analysis revealed a clear cell renal cell carcinoma, pT1b, G3, with negative margins. The maximum width of the rim of healthy tissue excised was 0.2 mm, with an evident pseudocapsule 0.7-0.8 mm thick. In the second case, a mini-enucleo-resection technique was pursued (Surface-Intermediate-Base Score = 1-2). A selective single layer renorrhaphy was performed at the end of the procedure. Pathology analysis revealed a low-grade oncocytic tumor, pT1b, with negative margins. The maximum width of the rim of healthy tissue excised was 1.5 mm, with no evidence of a pseudocapsule.

CONCLUSIONS: Notwithstanding the surgeon's intent to pursue an anatomical resection strategy, anatomo-pathological tumor's characteristics (*i.e.,* the presence of a pseudocapsule) could impact on the resection technique actually performed.

SC108

Three-arm off-clamp robot-assisted partial nephrectomy with the HUGO RAS system: introducing a novel technology for advanced robotic renal surgery

F. Prata, A. Ragusa, U. Anceschi, A. Iannuzzi, F. Tedesco, L. Cacciatore, A. Civitella, P. Tuzzolo, P. Callè, G. Raso, M. Fantozzi, M. Pira, S.M. Prata, G. Simone, R.M. Scarpa, R. Papalia (Rome)

BACKGROUND: Hugo™ RAS System (Medtronic, Minneapolis, MN, USA) has been conceived as four arms multiport modular robotic system with enhanced modularity. The aim of this study was to describe surgical setting and feasibility of off-clamp RAPN with a three-arms configuration to streamline the procedure.

METHODS: Between October 2022 and March 2023, eighteen consecutive off-clamp RAPN for renal tumor with Hugo™ RAS System were performed. Working space for the bed-side assistant and arms clashes are the two main drawbacks to overcome in surgical procedures with Hugo™ RAS. On this background, we conceived a trouble-free three-arms setting to ease and standardize RAPN setting with Hugo™ RAS. Perioperative data were collected. Postoperative complications were reported according to the Clavien-Dindo classification. The eGFR was calculated according to the CKD-EPI formula. Continuous variables were presented as median and IQR while frequencies were reported as categorical variables.

RESULTS: Off-clamp RAPNs were successfully performed in all cases without the need of conversion. Median age and BMI were 69 years (IQR, 60.5-73.5) and 26.3 kg/m^2 (IQR, 24.9-27.8), respectively. Median tumor size and R.E.N.A.L. Score was 31.5 mm (IQR, 26-34.7) and 5 (IQR, 5-7), respectively. Median docking and console time were 7 (IQR, 5-9) and 100 minutes (IQR, 68-125 minutes), respectively. No intraoperative complications occurred, as well as clashes between instruments or with bed-assistant. Two (11.1%) postoperative minor complications (Clavien-Dindo 2) were reported. Small sample size and short follow-up are the main limitations of this study.

CONCLUSIONS: The three-arms approach resulted to be feasible, provided satisfactory intra- and perioperative outcomes without showing unexpected collisions during procedures.

SMART (SC109-SC117)

Kidney cancer 2

SC109
Demographics and clinical characteristics of solitary fibrous tumors: a contemporary population-based analysis

SC110
The effect of surgical resection on cancer-specific mortality in pelvic soft tissue sarcoma according to histologic subtype and stage

SC111
99MTC- sestamibi SPECT/CT for the characterization of small renal masses: initial experience from a tertiary referral center

SC112
Development of a nomogram to predict benign pathology in a large series of minimally invasive partial nephrectomy

SC113
Prediction of long-term renal function impairment after minimally invasive partial nephrectomy through a new cart based model

SC114
Efficacy and safety of lumasiran in patients with primary hyperoxaluria type 1: 36-month analysis of the ILLUMINATE-A Trial

SC115
Lumasiran for patients with primary hyperoxaluria type 1 and impaired kidney function: 12-month analysis of the phase 3 ILLUMINATE-C Trial

SC116
The role of preoperative proteinuria in predicting renal function decline after nephrectomy for renal cell carcinoma

SC117
Impact of benign histology on perioperative complication and functional outcomes of robot assisted partial nephrectomy

SC109
Demographics and clinical characteristics of solitary fibrous tumors: a contemporary population-based analysis

M.L. Piccinelli, S. Tappero, A. Panuzio, C. Cano Garcia, F. Barletta, R. Incesu, A.F. Mistretta, S. Luzzago, Z. Tian, G. Musi, O. de Cobelli, P. Karakiewicz (Milan)

BACKGROUND: Solitary fibrous tumors represent a rare mesenchymal malignancy that can manifest anywhere in the body, including the pelvis and retroperitoneum. Due to the low prevalence of the disease, there is a lack of contemporary data regarding patient demographics and clinical outcomes. The aim of our study was to identify the current state of solitary fibrous tumors in a North American population-based descriptive analysis.

METHODS: Within Surveillance, Epidemiology and End Results database (2000-2019), we identified 581 patients diagnosed with a solitary fibrous tumor. Distribution of patient age and race, tumor size, tumor location, and extent of disease were documented. Kaplan-Meier plots estimated cancer-specific survival at five years according to patient age, tumor size, and tumor location.

RESULTS: Overall, median patient age at diagnosis was 64 years and the disease was predominantly documented in the Caucasian race/ethnicity (73%). Overall distribution of solitary fibrous tumor between male and female was equal. Solitary fibrous tumors were classified as localized in 47%, locally advanced in 36%, and metastatic in 17% of patients. The median size at diagnosis was 9,7 (6-14.5) cm. Specifically, solitary fibrous tumors located in sites of urologic interest (pelvis and retroperitoneum) were 22% (N.=125), with pelvis identified as the second most common location (13%) after chest (48%). Median size was 10,2 (7.8-13.6) *vs.* 14 (9-18) cm for pelvic and retroperitoneal solitary fibrous tumor, respectively, with retroperitoneal being the biggest tumors across all sites. Compared to other sites, pelvic solitary fibrous tumors were more frequently diagnosed as locally advanced (46%). Overall, 5-year cancer specific survival was 70%, while decreasing from 74 to 66% in patients older than 64 years. Cancer specific survival rates at five years for localized, locally advanced, and metastatic disease were 78, 72, and 53%, respectively. Specifically, pelvic solitary fibrous tumor cancer specific survival was 68% and retroperitoneal solitary fibrous tumor cancer specific survival was 73% at five years from diagnosis.

CONCLUSIONS: Pelvis is the second most common location of solitary fibrous tumors after chest. Five-year cancer specific survival of solitary fibrous tumor sited in urological locations was 68% for pelvis and 73% for retroperitoneum.

SC110
The effect of surgical resection on cancer-specific mortality in pelvic soft tissue sarcoma according to histologic subtype and stage

M.L. Piccinelli, G. Musi, A. Baudo, S. Tappero, C. Cano Garcia, F. Barletta, R. Incesu, S. Morra, L. Scheipner, Z. Tian, S. Luzzago, F.A. Mistretta, M. Ferro, F.S. Saad, S.F. Shariat, L. Carmignani, S. Ahyai, N. Longo, D. Tilki, A. Briganti, F.K.H. Chun, C. Terrone, O. de Cobelli, P.I. Karakiewicz (Milan)

BACKGROUND: The effect of surgical resection *vs.* no resection on cancer-specific mortality (CSM) is relatively unknown in soft tissue pelvic sarcoma, especially according to histologic subtypes: liposarcoma, leiomyosarcoma, sarcoma not otherwise specified (NOS).

METHODS: Within the Surveillance, Epidemiology, and End Results database (2000-2019), we identified 2,491 patients with pelvic soft tissue sarcoma. Cumulative incidence plots depicted CSM and other-cause mortality rates, according to histologic subtype and surgical resection status. Competing risks regression models tested for CSM independent predictor status of surgical resection in non-metastatic and metastatic patients.

RESULTS: Of 2491 soft tissue pelvic sarcoma patients, liposarcoma was most frequent (41%), followed by leiomyosarcoma (39%) and sarcoma NOS (20%), in that order. Surgical resection rates in liposarcoma *vs.* leiomyosarcoma *vs.* sarcoma NOS were 92 *vs.* 91 *vs.* 58% in non-metastatic patients and 55 *vs.* 49 *vs.* 23% in metastatic patients, respectively. In non-metastatic surgically resected patients, 5-year CSM rates according to histologic subtype were 10 *vs.* 32 *vs.* 27% in liposarcoma *vs.* leiomyosarcoma *vs.* sarcoma NOS, respectively. In multivariable competing risks regression, surgical resection exerted a protective effect in non-metastatic patients of all histologic subtypes (liposarcoma HR: 0.2; leiomyosarcoma HR: 0.5; sarcoma NOS HR: 0.4). In metastatic patients, surgical resection exerted a protective effect on leiomyosarcoma (HR: 0.6) but not in sarcoma NOS patients. In metastatic liposarcoma analyses could not be performed due to an insufficient number of observations.

CONCLUSIONS: In non-metastatic soft tissue pelvic sarcoma, surgical resection is invariably associated with lower CSM. Conversely, in metastatic patients, the protective association only applies to leiomyosarcoma.

SC111
99MTC- sestamibi SPECT/CT for the characterization of small renal masses: initial experience from a tertiary referral center

A. Bertini, F. Cei, C. Re, G. Musso, G. Rosiello, G. Fallara, G. Basile, D. Cignoli, D. Canibus, G. Pepe, L. Gianolli, F. De Cobelli, G. Brembilla, R. Lucianò, N. Tenace, R. Matloob, R. Bertini, A. Briganti, F. Montorsi, A. Salonia, A. Larcher, U. Capitanio (Milan)

BACKGROUND: Initial studies on Tc-sestamibi single photon emission computed tomography/computed tomography (SPECT/CT) on small renal masses (SMR) suggested its use to characterize renal oncocytoma (RO) from renal cell carcinoma (RCC). In this case series, we present the initial cases managed at our tertiary referral center.

METHODS: We prospectively collected data on 40 consecutive patients with a SMR diagnosed at our institution and submitted to Tc- SPECT/CT at our Institution between May 2021 and September 2022. Of all, pathological data, either from biopsy or surgery, are available for 25 patients. We assessed the sensitivity (SE), specificity (SP), positive predictive value (PPV), negative predictive value (NPP) and the diagnostic accuracy (through the Area Under the roc Curve - AUC) of the Tc- SPECT/CT to differentiate oncocytoma and benign renal masses from malignant ones.

RESULTS: Of 25 patients, 7 (28%) were females and 18 (72%) males. Median age at diagnosis was 64.9 (95% CI 57.1-72.1). Median max diameter at imaging was 3 cm (IQR 2.6-3.3). The SMR was diagnosed in 2 cases with the solely

MRI (8%), in 12 cases with a CT scan (48%) and in 11 with both (44%). In 7 cases the SMR resulted positive at the Tc-SPECT/CT scan, suggesting a high-density mitochondrial tissue. 10 cases were submitted to biopsy and 15 to robotic partial nephrectomy. Of 10 biopsies, 2 SMRs were also treated with ablation and 1 which resulted positive for clear cell (cc) RCC was submitted to active surveillance. Overall, there were 9 oncocytomas, 8 ccRCC, 6 papillary tumors (of which 1 type I and 3 type II), 1 chronic nephritis and 1 cystic lesion with low probability of malignancy. Overall, for oncocytomas, SE was 55.5%, SP 87.5%, PPV 71.4% and NPV 77.8. The accuracy in differentiating oncocytomas from SMR of other nature was 74.6%. Considering all kind of benign SMRs, SE was 50%, SP 86.7%, PPV 71.4% and NPV 72.2%. The accuracy in differentiating benign from malignant SMR was 71.8%.

CONCLUSIONS: Despite the relatively small sample size and the initial experience, Tc- SPECT/CT should be regarded as a promising, non- invasive technique with good accuracy in the detection of renal oncocytoma.

SC112
Development of a nomogram to predict benign pathology in a large series of minimally invasive partial nephrectomy

A. ULERI, A. Gallioli, P. Verri, A. Tedde, F. Sanguedolce, I. Sanz, A. Farré, O. Rodriguez Faba, A. Territo, P. Diana, J. Palou, A. Breda (Barcelona)

BACKGROUND: In the era of patient tailored decision making, we need precise tools to counsel patients. Patients with benign lesions are still being overtreated as many series of partial nephrectomy report a rate of benign lesion excised of 15-25%. The aim of this study was to identify the predictors of benign final pathology and develop a nomogram.

METHODS: Clinical and pathological data of patients underwent laparoscopic or robotic PN at our Institution from 2003 to 2022 were collected. Continuous and categorical variables were reported as median with interquartile range and frequencies, respectively. Mann-Whitney U Test was used to compare continuous variables, while the χ^2 test was used to compare categorical variables. Univariable and multivariable logistic regression models were used to evaluate the predictors of benign final pathology. Clinical utility was assessed using a decision curve analysis. Goodness of the model was assessed by the Hosmer-Lemeshow Test.

RESULTS: Five hundred sixty-eight patients undergoing minimally invasive partial nephrectomy were included in the analysis. Median age was 63 (55-70) years and Age-Adjusted Comorbidity Index (ACCI) 4 (3-5). 74% were men, 35 (6%) were solitary kidney. Median tumor size was 3 (2.2-4.0) and 10% were multiple lesions with a median PADUA Score of 8 (7-9). Median follow-up was 72 (38-108) months. At final pathology 144 (25%) patients had a benign lesion. These patients were older (64 *vs.* 60.9 years; P<0.01), were more often females (37 *vs.* 22%; P<0.01) had smaller lesions (2.8 *vs.* 3cm; P=0.01), multiple lesions (15% *vs.* 9%; P=0.03). At multivariate analysis only age (OR=1.03; 95% CI: 1.01-1.05; P=0.001), female gender (OR=2.57; 95% CI: 1.65- 3.99; P<0.001), multiple lesions (OR=2.36; 95% CI: 1.30-4.32; P=0.005) and tumor size (OR=0.75; 95% CI: 0.63-0.89; P<0.001) were associated with benign final pathology. Then a nomogram was created taking in consideration these covariates. Calibration plot showed a good accuracy of the model.

CONCLUSIONS: The developed nomogram can represent a useful tool to assess benign pathology probability and tailor treatment counsel based on malignity risk. Assessing the probability of benign pathology could help identify patients in whom the use of biopsy would play a role in avoiding surgery. Further studies need to external validate this tool before its clinical implementation.

SC113
Prediction of long-term renal function impairment after minimally invasive partial nephrectomy through a new cart based model

A. Farrè, A. Uleri, A. Gallioli, P. Verri, G. Basile, A. Territo, F. Sanguedolce, J. Aumatell, J.M. Gaya, A. Tedde, J. Palou, A. Breda (Barcelona)

BACKGROUND: The aim of this study was to provide a machine-learning based model to predict long-term renal function impairment after partial nephrectomy (PN).

METHODS: Data of consecutive patients who underwent minimally invasive PN from 2005 to 2022 in a tertiary center were analyzed. A minimum of 12 months of follow-up was required. We relied on a machine-learning algorithm, namely classification and regression tree (CART), to identify the predictors and associated clusters of chronic kidney disease (CKD) stage migration during follow-up.

RESULTS: 568 patients underwent minimally invasive PN at our center. A total of 381 patients met our inclusion criteria. Patients' median age was 63 (IQR 56-71) years. The median follow-up was 69 (IQR 38-99) months. A total of 103 (27%) patients experienced CKD stage migration at last follow-up. Progression of CKD stage after surgery, ACCI and baseline CKD stage were selected as the most informative risk factors to predict CKD progression, leading to the creation of four clusters. The CKD progression rates for cluster 1 (no CKD progression after surgery, baseline CKD stage 1-2, ACCI 1-4), 2 (no CKD progression after surgery, baseline CKD stage 1-2, ACCI ≥5), 3 (no CKD progression after surgery and baseline CKD stage 3-4-5), and 4 (CKD upstaging after surgery) were 6.9%, 28.2%, 37.1%, and 69.6%, respectively. The C-Index of the model was 0.75.

CONCLUSIONS: We developed a new model to predict long-term renal function impairment after PN where the perioperative loss of renal function plays a pivotal role to predict lack of functional recovery. This model could help identify patients in whom functional follow-up should be intensified to minimize possible worsening factors of renal function.

SC114
Efficacy and safety of lumasiran in patients with primary hyperoxaluria type 1: 36-month analysis of the ILLUMINATE-A Trial

R. Miano, J. Saland, J.C. Lieske, J.W. Groothoff, Y. Frishberg, H. Shasha-Lavs.ky, D. Magen, S. Moochhala, E. Simkova, M. Coenen, W. Hayes, J. Hogan, A. Sellier-Leclerc, Y. Bao, J.M. Gansner, S. Hulton (Rome)

BACKGROUND: Primary hyperoxaluria type 1 (PH1) is a rare genetic disease characterized by hepatic oxalate overproduction leading to kidney stones and progressive kidney

disease. Lumasiran is an RNAi therapeutic approved for the treatment of PH1 to lower urinary oxalate (UOx) and plasma oxalate levels in pediatric and adult patients. Here, we reported data from the 36-month (M) analysis of ILLUMINATE-A, a phase 3 trial of lumasiran (NCT03681184).

METHODS: ILLUMINATE-A is an ongoing phase 3 trial in patients age ≥6 years with genetically confirmed PH1 and an estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73m^2. A 6M double-blind, placebo-controlled primary analysis period is followed by an extension period (up to 54M) in which all patients receive lumasiran.

RESULTS: Of 39 patients enrolled, 24/26 in the lumasiran/lumasiran group and 13/13 in the placebo/lumasiran group entered and continue in the extension period. Mean 24-hour UOx reduction at M36 relative to baseline was 63% in the lumasiran/ lumasiran group and 55% in the placebo/lumasiran group (M30 postlumasiran initiation). At M36, the proportion of patients achieving 24-hour UOx excretion ≤1.5 × upper limit of normal was 76% in the lumasiran/lumasiran group and 92% in the placebo/lumasiran group. Mean baseline-to-M36 reductions in plasma oxalate were 36% and 37% in the lumasiran/lumasiran and placebo/lumasiran groups, respectively. In both groups, eGFR remained stable through M36. Kidney stone event rates decreased from 3.19/person-year during the 12M before consent to 0.70/person-year in the lumasiran/lumasiran group and from 0.54/person-year to 0.39/person-year in the placebo/lumasiran group. Medullary nephrocalcinosis generally remained stable or improved. The most common lumasiran-related adverse events were mild injection-site reactions (36% of patients).

CONCLUSIONS: Long-term treatment with lumasiran led to sustained UOx reduction through M36, with an acceptable safety profile in patients with PH1 and encouraging clinical outcomes data.

SC115
Lumasiran for patients with primary hyperoxaluria type 1 and impaired kidney function: 12-month analysis of the phase 3 ILLUMINATE-C Trial

R. Miano, Y. Frishberg, M. Michael, J.W. Groothoff, H. Shasha-Lavs.ky, J.C. Lieske, E. Simkova, A. Sellier-Leclerc, A. Devresse, F. Guebre-Egziabher, S.A. Bakkaloglu, C. Mourani, R. Saqan, R. Singer, R. Willey, J.M. Gansner, D. Magen (Rome)

BACKGROUND: Primary hyperoxaluria type 1 (PH1) is a rare genetic disease characterized by hepatic oxalate overproduction leading to progressive kidney disease. In PH1, plasma oxalate (POx) increases as kidney function declines; in CKD 3b–5, POx is typically elevated and is associated with an increased risk of systemic oxalosis, making it a relevant trial endpoint. In the ILLUMINATE-C 6-month (M) primary analysis, administration of lumasiran, an RNA interference therapeutic designed to reduce hepatic oxalate production, produced substantial POx reductions and acceptable safety in PH1 patients with impaired kidney function. In this study we presented the 12-month results.

METHODS: ILLUMINATE-C (NCT04152200) is an ongoing phase 3, single-arm study (cohort A: N.=6, no hemodialysis [HD] at study start; cohort B: N.=15, on HD). The primary analysis period is followed by an extension period (EP) of up to 54 months. Key inclusion criteria included genetically confirmed PH1, eGFR≤45 mL/min/1.73m^2, and POx≥20 μmol/L.

RESULTS: All 21 patients entered the EP (median [range] exposure, 14.2 [8.3-19.7] M). As of the M12 assessments, 2 Cohort A patients (baseline eGFR, 8.6-16.0 mL/min/1.73m^2) initiated HD. In cohort B, 1 patient received a kidney transplant, discontinued HD, and continued lumasiran; 1 received a liver/kidney transplant and discontinued lumasiran. POx means % reduction from baseline at M12 was 69.3% and 34.3% in cohorts A and B, respectively; mean absolute reduction was 60.7 and 42.4 μmol/L. POx AUC0-24h mean % reduction from baseline between HD sessions was 40.9% at M12 (cohort B). Most burdensome symptoms improved or remained stable with lumasiran. The most common lumasiran-related adverse events (AEs) were mild, transient injection-site reactions. There were no deaths or lumasiran-related serious or severe AEs, discontinuations, or withdrawals.

CONCLUSIONS: Lumasiran showed sustained POx reductions in PH1 patients with CKD 3b-5, with an acceptable safety profile through 12 M. The impact on systemic oxalosis and transplant outcomes will be further monitored in the EP.

SC116
The role of preoperative proteinuria in predicting renal function decline after nephrectomy for renal cell carcinoma

F. Portè, C. Palumbo, M. Nicolazzini, M. Taurino, G. Bondonno, M. Zacchero, A. Volpe (Novara)

BACKGROUND: Preoperative proteinuria is a prognostic factor of chronic kidney disease (CKD). We assessed the association of preoperative proteinuria and postoperative renal function after partial nephrectomy (PN).

METHODS: We retrospectively reviewed our records of patients who underwent a PN for a single malignant renal mass between 2000 and 2022. Single kidney patients were excluded. Patients with data on preoperative proteinuria on urine analysis were included (clinically significant proteinuria was defined as proteins ≥30 mg/dL). Baseline characteristics and eGFR differences over time between patients with and without proteinuria were evaluated with *t*-test and Mann-Whitney U Test. Univariate and multivariable logistic regression models (LRM) tested for presence of CKDIII or higher at 12-month and at last follow-up. Pre and postoperative eGFR were estimated using the Chronic Kidney Disease Epidemiology Collaboration (CDK-EPI) equation. Covariates were preoperative proteinuria and eGFR, age, smoke, diabetes, hypertension, and clinical size of renal mass.

RESULTS: Two hundred ninety-five patients were included, of whom 22 (7.4%) had preoperative proteinuria. Patients with proteinuria had higher rates of CKDIII () at baseline. No other significant differences were reported. At a median follow-up of 46.5 months (IQR 19-82), 117 patients developed de novo CKDIII, without differences in the two groups. No differences in decline in eGFR were observed. At univariate LRM, predictors of CKDIII at 12 months after PN were preoperative proteinuria (OR 3.2, 95% CI 1.4-7.8, P=0.006), age (OR 1.05, 95% CI 1.03-1.08, P=0.006) and baseline eGFR (OR 0.94, 95% CI 0.93-0.96, P<0.001), while at last follow-up only age (OR 1.06, 95% CI 1.03-1.06, P<0.001), hypertension (OR 2.04, 95% CI 1.21-3.37, P=0.005), and baseline eGFR (OR 0.94, 95% CI 0.93-0.96, P<0.001). At multivariable

LRM, only baseline eGFR predicted CKDIII at 12-month (OR 0.95, 95% CI 0.93-0.97, P<0.001) and at last-follow-up (OR 0.95, 95% CI 0.93-0.96, P<0.001).

CONCLUSIONS: Preoperative eGFR remains the main predictor of long-term renal function after PN. Preoperative proteinuria correlates with renal function at 12 months. Nonetheless, proteinuria is easily assessable before PN and may help identifying patients at higher risk of CKD. This may have an impact on both surgical approach and postoperative care, aiming at further minimizing potential risks for renal damage.

SC117
Impact of benign histology on perioperative complication and functional outcomes of robot assisted partial nephrectomy

E. Bologna, R.S. Flammia, U. Anceschi, A. Brassetti, M. Ferriero, R. Mastroianni, L. Misuraca, G. Tuderti, S. Guaglianone, M. Gallucci, A. Tufano, C. Leonardo, F. Porpiglia, D. Amparore, A. Minervini, A. Mari, A.A. Grasso, I. Derweesh, R. Autorino, D. Eun, A. Larcher, U. Capitanio, C.A. Bravi, A. Mottrie, G. Simone (Rome)

BACKGROUND: Partial nephrectomy (PN) represents the standard of care for localized kidney tumor. Nonetheless, a proportion of PN treated patients harbor benign histology (Bn) at final pathology report. Moreover, the contemporary surge in incidental diagnosis of renal masses may inadvertently increase the overall number of patients treated with PN for Bn lesion. Unfortunately, literature specifically addressing Bn tumors is scarce. To address this void, we investigated contemporary rates of Bn histology, as well as perioperative and functional outcomes of RAPN performed for Bn tumors.

METHODS: Whitin a multi-institutional database, we identified North American and European patients aged >18 years old treated with RAPN for localized renal masses (cT1-2). Then, 1:1 PSM between malignant (Mn) *vs.* Bn histology was performed adjusting for important confounders (age, sex, WIT, baseline eGFR, RENAL, BMI, ASA, hypertension, diabetes, solitary kidney status and multifocality). Cox regression model addressed any upstaging to CKD≥3a (CKD3a- upstaging) and to CKD ≥3b (CKD3b-upstaging), linear model addressed length of hospital stay (LOS) and logistic regression model addressed any perioperative complications and postoperative Acute Kidney Injury (AKI).

RESULTS: Overall, 2256 patients were identified. Of those, 530 (23%) harbored Bn. The majority were oncocytoma (47.1%) followed by angiomyolipoma (39.4%). After PSM, no differences in CKD3a-upstaging (HR: 1.26; 95% CI: 0.87-1.81; P=0.2), CKD3b-upstaging (HR: 1.04 95% CI 0.57-1.91; P=0.9), LOS (estimate: -0.22±0.21; P=0.3), any complications (OR: 1.14; 95% CI: 0.70-1.90; P=0.6) and postoperative AKI (OR: 0.97; 95% CI: 0.60-1.57; P=0.9) between Bn *vs.* Mn were detected.

CONCLUSIONS: Overall, more than one fifth of patients receiving RAPN for localized renal masses harbored Bn with a tiny percentage exhibiting high-grade complication. Despite accurate adjustments, Bn patients did not exhibit better outcomes than their Mn counterparts. Thus, these data are of primary importance when counseling patients treated with RAPN for Bn renal masses and questioned the benefit of RAPN as all-in-one strategy for diagnosis and treatment in those patients.

SMART (SC118-SC128)

Muscle invasive bladder cancer 1

SC118
Perioperative morbidity of robot-assisted radical cystectomy *vs.* open radical cystectomy in septuagenarians and octogenarians
SC119
Radical cystectomy video consensus: a simple and effective way to improve awareness of patients undergoing radical cystectomy
SC120
Predictors of developing cisplatin ineligibility in a contemporary cohort of bladder cancer patients treated with radical cystectomy at an Italian national cancer center
SC121
The immune-related adverse events paradox in locally advanced or metastatic urothelial cancer after atezolizumab immunotherapy: analysis of individual patient data from IMVIGOR210 and IMVIGOR211 trials
SC122
Impact of neoadjuvant immune-checkpoint inhibitor on intra- and postoperative outcomes in patients with muscle-invasive bladder cancer treated with radical cystectomy
SC123
Impact of neoadjuvant chemotherapy on perioperative morbidity in a contemporary cohort or bladder cancer patients treated with radical cystectomy
SC124
Defining the best candidates for radical cystectomy in elderly patients: a multicenter analysis
SC125
Robot assisted radical cystectomy with intracorporeal orthotopic neobladder: long-term gender-specific outcomes from a single-center series
SC126
Mid-term oncologic outcomes of open *vs.* robot-assisted radical cystectomy with totally intracorporeal urinary diversion: single center prospective randomized controlled trial
SC127
Implementation of Tytocare™ telemedicine system in postoperative home care after radical cystectomy: new technological tool for early complications detection and patient recovery management
SC128
Stage dependent survival in patients treated with neoadjuvant chemotherapy and radical cystectomy

SC118

Perioperative morbidity of robot-assisted radical cystectomy *vs.* open radical cystectomy in septuagenarians and octogenarians

F. Proietti, R.S. Flammia, U. Anceschi, A. Brassetti, M. Ferriero, R. Mastroianni, L. Misuraca, G. Tuderti, A. Tufano, C. Leonardo, E. Bologna, S. Guaglianone, M. Gallucci, G. Simone (Rome)

BACKGROUND: Multiple RCT compared robot-assisted radical cystectomy (RARC) *vs.* open radical cystectomy (ORC) in non-metastatic muscle-invasive BCa (MIBC) and concluded that RARC harbored shorter length of hospital stay (LOS) and less blood loss compared to ORC. However, those RCTs included relatively young patients with a median age of 60-70 years. As a consequence, we do not know to what extent these results may be generalizable to older patients. To address this void, we tested the association of RARC with better perioperative outcomes in patients aged older than 70 years.

METHODS: In our institutional prospective database, we identified patients >70 years treated with RARC *vs.* ORC for non-metastatic MIBC from 2016 to 2022. Exclusion criteria were orthotopic urinary diversion, not receiving an extended pelvic lymph node dissection, preoperative pelvic irradiation. Surgical procedures were performed by expert surgeons at a high-volume cancer center. To maximally reduce imbalances due to lack of randomization, 1:1 Propensity Score Matching (PSM) was applied between RARC *vs.* ORC adjusting for different covariates. First, logistic regression model addressed high-grade perioperative complications (Clavien 3-5). Second, linear regression addressed LOS and 24-hour Hb variation (ΔHb). Covariates were CCI, ASA, BMI, pathologic stage, neoadjuvant chemotherapy, preoperative Hb, chronic assumption of antiplatelet/anticoagulant, intraoperative blood units, urinary diversion (ureterocutaneous *vs.* ileal conduit) and ERAS protocol.

RESULTS: Overall, 170 patients were identified between RARC *vs.* ORC (54 *vs.* 116). After PSM, RARC exhibited lower median LOS (4 *vs.* 6 days, estimated reduction of 2.09±0.58-day, P<0.001), lower reduction in Hb at 24h (ΔHb -1.40 *vs.* -2.70, estimated difference of 1.42±0.25, P<0.001) and a lower rate of high-grade complications (1.9 *vs.* 22.2%, OR 0.07, 95% CI 0.01-0.36; P=0.014).

CONCLUSIONS: We observed shorter LOS, milder hemoglobin drops and lower high-grade complication rates in septuagenarian and octogenarian patients treated with RARC *vs.* ORC. Since RCTs addressing such a comparison among older patients are unlikely to be run, to date, these results strongly support the role RARC in older MIBC patients.

SC119

Radical cystectomy video consensus: a simple and effective way to improve awareness of patients undergoing radical cystectomy

F. Esperto, N. Deanesi, L. Cacciatore, A. Minore, G. Raso, A. Testa, F. Tedesco, R. Papalia, R.M. Scarpa (Rome)

BACKGROUND: In the age of information technology, new platforms are consulted by patients to acquire their own consciousness about medical treatments, even if often information found are not reliable. The European Association of Urology Patient Information (EAU PI) delivers, with the support of EAU guidelines, high quality video-content about surgical procedures with a language easy to understand for patients. The aim of this study was to assess the level of understanding and feasibility of video consensus administration in patients scheduled for radical cystectomy (RC) comparing it with standard written informed consensus.

METHODS: The EAU PI video content about RC was translated in Italian and implemented with possible complication explanation at the end of it. After Ethical Committee approval, from January 2021 to September 2021 all patients who underwent RC for bladder cancer (BC) at our institution were prospectively included in this study. A print-based traditional consensus was administered to all patients and, after that, a video information about RC showing potential complications. After paper-based consensus and video consensus, patients received a preformed Likert 10 Scale questionnaire to evaluate: 1) comprehension; 2) contents; 3) satisfaction; 4) simplicity; and 5) details; with a score from 1 to 10. Descriptive and variance analysis was performed through SPSS v27 (SPSS Inc., Chicago, IL, USA) with an alpha value of significance set at 0.05, comparing the different types of consensuses.

RESULTS: Thirty patients were included in our study and 50 questionnaires were evaluated. 17% (5) of patients were female and 83% (25) were male, 66.6 % (20) were aged 50–70 years, 33.4 % (10) over 70 years. Mean score±standard deviation (SD) for different domains analyzed was the following: mean comprehension score±SD was 6.5±0.58 in standard consensus group *versus* 8.2±0.725 in the video consensus group, P=0.0001. Mean contents score±SD was 6.4±0.4 in standard consensus group *versus* 8.4±0.82 in the video consensus group, P=0.0001. Mean satisfaction score±SD was 6.4±0.65 in standard consensus group *versus* 8.5±0.8 in the video consensus group, P=0.0001. Mean simplicity score±SD was 6.1±0.45 in standard consensus group *versus* 8.4±0.65 in the video consensus group, P=0.0001. Mean details score±SD was 6.25±0.3 in standard consensus group *versus* 8.8±0.9 in the video consensus group, P=0.0001*U Mann-Whitney Test for independent samples.

CONCLUSIONS: All the domains analyzed showed a higher statistically significant appreciation for video consent compared to traditional informed consent. Overall satisfaction, with a mean score of 8.4 out of 10, showed to our advice the way to chase for the future. Video consent represents a simple and comprehensive tool for patients and can improve their awareness and satisfaction.

SC120

Predictors of developing cisplatin ineligibility in a contemporary cohort of bladder cancer patients treated with radical cystectomy at an Italian national cancer center

F. Proietti, R.S. Flammia, U. Anceschi, A. Brassetti, M. Ferriero, R. Mastroianni, L. Misuraca, G. Tuderti, A. Tufano, L.C. Licari, C. Leonardo, S. Guaglianone, M. Gallucci, G. Simone (Rome)

BACKGROUND: Renal function decline (RFD) represents one of the main drawbacks of radical cystectomy (RC) by preventing cisplatin- based chemotherapy (CHT) when required, as well as leading to end-stage renal disease in long survivors. Consequently, identifying predictors of RFD is fundamental for adequate counseling and precise management. Thus, we

aimed at identifying these predictors based on a contemporary cohort of BCa patients treated with RC at an Italian high-volume cancer center.

METHODS: Within our prospectively maintained database, we identified RC-treated BCa patients (anyT, anyN, M0) from 2016 to 2022. Patients with baseline eGFR<50 mL/min were excluded due to cisplatin ineligibility. Surgical procedures were performed by two expert surgeons. The endpoint of interest was defined as newly onset eGFR<50 mL/min (pCKD) during follow-up. Kaplan-Meier analysis depicted pCKD-free survival. Cox regression analyses addressed pCKD according to potential risk factors.

RESULTS: Overall, 201 patients were identified exhibiting three-year pCKD-free survival rate of 71.2%. After multivariable adjustment, only Charlson Comorbidity Index (HR 1.34; P=0.048), non-organ confined stage (HR 3.05, P=0.005), perioperative acute kidney injury (HR 2.07; P=0.028), postoperative ureteric stricture (HR 2.31; P=0.008) and postoperative UTI (HR 2.17; P=0.017) were associated with pCKD.

CONCLUSIONS: At 3-year follow-up, one out of four patients will be ineligible to cisplatin-based CHT based on eGFR<50 mL/min. Despite immunotherapy approval, cisplatin-based CHT still represents the first-line therapy due to superior oncologic outcomes. Early identification and prompt treatment of ureteric strictures and UTI especially in patients with advanced pathologic stages should be kept into account to maximize cisplatin eligibility after RC.

SC121
The immune-related adverse events paradox in locally advanced or metastatic urothelial cancer after atezolizumab immunotherapy: analysis of individual patient data from IMVIGOR210 and IMVIGOR211 trials

D. Robesti, L. Nocera, F. Belladelli, J.G. Schultz, G. Fallara, L. Marandino, F. Montorsi, P. Msaouel, A. Necchi, A. Martini (Milan)

BACKGROUND: We investigated the association between irAEs and oncological outcomes in patients with advanced urothelial carcinoma receiving ICIs, and whether the administration of systemic corticosteroids diminishes therapeutic impact.

METHODS: The association between irAEs occurrence and clinical progression-free survival (PFS), overall survival (OS), and cancer-specific survival (CSS) was tested by means of multivariable Cox or competing-risks regression, when appropriate. Patients experiencing irAEs were further stratified based on systemic corticosteroids administration. A sensitivity analysis was conducted by repeating all the analyses with median time to irAE as landmark point.

RESULTS: We relied on individual participant data from two prospective trials for advanced urothelial cancer: IMvigor210 and IMvigor21. A total of 896 patients who received Atezolizumab for locally advanced or metastatic urothelial carcinoma were considered. Overall, irAEs were recorded in 195 patients, median time to irAEs was 64 days. On multivariable analysis, irAEs were inversely associated with the risk of disease progression (HR=0.50; 95% CI=0.40-0.61; P<0.001), overall mortality (HR=0.51; 95% CI=0.41-0.64; P<0.001), and cancer-specific mortality (SHR=0.55; 95% CI=0.45-0.72; P<0.001). Moreover, our results did not refute the supposition that the administration of systemic corticosteroids does not impact oncological outcomes (PFS: HR=0.92 95% CI=0.62-1.34; P=0.629; OS: HR=0.86 95% CI=0.51-1.64; P=0.613; CSS: SHR=0.90 95% CI=0.60-1.36; P=0.630). The sensitivity yielded consistent findings.

CONCLUSIONS: The development of irAEs while receiving atezolizumab treatment was associated with improved oncological outcomes, namely overall and cancer-specific mortality, and progression free survival. These findings seem to not be substantially affected by administration of systemic corticosteroids.

SC122
Impact of neoadjuvant immune-checkpoint inhibitor on intra- and postoperative outcomes in patients with muscle-invasive bladder cancer treated with radical cystectomy

G. Avesani, F. Pellegrino, C. Re, R. Leni, G. Basile, P. Scilipoti, M. Longoni, D. Cannoletta, G. Gandaglia, U. Capitanio, R. Colombo, A. Necchi, D. Raggi, A. Salonia, A. Briganti, F. Montorsi, M. Moschini (Milan)

BACKGROUND: Neoadjuvant therapy is often used before radical cystectomy (RC) for muscle invasive bladder cancer (MIBC). Immune- checkpoint inhibitors (ICI) have been investigated and largely used in a trial setting as a neoadjuvant treatment (NT). We evaluated the impact of neoadjuvant ICI (NICI) on intra- and postoperative complications in patients with MIBC treated with RC.

METHODS: Five hundred twelve patients with MIBC treated with RC from 2015 to 2022 at our institution were evaluated. Robot or open approach was performed according to expertise of the surgeon. The Pearson's χ^2 test, the Wilcoxon Rank Sum Test, and a multivariable logistic regression model (MVA) were used to compare intra and postoperative complications focusing upon patients who did not receive any NT (nonNT group) and those who received NICI therapy (NICI group).

RESULTS: Overall, 111 patients received standard neoadjuvant chemotherapy, 104 received NICI therapy and 297 did not receive any NT (nonNT). Median age was similar among the NICI and the nonNT group (69 *vs.* 72 years); 91 (88%) and 253 (44%) patients were male in the NICI and nonNT groups, respectively. Patients who did not receive any treatment had a higher burden of comorbidities with a Charlson Comorbidity Index (CCI≥2 in 60% *vs.* 41%) and a higher pT stage (pT≥3 in 47% *vs.* 21%) as compared to NICI group. At univariable analysis, patients in the NICI group had a lower risk of overall (21% *vs.* 59%) and severe (7% *vs.* 37%) intra-operative complications compared to nonNT patients. Bleeding requiring transfusions was in 3% *vs.* 29% in NICI and nonNT group, respectively. The rate of severe postoperative complications (Clavien-Dindo>2) was similar in the two groups (34% *vs.* 30%, P=0.4). The incidence of post operative fever requiring antibiotic therapy was higher in patients treated with NICI compared to nonNT group (45% *vs.* 31%, P=0.023). At MVA, NICI was inversely associated with the risk of any (OR: 0.40; P=0.002) and severe intraoperative complications (OR: 0.28; P=0.004), and bleeding requiring transfusions (OR: 0.19; P=0.008;)

CONCLUSIONS: Patient with MIBC treated with RC who underwent NICI had lower intraoperative complications compared to nonNT group. Postoperative complications were the

same between the two groups while NICI patients developed post operative fever requiring antibiotic treatment in a higher percentage.

SC123
Impact of neoadjuvant chemotherapy on perioperative morbidity in a contemporary cohort or bladder cancer patients treated with radical cystectomy

L.C. Licari, R.S. Flammia, U. Anceschi, A. Brassetti, M. Ferriero, R. Mastroianni, L. Misuraca, G. Tuderti, S. Guaglianone, C. Leonardo, M. Gallucci, G. Simone (Rome)

BACKGROUND: Neoadjuvant chemotherapy (NAC) prior to radical cystectomy (RC) represents the standard of care for MIBC. Nonetheless, <25% of MIBC patients received NAC. This lack of adherence may be due to the fact that patients with MIBC usually harbor multiple comorbidities which, if aggravated by NAC, would further increase risk of perioperative morbidity and mortality. Thus, we relied on our institutional cohort yielding a significant proportion of patients receiving neobladder, as well as patients treated with totally intracorporeal robot assisted radical cystectomy (iRARC). We hypothesized than at high- volume center, NAC does not affect perioperative morbidity.

METHODS: Whitin our prospective database, we identified patients cT2-4a/cN0/cM0 treated with RC + PLND from 2016 to 2022. Exclusion criteria were preoperative pelvic irradiation and variant histology. Surgical procedures were performed by expert surgeons. To maximally reduce imbalances due to lack of randomization, 1:1 Propensity Score Matching (PSM) was applied between NAC-yes *vs.* NAC-no adjusting for important confounders. After PSM, logistic regression and linear models tested the association between NAC status and different endpoints: high-grade (Clavien 3-5) complications, length of hospital stay (LOS), operative time (OT) and 24-hour Hb drop (ΔHb), postoperative transfusion rate and postoperative Acute kidney Injury (AKI) as defined by RIFLE criteria.

RESULTS: Among 317 patients identified, 31% received NAC, 43% underwent iRARC and 43% received orthotopic ileal neobladder. NAC-yes patients were younger (64 *vs.* 71; P<0.001) with lower Charlson Comorbidity Index (3 *vs.* 4; P<0.001). After 1:1 PSM, no differences were detected in high-grade complications (12.5 *vs.* 11.2%), median OT (208 *vs.* 205 min.), median LOS (7 *vs.* 7 days), ΔHb (-1.80 *vs.* -1.80 g/dL), postoperative transfusions (46.0 *vs.* 42.5%) and AKI (11.0 *vs.* 13.4%) according to NAC yes *vs.* no, respectively (all P>0.05).

CONCLUSIONS: After PSM, NAC failed to show any association with perioperative morbidity despite the high proportions of patients receiving neobladder and/or iRARC. In consequence, urologists should maximally adhere to guidelines recommending NAC prior to RC in MIBC patients.

SC124
Defining the best candidates for radical cystectomy in elderly patients: a multicenter analysis

F. Dehò, C. Re, P. Capogrosso, E. Zaffuto, R. Leni, F. Cei, F. Pellucchi, P. Maggio, G. Gianesini, G. Carcano, A. Briganti, A. Salonia, F. Montorsi, M. Moschini (Varese)

BACKGROUND: Muscle invasive bladder cancer (MIBC) is a common malignancy amongst elderly and the first line treatment is radical cystectomy. However, the benefit of RC is often questioned in elderly patients. The aim of this study was to define the best candidate to propose RC in elderly individuals with MIBC.

METHODS: One hundred two patients aged ≥80 with MIBC consecutively treated with RC from 2010 to 2022 at two tertiary care referral centers were identified. All patients were treated with either open or robot-assisted RC, according to the expertise of the surgeon. Urinary diversion was performed in all cases with ureterocoutaneous or ileus conduit reconstruction. Comorbidities were scored with Charlson Comorbidity Index (CCI) and preoperative risk was based on the American Society of Anesthesiologists (ASA) Score. Kaplan-Meier analysis estimated overall survival (OS) after surgery. A Cox-regression model was used to test preoperative variables associated with better OS; age was included as a binary variable considering the median value as a cutoff.

RESULTS: Overall, median (IQR) age was 82 (81-84), which resulted in 40(39%) patients aged 80-82 *vs.* 62 (61%) aged >82. A total of 36 (90%) *vs.* 48 (77%) were male in the <82 group and in the >82 group, respectively. The burden of comorbidities was significant with 98% (100) of patients reporting a CCI≥2 and an ASA Score ≥3 in 58% (57) of cases. Postoperative complications within the first year after surgery occurred in 75.5% (74) of cases, with 34.6% (34) reporting a Clavien-Dindo ≥3 event. Overall, CCI, BMI and rate of complications were comparable between the two groups (P>0.1). At Kaplan-Meier analysis, the estimated OS at 24 months after surgery in patient aged <82 was 66% (95% CI 49-79) *vs.* 49% (95% CI 36-61) in patients aged>82, respectively (P=0.009). At Cox regression analysis, being older than 82 years was associated with worse overall survival post-RC (HR: 2.02; 95% CI: 1.12-3.61; P=0.02) after adjusting for sex and ASA Score.

CONCLUSIONS: Encouraging survival outcomes can be achieved after RC even in the elderly although in our series patients younger than 82 years appear to benefit the most regardless of comorbidities.

SC125
Robot assisted radical cystectomy with intracorporeal orthotopic neobladder: long-term gender-specific outcomes from a single-center series

G. Tuderti, R. Mastroianni, U. Anceschi, A.M. Bove, A. Brassetti, S. D'Annunzio, M. Ferriero, L. Misuraca, A. Iannuzzi, A. Ragusa, R. Papalia, S. Guaglianone, M. Gallucci, G. Simone (Rome)

BACKGROUND: There are few data about gender-specific outcomes assessment after robot assisted radical cystectomy (RARC) with intracorporeal orthotopic neobladder (i-ON). The aim of this study was to compare perioperative and long-term oncologic and functional outcomes between male and female patients treated with RARC-ION in a single high-volume center.

METHODS: All patients treated after January 2012 were included in the analysis. Baseline demographic, clinical, perioperative, pathologic, oncologic, and functional data were reported. The χ^2 and Student's *t*-test were performed to compare categorical and continuous variables, respectively. Kaplan-Meier method was performed to compare oncologic outcomes, day- and night- time continence recovery probabilities over time.

RESULTS: Out of 250 consecutive patients, 193 were male (77.2%). The two cohorts showed comparable overall and severe perioperative complications rates (P=0.36 and P=0.22, respectively). Eight-year disease-free survival (DFS), cancer-specific survival (CSS) and Overall survival (OS) rates were comparable between male and female cohorts (DFS:64% *vs.* 74.5%, P=0.47; CSS:62.5% *vs.* 81%, P=0.13; OS:59.8% *vs.* 73.1%, P=0.26). Concerning functional outcomes, the two cohorts had comparable mean eGFR at last follow-up (P=0.78) and comparable probabilities of developing newly onset severe CKD stage (P=0.84). One-year trifecta (0.36) and tetrafecta achievement rates were comparable (P=0.36 and P=0.20, respectively). Female patients displayed a significantly higher risk of neobladder stone formation (21.1% *vs.* 7.3%, P=0.005) and need for intermittent self-catheterization (24.6% *vs.* 4.7%; P<0.001). Male patients reported significantly higher day-time continence (one year: 75.6% *vs.* 61%, P=0.01), and night-time continence recovery (one year: 51.8% *vs.* 37.2%, P=0.03) probabilities.

CONCLUSIONS: Long-term oncologic outcomes were largely comparable between male and female patients receiving RARC-iON. With regard to functional outcomes, female patients are exposed to higher risks of neobladder stones formation and need for self-catheterization and displayed significantly lower daytime and night-time continence recovery probabilities.

SC126
Mid-term oncologic outcomes of open *vs.* robot-assisted radical cystectomy with totally intracorporeal urinary diversion: single center prospective randomized controlled trial

R. Mastroianni, G. Tuderti, U. Anceschi, A.M. Bove, A. Brassetti, S. D'Annunzio, M. Ferriero, L. Misuraca, S. Guaglianone, M. Gallucci, G. Simone (Rome)

BACKGROUND: Radical Cystectomy (RC) with urinary diversion (UD) is still considered a complex surgery associated with significant morbidity. Open radical cystectomy (ORC) remains the reference option of treatment, even if adoption of robot-assisted RC (RARC) is rapidly increasing. In this study, we assessed mid-term oncologic outcomes from a randomized controlled trial (RCT) comparing ORC and RARC with totally intracorporeal (i) urinary diversion (UD) (Clinical Trials: NCT03434132).

METHODS: Institutional review board approval was obtained. Patients were eligible for randomization if they had a diagnostic TURBt with cT2-4, cN0, cM0, or recurrent high-grade non-muscle invasive bladder cancer (BC) and no anesthesiologic contraindications to robotic surgery. Between January 2018 and September 2020, 116 patients were enrolled with a covariate adaptive randomization process based on: BMI, ASA Score, baseline hemoglobin, planned UD (padual ileal bladder/ileal connduit), neoadiuvant chemotherapy and cT-stage. Aim of this study was to evaluate oncologic outcomes, such as: overall survival (OS), cancer specific survival (CSS), disease free survival (DFS) and metastasis free survival (MFS). Continuous and categorical variables were compared using Student's *t*-test and χ^2 test, respectively. Kaplan-Meier (KM) method and the log-rank test were applied to assess survival outcomes.

RESULTS: Overall, 116 patients were enrolled (RARC: 58 *vs.* ORC: 58). Both groups were homogeneous for all clinical features (all P>0.15). In the robotic group, UD was performed in all cases with a totally intracorporeal approach, with no need of open conversion. Pathologic data were reported. Overall, 23 (19.9%) patients had a high-risk non-muscle invasive BC. Homogeneous distribution of cT stages was confirmed at final pT-stages (P=0.78) and pN-stages (P=0.91). Soft tissue surgical margins were negative in all cases. Two patients were lost to follow-up, one for each arm. At a median follow-up of 32 mo (IQR 25-43), KM analysis displayed comparable OS (2yr: RARC 79% *vs.* ORC 82%; P=0.35), CSS (2yr: RARC 84% *vs.* ORC 92%; P=0.79), DFS (2yr: RARC 78% *vs.* ORC 80%; P=0.91) and MFS (2yr: RARC 82% *vs.* ORC 78%; P=0.61) probabilities.

CONCLUSIONS: This RCT confirms comparable oncologic outcomes between ORC and RARC with totally iUD.

SC127
Implementation of Tytocare™ telemedicine system in postoperative home care after radical cystectomy: new technological tool for early complications detection and patient recovery management

M. Sica, D. Amparore, S.T. De Cillis, E. Checcucci, A. Piana, F. Piramide, G. Volpi, M. Burgio, P. Verri, A. Quarà, G. Busacca, M. Colombo, M. Mandaletti, A. Giordano, D. Cidda, A. Sterrantino, V. Garzena, M. Manfredi, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: The aim of this study was to assess the role of Tytocare™ telemedicine system (TytoCare, New York, NY, USA) in the postoperative home care of patient underwent radical cystectomy (RC).

METHODS: Tytocare™ system is composed by an all-in-one hand-held device that monitor body temperature, heart rate, cardiac, pulmonary and abdominal sounds and wound/ostomy appearance via an in-built camera; a mobile phone app used by the patients to interact with the Tytocare™ device, send data and pictures to health care providers and perform teleconsultations; an online platform used by the health care provider to evaluate patient's clinical parameters and to perform teleconsultations. Patients underwent RC from 03/2022 to 09/2022 were provided with Tytocare™ Mobile Phone App and Tytocare™ hand- held device during the hospital stay and at the time of discharge. Demographics and perioperative data were recorded during hospitalization. Postoperative complications (classified according to Clavien-Dindo), diuresis, bowel motility and canalization, body temperature, ostomy status and surgical wound status were recorded through the device weekly for the first 30 days after discharge. Moreover, a teleconsultation was performed at the same time points for each patient.

RESULTS: Eleven patients were prospectively involved in this study (10 male, 1 female). Mean (SD) age and BMI were 63.1 (+11.7) and 23.4 (+1.9), respectively. Furthermore, 3/11 (27.2%) of patients underwent orthotopic Y neobladder, whilst 8/11 (73.8%) underwent ileal conduit diversion. Seven on 11 (63.6%) RC were performed robotically. Median (IQR) hospital stay was 10 (8-13) days. 3/11 (27.2%) postoperative complications were recorded between discharge and 1month follow-up, namely 2 Clavien-Dindo grade II (1 ostomy dehiscence and 1 surgical wound infection with fever) and 1 grade III (acute kidney failure with serum creatinine of 8.9 mg/dL).

All the complications were detected within 48 hours from their onset (*via* in-built camera and diuresis contraction report) and promptly managed thanks to the data collected *via* the Tytocare™ system.

CONCLUSIONS: Postoperative home care with Tytocare™ system allowed an early detection and prompt management of postoperative complications and recovery of patient underwent RC.

SC128
Stage dependent survival in patients treated with neoadjuvant chemotherapy and radical cystectomy

E. Tonin, S.F. Shariat, F. Soria, E. Di Trapani, L.S. Mertens, B.W.G. van Rhijn, C.P. Dinney, P.C. Black, P.E. Spiess, D.M. Carrion, B. Pradere, R. Pichler, R. Filippot, A. Mari, M. Moschini, D. D'Andrea (Bologna)

BACKGROUND: The aim of this study was to investigate the differential stage-dependent outcomes of patients undergoing radical cystectomy (RC) with or without neoadjuvant chemotherapy (NAC).

METHODS: We performed a retrospective analysis of 1,422 patients with cT2-4N0 muscle invasive bladder cancer (MIBC) treated with RC, with or without cisplatin-based NAC, originating from our multicenter cooperation program (treated period: 1992 to 2021). Patients were stratified according to their pathologic stage at RC. Cancer-specific survival (CSS) and overall survival (OS) were calculated using mixed-effects Cox analysis.

RESULTS: Analysis was conducted on 761 patients treated with NAC followed by RC and 661 patients treated with RC only. The median follow-up was 19 months (IQR 6-47). Of 337 (24%) patients who died, 259 (18%) died of bladder cancer. On univariable analyses, increased pathologic stage was significantly associated with worse CSS (HR: 1.59; 95% CI: 1.46-1.73; P<0.01) and worse OS (HR: 1.58; 95% CI: 1.47-1.71; P<0.001). On multivariable mixed-effects model patients after RC only had significantly worse CSS with stage pT≥3/N1-3 and worse OS with stage pT≥2/N0-3 compared to those with stage pT≤1N0. Patients after RC and NAC had significantly worse CSS and OS already at stage ypT≥2/N0-3 compared to those with ypT≤1N0. On subgroup analyses, CSS (HR: 4.26; 95% CI: 2.03-8.95; P<0.001) but not OS (HR: 1.1; 95% CI: 0.5-2.4; P=0.81) was worse for patients with stage pT2N0 after NAC *versus* no NAC. However, on multivariable analysis, this difference was not maintained.

CONCLUSIONS: NAC improves pathologic stage at the time of RC. Patients with residual MIBC after NAC have worse survival outcomes compared to those with the same pathologic stage who did not receive NAC, suggesting a need for better adjuvant therapy (*e.g.,* checkpoint inhibition) in these patients.

SMART (SC129-SC132)

Kidney transplantation

SC129
Double J stent simple removal with a single-use flexible cystoscope in renal transplanted patients

SC130
Renal functional outcomes and risk of chronic kidney disease after nephrectomy in living kidney donors: analysis according to age categories

SC131
The impact of preemptive status and dialysis duration on kidney transplantation from donors after brain death: a single-center experience

SC132
Kidney transplantation from expanded-criteria donors after brain death: is it a safe and valuable source of grafts in contemporary practice?

SC129
Double J stent simple removal with a single-use flexible cystoscope in renal transplanted patients

A. Bosio, E. Alessandria, E. Vercelli, L. Micai, C. Gozzo, G. Bertello, C. Alice, A. Greco, G. Pasquale, L. Biancone, P. Gontero (Turin)

BACKGROUND: A double J (DJ) stent is usually inserted during renal transplantation in order to protect the ureter-bladder anastomosis and is mostly removed by flexible cystoscopy about one month after surgery. DJ removal with a single use flexible cystoscope in immunosuppressed patients should have the potential benefit of reducing infections compared to reusable flexible cystoscopes. Isiris® (Coloplast, Humlebæk, Denmark) is a single-use flexible cystoscope with an integrated forceps inside that was developed to optimize DJ removal and save staff hours and resources. It has its own screen and movie system, reusable and included in the packaging, and can be used in any outpatient setting or at the bed of the patients while they are in the ward. The aim of our study was to investigate the easiness, quickness, reproducibility, and safety of DJ removal with Isiris® in renal transplanted patients.

METHODS: Renal transplanted patients who underwent double J removal with Isiris® single-use flexible cystoscope at Molinette University Hospital of Turin from December 2019 to March 2023 were enrolled in a prospective observational study. Need for further procedures or anesthesia were considered together with median procedure time – from instrument introduction to double J extraction –, instrument and patient preparation time, Visual Analogue Scale (VAS) Score and complications. After removal, patients were also asked if they would choose to undergo the same procedure again, in case they would need to remove another double J stent in the future.

RESULTS: One hundred thirty-seven transplanted patients were enrolled in the study and underwent double J removal with Isiris® disposable cystoscope. Median (IQR) patients' age was 58 (48, 66) years. 59.8% of patients were males, 40.2% females. All double J stents were removed easily, without need for further procedure or anesthesia. Median (IQR) time for instrument and patient preparation was 5 (3, 7) minutes. Median (IQR) procedure time was 40 (38, 42) seconds. Median [IQR] VAS Score was 1 (0, 5). Furthermore, 98.5% of patients would choose to undergo the same procedure again in case they would need to remove another double J stent. No serious procedure-related complications occurred, both in patients with a negative preoperative urine culture and in patients with a positive one.

CONCLUSIONS: DJ removal with Isiris® single-use flexible cystoscope in renal transplanted patients proved to be easy, quick, reproducible and safe. Patients' tolerance for the procedure was extremely high and almost all of them would choose to repeat the procedure again in the same way in case they would need to remove another double J stent in the future.

SC130
Renal functional outcomes and risk of chronic kidney disease after nephrectomy in living kidney donors: analysis according to age categories

S. Cavalli, C. Palumbo, F. Poletti, F. Porte', M. Nicolazzini, M. Gambelunghe, D.P. Pesce, G. Marchioro, A. Volpe (Novara)

BACKGROUND: Living kidney donors are carefully screened, but despite overall good health may have a higher risk of developing renal function impairment. We evaluated estimated glomerular filtration rate (eGFR) over time and risk of *de-novo* chronic kidney disease (CKD) after nephrectomy in living kidney donors according to three age groups.

METHODS: Using our institutional database of kidney transplantation, we extracted data from 2006 to 2022. Pre and postoperative eGFR were estimated using the Chronic Kidney Disease Epidemiology Collaboration (CDK-EPI) equation (mL/min/1.73m^2). Only patients with baseline eGFR≥60 mL/min and a minimum follow-up of 6 months were included. Three age group were identified according to tertiles, namely <50 *vs.* 50-59 *vs.* ≥60 years. Differences in terms of baseline characteristics and functional outcomes were compared among the three groups and were analyzed with Student's *t*-test or χ^2 test accordingly.

RESULTS: Overall, 137 patients were included. Median age was 55 (IQR 48-62). Median BMI was 25 (22.6-27.1). 41 patients (29.9%) were male. Mean preoperative eGFR was 92,5 (±1.3 SD). *De-novo* CKDIII or higher occurred in 55 (40.1%) and 64 (46.7%) patients at 6- and 12-month after nephrectomy, respectively. Distribution according to age groups were as follows: 39 patients (28.5%) aged <50 years, 53 patients (38.7%) aged 50-59 and 45 patients (32.8%) aged ≥60. Predonation eGFR was significantly higher in younger patients (median eGFR 101.7 [IQR 84.2-109.4]), median eGFR 96.6 [85.1-103.3] in patients 50-59 years old, and median eGFR 79.2 [71.5-91.4] in patients ≥60 years, (P<0.001). Similarly, eGFR at 6- and 12 months postdonation were significantly higher in patients <50 years (median eGFR 63.2 [55.7-75.1] at 6 months and median eGFR 62 [55.8-74.5] at 12 months), compared to patients ≥60 years (median eGFR 50.8 [45.3-60.4] at 6 months and median eGFR 51.5 [43.9-59.6] at 12 months). Patients aged ≥60 years more frequently developed *de-novo* CKDIII or higher, compared to those aged 50-59 and <50 years, at both 6 months (60% *vs.* 32.1% *vs.* 28.2%, respectively P=0.002) and at 12 months postdonation (75.6% *vs.* 35.8% *vs.* 28.2%, respectively P<0.001).

CONCLUSIONS: A non-negligible proportion of living kidney donors develops *de-novo* CKDIII in the first year after nephrectomy. Donors with higher age have lower eGFR after donation and are at higher risk of developing CKDIII or higher. These patients should receive a specific predonation counseling as well as a more intense postdonation follow-up.

SC131
The impact of preemptive status and dialysis duration on kidney transplantation from donors after brain death: a single-center experience

D. Stracci, A. Pecoraro, C.L. Catucci, M.L. Gallo, A. Mariotti, E. Dibilio, R. Nicoletti, V. Li Marzi, P. Spatafora, F. Sessa, D. Facchiano, M. Gacci, S. Serni, R. Campi (Florence)

BACKGROUND: Kidney transplantation (KT) is gold-standard treatment for patients with end-stage renal disease, providing better survival outcomes and quality of life, if compared to dialysis. In this scenario, donors after brain death represent the main source of grafts, but their outcomes are influenced by several graft-, donor-, and recipient-rela-

ted factors, including preoperative dialysis and its duration. Therefore, the aim of this study was to evaluate the impact of preemptive status and dialysis duration before KT from donors after brain death (DBD) on perioperative outcomes and mid-term functional outcomes.

METHODS: We queried our prospectively maintained database to select patients' data undergoing RAKT or OKT from DBDs at a single Academic Center between January 2017 and September 2022. RAKT was performed according to the principles of the Vattikuti-Medanta technique, following a multi-step decision-making process, involving both technical and logistical factors, to assess the feasibility. Postoperative complications were classified according to the Clavien-Dindo classification. Recipients were stratified in pre-emptives, patients with history of dialysis ≤6 months before KT, patients with history of dialysis >6 months and ≤12 months before KT, patients with history of dialysis >12 months before KT.

RESULTS: Overall, 216 patients were included (189 [87.5%)] OKTs and 27 [12.5%] RAKTs). The study cohorts were comparable except for a higher rate of extended criteria donor (47.1% *vs.* 22.2%; P=0.01), a lower number of pre-emptive recipients (4.2% *vs.* 33.3%; P<0.01) and a higher median recipients' age (51 *vs.* 45 years; P=0.03) in the OKT group. Median operative time was higher in the RAKT group (220 *vs.* 191 min; P<0.01), median rewarming time was significantly lower for RAKT (38 *vs.* 58 min; P<0.01). No significant differences between RAKT and OKT regarding the intraoperative, overall, and major postoperative complications and DGF were recorded. At hospital discharge, RAKT cohort had higher median eGFR (43.0 *vs.* 33.9 mL/min; P=0.03). At a median follow-up of 23 months (IQR 9-39), higher median eGFR was recorded in the RAKT cohort (66.0 *vs.* 51.0 mL/min), no difference in dialysis-free and overall survival. At univariable analysis, recipient-related and donor-related factors, but not surgical approach, were independent predictors of delayed graft function and high-grade postoperative complications. At multivariable analysis, recipient-related factors were found to be predictors of dialysis at last follow-up.

CONCLUSIONS: Although our study is limited by its non-randomized nature and the relatively small sample size, it provides interesting evidence regarding the comparable perioperative and mid-term functional outcomes of RAKT from deceased donors with the gold standard OKT in selected recipients. Larger multicenter studies with longer follow-up are needed to validate our structured, multi-step decision-making process and to define the best indications and limits of robotics in this clinical scenario.

SC132
Kidney transplantation from expanded-criteria donors after brain death: is it a safe and valuable source of grafts in contemporary practice?

A. Pecoraro, D. Stracci, C.L. Catucci, A. Mariotti, M.L. Gallo, R. Nicoletti, A. Alberti, V. Li Marzi, F. Sessa, P. Spatafora, A. Sebastianelli, S. Giancane, M. Gacci, S. Sergio, R. Campi (Florence)

BACKGROUND: Due to the current profound mismatch between the demand and the offer of kidneys for transplantion, the use of grafts from expanded-criteria donors after brain death (ECD) has been warranted to increase the number of KTs. Yet, KT from such "marginal" donors carries higher perioperative risks and estimated worse functional results. In this study we sought to compare perioperative and mid-term outcomes of KT from ECDs *vs.* standard-criteria donors (SCD).

METHODS: After ethical committee approval, we queried our prospectively maintained database to select patients undergoing robot- assisted KT (RAKT) or open KT from ECDs and SCDs at a single Academic Center between January 2017 and September 2022. ECDs were defined as donors aged >60 or 50-59 years with two of the following features: history of hypertension, terminal serum creatinine ≥1.5 mg/dL, or death resulting from a cerebrovascular accident. Per regional protocol, all grafts from ECDs underwent a biopsy to check for suitability for KT. Postoperative complications were classified according to the Clavien-Dindo (CD) classification.

RESULTS: Overall, 216 KTs were included (56% from SCDs and 44% from ECDs). The ECD cohort significantly differed from the SCD cohort regarding most donor-related characteristics, median cold ischemia time (16 *vs.* 14 hours, P<0.01), higher median recipient age (58 *vs.* 45 years; P<0.01) and lower use of RAKT (6.3% *vs.* 17.4%, P<0.02). While no differences were recorded between the two groups regarding the re-warming time, a higher rate of intraoperative adverse events was recorded for KT from ECDs (8.4% *vs.* 2.5%; P<0.05). During the early postoperative period, recipients from ECDs experienced a higher rate of delayed graft function (21.1% *vs.* 9.3%; P=0.01), CD grade >3 complications (18.9% *vs.* 9.1%; P=0.03) and a longer median hospital stay (15 *vs.* 13 days, P<0.03). At hospital discharge, the median eGFR was significantly lower for recipients from ECDs (26.2 *vs.* 41.8 mL/min/1.73m^2; P<0.01). The same finding was recorded at a median follow-up of 23 (IQR 9-39) months (median eGFR 28.7 *vs.* 59.0 mL/min/1.73m^2; P<0.01), despite a comparable proportion of patients who were dialysis-free (93.9% *vs.* 97.5%; P=0.7). At univariable analysis, donor status (ECD *vs.* SCD) and recipient-related factors significantly predicted the risk of DGF and major surgical complications. At multivariable analysis, only recipient BMI, and duration of dialysis before KT were significantly associated with the risk of dialysis at last follow-up.

CONCLUSIONS: ECDs represent a non-negligible source of grafts in our contemporary KT practice. KT from ECDs carry higher intra- and perioperative risks as compared to KT from SCDs and is associated with worse mid-term functional outcomes as well as higher costs of care. Further efforts are needed to improve the outcomes of KT from ECDs. The use of hypothermic/normothermic perfusion machines to preserve and/or regenerate kidneys from ECDs might be of value in this setting.

SMART (SC133-SC138)

Penile cancer

SC133
Oncological outcomes of thulium-yttrium-aluminium-garnet (Tm:YAG) laser ablation for penile cancer

SC134
ICG-guided robot-assisted video-endoscopic radical inguinal lymphadenectomy for penile cancer

SC135
Organ preservation and oncological efficacy of peniscopically controlled CO_2 laser excision of penile squamous cell carcinoma: early and late results in a high-volume center

SC136
Platelet to lymphocyte ratio (PLR) as independent predictor of lymph node status in penile cancer

SC137
Penile lesions: a glimpse into the rarity of the metastatic tumor of the penis

SC138
Inguinal lymphadenectomy for penile cancer: interim results from a prospective randomized clinical trial comparing open *vs.* video-endosopic approach

SC133
Oncological outcomes of thulium-yttrium-aluminium–garnet (Tm:YAG) laser ablation for penile cancer

F.A. Mistretta, A. Zago, E. Santangelo, S. Caramella, M.L. Piccinelli, S. Luzzago, E. Di Trapani, A. Cioffi, D.V. Matei, R. Bianchi, A. Brescia, M. Ferro, G. Renne, M. Tozzi, G. Musi, O. de Cobelli (Milan)

BACKGROUND: The aim of this study was to report oncological outcomes after thulium-yttrium-aluminium-garnet (Tm:YAG) laser ablation for penile cancer patients.

METHODS: We retrospectively analyzed 71 patients with ≤cT1 penile cancer (2013-2022). All patients underwent Tm:YAG ablation with a RevoLix 200 W continuous-wave laser (DIMED S.r.l., Carmagnola, Turin, Italy). First, Kaplan-Meier plots and multivariable Cox regression models tested local tumor recurrence rates. Second, Kaplan-Meier plots tested progression-free survival (≥T3 and/or N1-3 and/or M1).

RESULTS: Median (IQR) follow-up time was 38 (22-58) months. Overall, 33 (50.5%) patients experienced local tumor recurrence. Specifically, 19 (29%) *vs.* 9 (14%) *vs.* 5 (7.5%) patients had 1 *vs.* 2 *vs.* 3 recurrences over time. In multivariable Cox regression models, a trend for higher recurrence rates was observed for G3 tumors (HR:6.1; P=0.05), relative to G1. During follow-up, 12 (18.5%) *vs.* 4 (6.0%) *vs.* 2 (3.0%) men were re-treated with 1 *vs.* 2 *vs.* 3 Tm:YAG laser ablations. Moreover, 11 (17.0%) and 3 (4.5%) patients underwent glansectomy and partial/total penile amputation. Last, 5 (7.5%) patients experienced disease progression. Specifically, TNM stage at the time of disease progression was: 1) pT3N0; 2) pT2N2; 3) pTxN3; 4) pT1N1 and 5) pT3N3, respectively.

CONCLUSIONS: Tm:YAG laser ablation provides similar oncological results as those observed by other PSS procedures. In consequence, Tm:YAG laser ablation should be considered a valid alternative for treating selected penile cancer patients.

SC134
ICG-guided robot-assisted video-endoscopic radical inguinal lymphadenectomy for penile cancer

A. Brassetti, A.M. Bove, A. Umberto, M. Ferriero, C. Leonardo, R. Mastroianni, L. Misuraca, S. Flammia, F. Proietti, G. Tuderti, S. D'Annunzio, G. Simone (Rome)

BACKGROUND: Inguinal lymphadenectomy (ILND) is the standard of care for patients with invasive squamous cell carcinoma (SCC) of the penis, dictating prognosis, adjuvant therapies, and surveillance strategies. Surprisingly, it remains underutilized, mainly due to the morbidity associated with the open approach. The robot-assisted approach has been recently introduced to help mitigate wound-related complications but its capability to provide an adequate lymph nodes (LNs) yield has been disputed.

METHODS: We present the case of a 73-year-old man who presented with a cT3 tumor of the gland and palpable LNs treated with indocyanine- green (ICG)-guided bilateral robot-assisted video-endoscopic inguinal lymphadenectomy (RAVEIL). The patient was placed in a low lithotomy position, 20 degrees Trendelemburg, with the abduction of the lower limbs. The surgical fields, corresponding to the Scarpa Triangles, were marked and the approximate location of the femoral vessels highlighted. A small incision was created at the caudal edge of each triangle and a subcutaneous working space was created with the fingertip, below the Camper's Fascia. One single 12 mm laparoscopic trocar and 3 robotic ports were placed. The already available working space above the Fascia Lata (FL) was enlarged. In order to perform a radical lymphadenectomy, the FL was incised, and the underlying space developed. All the tissue covering the pectineus muscle was progressively removed. The sapheno-femoral junction was located and dissected to identify that the Great Saphenous Vein (GSV) and femoral vessels. The deep inguinal LNs were dissected and excised from the femoral vein. The superficial inguinal LNs, located around the GSV, were excised until the bare Camper's Fascia was left. The ICG was injected in the penile tumor and the FireFly camera mode was used enhance the identification of the tumor-draining nodes and improve LNs yield.

RESULTS: Operation time was 305 minutes, considering partial penectomy and radical RAVEIL. The patient was discharged on postoperative day (POD) 2 and the inguinal drains on POD 22. No intra- or postoperative complications were observed. At final pathology, a pT3N0 (0/28) squamous cell carcinoma of the penis was diagnosed. At 27-month follow-up, the patient is recurrence-free.

CONCLUSIONS: RAVEIL is safe and effective also when a radical ILND is required, and surgical morbidity is negligible. An ICG-guided approach could enhance the identification of the tumor-draining nodes and improve LNs yield. Its impact on oncologic outcomes should be assessed in large series.

SC135
Organ preservation and oncological efficacy of peniscopically controlled CO_2 laser excision of penile squamous cell carcinoma: early and late results in a high-volume center

V. Lorusso, S. Nazzani, A. Macchi, S. Stagni, D. Biasoni, T. Torelli, R. Darisi, C. Colbacchini, M. Zimatore, M. Claps, L. Cattaneo, T. Cascella, R. Lanocita, E. Montanari, O. de Cobelli, M. Catanzaro, N. Nicolai (Milan)

BACKGROUND: The aim of this study was to evaluate safety and early and long-term efficacy of CO_2 laser conservative treatments for non-ulcerative squamous cell carcinoma (SCC) of the penis.

METHODS: Within our institutional database (2002–2022, included), we identified 122 consecutive cT1-2 cN0 cM0 patients with penile SCC who underwent CO_2 laser conservative treatments. Histologically confirmed local relapse was recorded. Local recurrences were classified as early relapses when occurring <2 years and as late new tumor recurrences when occurring >2 years after first laser treatment. Predictors of disease relapse were analyzed with univariable and multivariable Cox regression models (MCRM).

RESULTS: Median follow-up was 36 months (interquartile range [IQR] 21-73 months). Median age was 62 years (IQR: 51-69 years). Median lesion size was 10 mm (IQR 5-15 mm). Usual SCC (86.9%) was the most frequent histology followed by basaloid SCC (5.7%) and other SCC (7.4%). 62 patients had penile intraepithelial neoplasia (PeIN) (51.6%), 30 had pT1m (24.6%), 28 had pT1 (23%) and one had pT2 (0.8%), two patients were classified as pTx. In case of infiltrative lesions, tumor grade was G1 in 37 (60.7%), G2 in 20 (32.8%), G3 in 4 (6.5%). No immediate complications were recorded. 4 patients

experienced postoperative phimosis and one had meatal stenosis. After first excision, 25 patients (20.5 %) underwent radicalization, due to positive margins or aggressive disease. During the follow-up 49 patients had disease recurrence. Early relapses and late recurrences occurred in 28 (22%), and in 21 patients (18%), respectively. Recurrences were treated with new CO_2 laser excision in 39 (80%), partial amputation in 8 (16%), glansectomy and circumcision (2%) in one patient each (2%). Proportion of penis preservation was 93.4% and 92.6% at 2 and 5 years. Independent predictors of overall and early relapse were not identified at MCRMs. Conversely, pT1 stage (hazard ratio [HR]: 13; confidence interval [CI]: 1.4-73; P value = 0.02) and flat lesions (HR: 7.9; CI: 1.06-59; P=0.04) achieved independent predictor status for late recurrences. Finally, two patients developed inguinal nodal disease during follow-up. No cancer-related deaths were recorded.

CONCLUSIONS: As far as we know, this is the largest cohort of patients with penile cT1-T2 SCC who underwent conservative CO_2 laser treatment. Although recurrences were as frequent as 40% in a time span of three years, most patients preserved their organ. Some factors can be of use in preventing or anticipating late recurrences.

SC136
Platelet to lymphocyte ratio (PLR) as independent predictor of lymph node status in penile cancer

R. Muscariello, L. Napolitano, F. Passaro, A. Izzo, G. Quarto, L. Castaldo, D. Franzese, G. Grimaldi, G. Spena, B. Barone, G. Pezone, P. Alvino, A. Tufano, S. Desicato, P. Del Prete, S. Perdonà (Naples)

BACKGROUND: The aim of this study was to investigate the association between preoperative platelet to lymphocyte ratio (PLR) and preoperative lymph node status in penile cancer.

METHODS: Clinical data of 60 consecutive male patients with penile cancer who underwent surgery at our institution between 2016 and 2022, were collected and retrospectively analyzed. PLR was obtained from preoperative blood analyses performed within 1 month from hospital admission. The association of NLR with lymph node status obtained from histological reports was further analyzed. Statistical analysis was performed using Mann–Whitney U test for continuous variables assuming P<0.05 as statistically significant.

RESULTS: Sixty patients were included in the study with a mean age of 66.88±14.36 years. No statistically and clinically significant differences were reported at baseline. Mean PLR was significantly higher in patients with positive lymph node status compared to negative lymph node status (193.76±129.55 *vs*. 122.50±54.25; P=0.028).

CONCLUSIONS: Elevated preoperative PLR is an independent predictor of positive lymph node status in patients with penile cancer, suggesting a promising role of neutrophil to lymphocyte ratio as prognostic biomarker for penile tumors.

SC137
Penile lesions: a glimpse into the rarity of the metastatic tumor of the penis

A.F. De Rose, F. Ambrosini, F. Vecco, F. Gallo, N. Piol, G. Mantica, C. Terrone (Genoa)

BACKGROUND: Penile metastases are rare and often occur in the setting of systemic disease. The most common primary malignancies are urogenital cancers (69%) followed by gastrointestinal cancers (19%). Clinical presentation ranges from pain, penile nodules, lower urinary tract symptoms, hematuria, or priapism. We present the clinicopathologic and oncologic outcomes of patients treated for penile cancer with an emphasis on metastatic tumors in the penis.

METHODS: We retrospectively analyzed patients surgically treated for penile cancer at two institutes between January 2015 and January 2023. Data were collected on patients' characteristics, histologic factors, and oncologic outcomes. Descriptive statistical analysis of the cohort was performed.

RESULTS: Overall, 37 patients were identified, 8 of whom had metachronous penile metastasis. The median (interquartile range) age of the entire cohort was 71.5 (79.5-57) years. In all cases, patients presented with pain and a penile nodule/mass. Staging nuclear magnetic resonance imaging and/or contrast-enhanced computed tomography scan of the pelvis were always performed. The interval between primary and penile metastasis ranged from 3 to 57 months. Metastatic urothelial carcinoma from the bladder (BC) or urethra (UC) included 3 cases and one case respectively. In all cases, invasion of the corpora cavernosa (CC) was found; in one patient the tumor was even located in the glans. Total penectomy (TP) and perineal urethrostomy (PU) combined with systemic chemotherapy were the treatments of choice. The 3 patients with BC died after 6, 8, and 14 months, respectively. The patient with primary UC is still alive after 12 months. Metastatic adenocarcinoma of the colon corresponds to one case. The metastases involved the corpus spongiosus and CC. The patient received TP and PU combined with systemic chemotherapy and radiation therapy. He is alive and he has a follow- up of 14 months. A 78-year-old patient presented with metachronous penile metastasis from a clear cell renal carcinoma (pT1b, G2, pNx, R0) and he was managed with TP and PU. He was lost to follow-up. One case had a history of a surgically removed melanoma of the lower limb and he presented 12 months later with a melanocytic penile lesion. He underwent penile excision, and pathology revealed metastatic malignant melanoma with spindle-cell features. He is alive after an 8-month follow-up. A 21-year-old patient with a history of medullary plasmacytoma diagnosed 13 months earlier presented with a 0.5 cm penile mass treated with surgical excision. The patient died 8 months later after a disruptive recurrence and an attempt to salvage debulking pelvic surgery.

CONCLUSIONS: Penile metastases are rare, and they are usually a metachronous manifestation of disseminated disease. The management is challenging, and it should consider cancer-specific survival averages over one year, and patients' quality of life.

SC138
Inguinal lymphadenectomy for penile cancer: interim results from a prospective randomized clinical trial comparing open *vs.* video-endoscopic approach

F. Peretti, M. Falcone, M. Preto, L. Cirigliano, I. Ferro, N. Plamadeala, M. Scavone, C. Ceruti, P. Gontero (Turin)

BACKGROUND: The aim of this study was to compare surgical and oncological outcomes between open inguinal

lymphadenectomy (OIL) and video-endoscopic inguinal lymphadenectomy (VEIL) in patients affected by penile cancer (PC).

METHODS: From October 2019 to March 2022 a single center prospective randomized clinical trial including patients underwent either staging or radical inguinal lymphadenectomy for PC was conducted. Patients were randomized to receive OIL on one limb and VEIL on contralateral side. Inclusion criteria where having received a diagnosis of PCa with indication to undergo either staging or radical ILAD. The operative time, the rate of intra- and postoperative complications (classified according to the Clavien-Dindo classification), the number of lymph nodes removed, the number of positive lymph nodes, the disease-free survival (DFS) and cancer-specific survival (CSS) during the follow-up period were analyzed. The trial was approved by local ethical committee and registered on clinicaltrial.gov (00025/2020).

RESULTS: Thirty-four inguinal lymphadenectomies for PC were performed (17 patients). Among them 14 patients (28 inguinal lymphadenectomy) full-filled the inclusion criteria and where therefore included in the trial. The median follow-up was 14 months (IQR 6-17). No statistically significant differences in terms of operative times, number of lymph nodes removed, 1-year DFS and 1-year CSS were detected. Drainage maintenance days were significantly shorter (P=0.012) in the VEIL group 15 (IQR 13-17) than in the OIL group 27 (IQR 20-41). No intraoperative complications were recorded. Postoperative complications occurred in 3 cases (21.4%) in VEIL group and in 8 cases (57.1%) in OIL group (P= 0.049).

CONCLUSIONS: Despite the fact that both techniques seem to ensure comparable oncological results, VEIL may guarantee an advantage over OIL in term of surgical outcomes. Further high-powered studies are warranted to confirm these preliminary results.

SMART (SC139-SC150)

Kidney cancer 3

SC139
Assessment of VENUSS and GRANT models for individual prediction of cancer-specific survival in surgically treated non-metastatic papillary renal cell carcinoma

SC140
Rate and predictors of early postoperative complications of kidney cancer surgery for non-metastatic (CT1-T4N0-1M0) renal masses at a high-volume center

SC141
Venous tumor thrombus in renal cell carcinoma: locally advanced or metastatic disease?

SC142
Concordance of renal sinus or calyces invasion between preoperative imaging and final pathology after surgery for kidney cancer

SC143
Unveil the interplay between baseline renal function, warm ischemia time and tumor complexity when assessing renal functional outcomes of on-*vs.* off-clamp robot-assisted partial nephrectomy

SC144
Functional outcomes after surgery in patients with renal cancer and tumor thrombus

SC145
3D-derived volumetric and morphologic parameters to predict complications after robotic partial nephrectomy in patients with renal cancer

SC146
Defining the most useful intermediate endpoint for overall survival in intermediate and high-risk clear cell carcinoma

SC147
The current role of renal tumor biopsy in the management of small renal masses: long-term results from a prospective, single-institutional database

SC148
Surgical counseling in the 3RD millennium: the hologram project

SC149
Outcomes in robotic assisted partial nephrectomy and microwave ablation of renal masses according to the RCC Guidelines panel novel TNM proposal

SC150
Robot-assisted radical nephrectomy and inferior vena cava level I-III thrombectomy: perioperative and mid-term oncologic outcomes

SC139
Assessment of VENUSS and GRANT models for individual prediction of cancer-specific survival in surgically treated non-metastatic papillary renal cell carcinoma

M.L. Piccinelli, S. Tappero, C. Cano Garcia, F. Barletta, R. Incesu, S. Morra, L. Scheipner, Z. Tian, S. Luzzago, F.A. Mistretta, M. Ferro, F. Saad, S.F. Shariat, S. Ahyai, N. Longo, D. Tilki, A. Briganti, F.K.H. Chun, C. Terrone, O. de Cobelli, G. Musi, P.I. Karakiewicz (Milan)

BACKGROUND: The aim of this study was to test the ability of VENUSS and GRANT models to predict 5-year cancer-specific survival in a North American population.

METHODS: Within the Surveillance, Epidemiology, and End Results database (2004-2019), we identified 4,184 unilateral surgically treated non-metastatic papillary renal cell carcinoma patients. The original VENUSS and GRANT risk categories were applied to predict 5-year cancer-specific survival. Accuracy, calibration, and decision curve analyses tested the cohort with a cross-validation method.

RESULTS: VENUSS and GRANT categories represented independent predictors of cancer-specific mortality. In cross-validation, the accuracy of the VENUSS and GRANT risk categories was 0.73 and 0.65, respectively. Both models showed good calibration and performed better than random predictions in decision curve analysis. Limitations of this study include the retrospective nature of the study and the absence of a central pathological review.

CONCLUSIONS: VENUSS risk categories fulfilled prognostic model criteria for predicting cancer-specific survival five years after surgery in North American non-metastatic papillary renal cell carcinoma patients as recommended by guidelines. Conversely, GRANT risk categories did not. In consequence, VENUSS risk categories represent an important tool for counselling, planning follow-up and selection for appropriate adjuvant trial designs in papillary renal cell carcinoma patients.

SC140
Rate and predictors of early postoperative complications of kidney cancer surgery for non-metastatic (CT1-T4N0-1M0) renal masses at a high-volume center

D. Stracci, L. Mazzola, N. Firenzuoli, R. Mariottini, A. Mariotti, M.L. Gallo, R. Nicoletti, E. Dibilio, R. Ferretti, F. Solazzi, S. Costagli, F. Sessa, P. Spatafora, S. Giancane, M. Gacci, S. Serni, R. Campi (Florence)

BACKGROUND: During the last years, several efforts have been carried out to minimize the postoperative rate of complications after surgery for non-metastatic renal mass and (*i.e.*, centralization of care, minimally invasive surgery, etc.), considering their potential impact on patients' health and costs. In addition, some nomograms estimating the probability of postoperative complications have been proposed, but none has been universally adopted for the real-life setting. Therefore, the aim of our study was to evaluate the rate and predictors of and postoperative complications.

METHODS: After ethical committee approval, we queried our prospectively maintained databases to identify patients with a single non-metastatic renal mass (cT1-4N0-1M0), surgically treated between January 2017 and September 2022 at a single high-volume Academic Institution. Tumor complexities were evaluated using the PADUA Score. Surgeons' experiences were evaluated using the number of partial (PN) or radical nephrectomy (RN) performed during the study period. The main study endpoint was to evaluate the proportion of patients who experienced any grade postoperative complications (AGC), focusing on potential predictors of postoperative complications ≥grade 2 according to the Clavien-Dindo classification (CDC).

RESULTS: Overall, 761 patients were included (608 [79.9%] PN; 153 [20.1%] RN). Median age at diagnosis was 66 years (IQR 56- 74), median BMI 25.7 (IQR 23.7 - 28.7), median Charlson Comorbidity Index 3 and median tumor diameter 3.7 cm (IQR 2.6-5.4). AGC were recorded in 157 (20.6%). Of these, while 112 (14.7%) were classified as grade 2 according to CDC, 12 (1.6%) were registered as grade 3 or more. One postoperative death was recorded, due to hemorrhagic shock after RN. No significant differences in terms of patient- and surgery-related factors were observed. However, patients who experienced AGC had a more advanced cT stage and a higher rate of right-sided tumor (59.2% *vs.* 47.7%, P<0.01). The median hospital stay was significantly higher for those patients who experienced AGC after surgery (3 *vs.* 6 days, P<0.01). At univariable analysis, significant predictors of postoperative adverse events ≥2 according to CDC in our cohort were PADUA Score, tumor diameter/cT stage at preoperative imaging, treatment with anticoagulant drugs and operative time. At the subsequent multivariable analysis, including operative time, only operative time was maintained as a predictor of postoperative complications ≥2 grade according to CDC.

CONCLUSIONS: Our study highlights the non-negligible postoperative morbidity associated with performing a PN or RN in patients with non-metastatic renal masses. Complication rates are influenced by several patient-, tumor- and surgery-related factors. Awareness of these predictors is essential to optimize oncological, functional results, and complication rates.

SC141
Venous tumor thrombus in renal cell carcinoma: locally advanced or metastatic disease?

G. Musso, G. Basile, A. Nini, G. Rosiello, G. Fallara, C. Re, F. Cei, F. Belladelli, D. Cignoli, D. Canibus, S.P.S. Pinto, I. Rowe, R. Lucianò, N. Tenace, A. Necchi, L. Marandino, D. Raggi, A. Salonia, A. Briganti, R. Matloob, R. Bertini, F. Montorsi, A. Larcher, U. Capitanio (Milan)

BACKGROUND: Renal cell carcinoma (RCC) with venous tumor thrombus (TT) is associated with worse outcomes. It is debated whether the presence of TT should be classified as a locally advanced or metastatic disease. The aim of the study was to compare the survival outcomes of patients with TT to those with lymphatic or metastatic involvement.

METHODS: Overall, 79 TT+ cN0 cM0 (Group A) patients, 235 TT- cN1 cM0 (Group B) and 114 TT- cN0 single site cM1 (Group C) treated with radical (RN) or partial nephrectomy (PN) (with thrombectomy, in case of TT) were identified from a prospectively collected single-center database of 3,796 patients. Kaplan-Meier curves were used to compare the 5-year progression- free survival (PFS) and cancer-specific survival (CSS) among the three groups. Finally, univariable, and mul-

tivariable Cox regression analyses (MVA) investigated predictors of progression and cancer-specific mortality (CSM) among age, gender, Charlson Comorbidity Index, tumor size, tumor grade and the three different groups of patients.

RESULTS: After a median follow-up of 43 months [interquartile range (IQR): 20-78], the 5-year PFS rates were 37% (95% CI: 27-50), 71% (95% CI: 65-78) and 29% (95% CI: 21-41) (P<0.0001) for Group A *vs.* B *vs.* C, respectively. The 5-year CSS rates were 76% (95% CI: 66.1-87), 86% (95% CI: 82-92) and 42% (95% CI: 33-54) (P<0.0001), for Group A *vs.* B *vs.* C, respectively. At MVA, group B had a low risk of PFS [hazard ratio (HR) 0.27, 95% CI: 0.19-0.38, P<0.0001] and CSM (HR 0.17, 95% CI: 0.11-0.26, P<0.0001) as compared to group C. Similarly, group A had a lower risk of progression (HR: 0.65, 95CI: 0.45-0.94, P=0.02) and CSM (HR: 0.34, 95% CI: 0.20-0.57, P<0.0001) as compared to group C.

CONCLUSIONS: TT+ cN0 cM0 RCC patients had higher risk of progression and mortality than TT- cN1 cM0 but lower risk relative to TT- cN0 cM1 patients. Thus, TT+ cN0 cM0 RCC should be regarded as a locally advanced disease. In this setting, surgical treatment is a therapeutic option with curative intent.

SC142
Concordance of renal sinus or calyces invasion between preoperative imaging and final pathology after surgery for kidney cancer

F. Cei, N. Tenace, G. Basile, G. Musso, C. Re, G. Fallara, G. Rosiello, F. Belladelli, D. Cignoli, D. Canibus, I. Rowe, F. De Cobelli, G. Brembilla, R. Pennella, A. Della Corte, G. Guazzarotti, R. Bertini, A. Briganti, M. Colecchia, F. Montorsi, A. Salonia, A. Larcher, R. Lucianò, U. Capitanio (Milan)

BACKGROUND: Renal sinus involvement and calyces invasion may jeopardize surgical and oncological outcomes in case of underperformance of standard imaging. In the current study, we analyzed the concordance between preoperative imaging and final pathology in a large series of patients undergoing nephrectomy for Renal Cell Carcinoma (RCC).

METHODS: We included 346 consecutive patients who were treated with RN for non-metastatic RCC. Two expert urologists prospectively reviewed all CT scans. One dedicated genito-urinary pathologist prospectively reviewed every single kidney specimen blinded to axial imaging characteristics. Concordance rates with final pathological reports were calculated with a specific focus on renal sinus involvement and calyces invasion. Finally, we relied on multivariable logistic regression analyses (LRM) to validate the results.

RESULTS: Median clinical tumor size was 70 mm (Interquartile range [IQR]: 55-89 mm). The rate of renal sinus involvement was 76% and the concordance rate between radiological score and pathological report was 44%. Rates of over-and underestimation were 65% and 20%, respectively. At LRM, after adjusting for every PADUA item, no correlation between renal sinus involvement at imaging and renal sinus infiltration at pathology was found (OR 0.76, 95 % CI 0.09-4.37; P=0.8). Of 256 patients in whom calyces invasion was detected, concordance between radiological imaging and final pathology was recorded in 46%patients. Rates of over- and underestimation were 94% and 3%.

CONCLUSIONS: At final pathology after RN, sinus involvement and calyces invasion are not confirmed in more than one case out of two. Specifically, such discordance has two major clinical implications: radiological overestimation may exclude conservative surgical approaches leading to a non-negligible risk of overtreatment. Secondly, radiological underestimation of renal sinus infiltration may lead to more conservative treatment approaches in patients, potentially jeopardizing oncological outcomes in terms of positive surgical margins, local recurrence, and clinical progression.

SC143
Unveil the interplay between baseline renal function, warm ischemia time and tumor complexity when assessing renal functional outcomes of on- *vs.* off-clamp robot-assisted partial nephrectomy

R.S. Flammia, U. Anceschi, A. Brassetti, M. Ferriero, R. Mastroianni, L. Misuraca, G. Tuderti, M. Gallucci, A. Tufano, E. Bologna, C. Leonardo, F. Porpiglia, D. Amparore, A. Minervini, A. Mari, A.A. Grasso, R. Autorino, D. Eun, A. Larcher, U. Capitanio, G. Simone (Rome)

BACKGROUND: Off-clamp robot-assisted partial nephrectomy (RAPN) has been introduced as an alternative to on-clamp RAPN aiming at maximally reduce warm ischemia time (WIT). However, not all studies agreed with the theoretical benefit of off- *vs.* on-RAPN in term of postoperative and functional outcomes. It might be postulated that prolonged warm ischemia time (WIT), needed when approaching complex renal masses, as well as baseline eGFR may influence the results of such a comparison. In this study, we aimed at showing the interplay between WIT, tumor complexity and baseline eGFR.

METHODS: Whitin a multi-institutional database we identified patients treated with RAPN for kidney neoplasm (cT1-2, cN0, cM0). Exclusion criteria were multiple renal masses, solitary kidney, selective clamping. LOESS curve depicted the association between WIT and RENAL Score. Multivariable Cox regression model addressing any upstaging to CKD≥3a (CKD- upstaging) tested the effect of WIT, baseline eGFR and RENAL Score while adjusting for important confounders (age, sex, BMI, ASA, hypertension, and diabetes). The "ggeffect" R package (R Foundation for Statistical Computing, Vienna, Austria) allowed to estimate the CKD-upstaging free survival probability according to WIT, RENAL Score, and baseline eGFR.

RESULTS: Overall, 1015 patients were identified between on- *vs.* off-RAPN (37 *vs.* 63%, respectively). LOESS curve showed a statistically significant increase in WIT, when approaching more complex renal masses (P<0.001). Interestingly, for RENAL Score ≥10, off-RAPN required a median WIT ≥25 minutes. In multivariable Cox regression model, WIT (HR: 1.02; 95% CI: 1.01-1.03; P<0.001), baseline eGFR (HR: 0.97; 95% CI: 0.96-0.98; P<0.001) and RENAL Score (HR: 1.14; 95% CI: 1.07-1.21; P<0.001) were all independent predictors of CKD-upstaging. Estimated probability was graphically displayed.

CONCLUSIONS: We observed that when approaching more complex RENAL masses on-clamp RAPN may results in prolonged WIT which in turn would drastically increase the risk of renal function decline especially in those patients harboring lower baseline eGFR. In this complex situation, off-RAPN would undoubtedly reduce risk of renal function deterioration by limiting to zero WIT which represents the main surgical modifiable factor.

SC144
Functional outcomes after surgery in patients with renal cancer and tumor thrombus

G. Rosiello, F. Cei, N. Tenace, G. Basile, G. Musso, C. Re, G. Fallara, R. Matloob, F. Belladelli, D. Cignoli, D. Canibus, I. Rowe, F. De Cobelli, G. Brembilla, R. Lucianò, R. Bertini, A. Briganti, R. Colombo, F. Montorsi, A. Salonia, A. Larcher, U. Capitanio (Milan)

BACKGROUND: Up to 15% of patients with locally advanced renal cell carcinoma (RCC) harbor tumor thrombus (TT). In this study, we aimed at evaluating the impact of TT on short and long-term renal function after surgery in a contemporary cohort of RCC patients.

METHODS: Within a prospective maintained database, 1,307 patients undergoing radical nephrectomy for non-metastatic RCC between 2000 and 2021 at a single tertiary center were identified. Renal function was calculated based on estimated glomerular filtration rate (eGFR). Acute kidney injury (AKI) was defined according to the RIFLE criteria and chronic kidney disease (CKD) as eGFR<60 mL/min for >3 months after surgery, according to the K-DIGO G-categories definition. Multivariable logistic regression analyses assessed the impact of TT on the risk of postoperative AKI, after accounting for age, preoperative eGFR, blood loss and tumor characteristics. Multivariable Poisson regression analyses estimated the risk of eGFR decrease after surgery and a local polynomial smoother weighted function was used to graphically explore eGFR over time according to presence of TT.

RESULTS: Overall, 173 (13%) patients showed TT at preoperative imaging. Median age at surgery was 63 (interquartile range [IQR]: 54-72) years. Patients with tumor thrombus showed lower BMI (22 *vs.* 26 kg/m^2), preoperative Hb (11 *vs.* 13 g/mL) and eGFR (67 *vs.* 80 mL/min) relative to the overall RCC population. Clinical tumor size was higher in patients with tumor thrombus (9.2 *vs.* 6.5 cm). After adjusting for several confounders, presence of TT predicted higher risk of postoperative AKI (OR: 1.57; 95% CI: 1.33-1.73; P<0.001). Median functional follow-up was 49 (18-85) months. CKD upstage was shown in 57 *vs.* 38% (P<0.001) of patients with *vs.* without tumor thrombus, respectively. At multivariable analyses, presence of TT resulted an independent predictor of greater eGFR decrease at last follow-up (P<0.001).

CONCLUSIONS: Presence of TT in patients undergoing kidney surgery for RCC represents a risk factor for worse long term renal function. Specifically, these patients experience higher rate of postoperative AKI, as well as of CKD upstage during follow-up. Moreover, while in absence of tumor thrombus a progressive eGFR decline has been observed over time, patients with tumor thrombus experience an important eGFR decrease postoperatively, up to 20% of preoperative eGFR, which remains virtually stable over time.

SC145
3D-derived volumetric and morphologic parameters to predict complications after robotic partial nephrectomy in patients with renal cancer

L. Bianchi, A. Mottaran, B. Bortolani, L. Cercenelli, M. Presutti, S. Boschi, L. Spinozzi, R. Melloni, R. Scarlatti, A. Pissavini, S. Amirhassankhani, M. Droghetti, C. Gaudiano, A. Rustici, L. Tartarini, R. Golfieri, E. Marcelli, R. Schiavina, E. Brunocilla (Bologna)

BACKGROUND: 3D models may improve the understanding of renal tumor anatomy. The aim of this study was to evaluate the impact of novel volumetric and morphologic parameters derived from anatomical 3D modeling, to predict complications after robot assisted partial nephrectomy (RAPN).

METHODS: Overall, 123 patients with organ-confined renal mass were treated with RAPN and were prospectively enrolled. Before surgery, 3D virtual modeling from preoperative high fidelity computed tomography was achieved. Based on the 3D models, bioengineers and urologists calculated the following volumetric and morphological 3D-derived parameters using Meshmixer (Autodesk, Inc., San Francisco, CA, USA) and Matlab (MathWorks, Natick, MA, USA) software: VT (cm^3) (*i.e.* volume of the tumor);VT/VK (*i.e.* ratio between the tumor volume and the ipsilateral kidney volume); CSA3D (*i.e.* Contact Surface Area [cm2]); UCS3D (*i.e.* contact of the tumor to the Urinary Collecting System); Tumor-Artery3D: cortical tumor with blood supply by tertiary segmental arteries (score = 1); medullary tumor with blood supply by secondary segmentary artery (score = 2); hilar tumor with blood supply by primary segmentary or main renal artery (score = 3); ST (*i.e.* sphericity of the tumor,): continuous parameter to quantify how closely the shape of the tumor approaches that of a mathematically perfect sphere (ST=1); ConvT: (*i.e.* convexity of the tumor,): continuous parameter to quantify the regularity of tumor 3D morphology, obtained as ratio between the tumor volume and the smallest volume that fully encloses it, and that is convex at all points; These novel 3D-derived parameters were evaluated and analyzed in the overall population. The association between these parameters and the occurrence of overall complications was tested using univariate and multivariate logistic regression analysis.

RESULTS: Overall, 95 (77.2%), 26 (21.2%) and 2 (1.6%) patients had cT1a, cT1b and cT2a renal cancer, respectively; the median tumor diameter at CT scan was 2.9 cm (IQR 2.1-4.0). The intraoperative arterial clamping approach was clampless in 43 (35%), non-selective in 40 (32.5%) and selective/super-selective in 40 (32.5%) patients. Overall, 6 (4.8%) experienced intraoperative complications and 21 (17%) patients had postoperative complications (11.3% Clavien 1-2 and 5.7% Clavien ≥3). At univariate analysis, UCS3D, Tumor-Artery3D 2 and 3 (*i.e.*, tumor with primary or secondary segmental arteries supply; Augmented Anatomy, Heist, Germany) and CSA3D were significantly related to higher risk of overall complications (all P≤0.01). At multivariate logistic regression, Tumor-Artery3D Score 3 (OR: 4.47) was the only independent predictor of overall complications (P≤0.03).

CONCLUSIONS: 3D modelling may provide novel volumetric and morphological parameters to predict overall complications after RAPN. Patients with arterial blood supply form main artery or first segmentary branch had significantly higher risk of postoperative complications after RAPN.

SC146
Defining the most useful intermediate endpoint for overall survival in intermediate and high-risk clear cell carcinoma

G. Fallara, A. Martini, G. Rosiello, F. Belladelli, G. Musso, F. Cei, G. Basile, C. Re, D. Cignoli, F. De Cobelli, G. Brembilla, L. Marandino, D. Raggi, G. Gandaglia, E. Mazzone, M. Moschini, A. Stabile, A. Briganti, A. Necchi, F. Montorsi, A. Salonia, A. Larcher, U. Capitanio (Milan)

BACKGROUND: In the era of adjuvant therapy for clear cell renal cell carcinoma (ccRCC), there is a need to verify the strength of intermediate clinical endpoints (ICEs) to predict long-term overall survival (OS). In fact, the value of progression free survival (PFS) as an early surrogate proxy for OS is still debated. The aim of this study was to statistically test the role of PFS in predicting long-term OS in patients with intermediate/high-risk clear cell carcinoma.

METHODS: Within a prospectively maintained database, we selected patients who fulfilled inclusion criteria of the KEYNOTE-564. Patients did not receive adjuvant or salvage therapy. The impact of PFS within 6 months, 1, 2, 3, and 5 years after surgery on the risk of OS was evaluated in multivariable Cox regression analyses using time-varying and landmark analysis approaches. Discrimination was assessed using Harrell's C Index.

RESULTS: Overall, 420 patients were included in the analysis. Median follow-up for survivors was 72 months. The 5- and 10-year OS were 57% (95% CI: 51-63) and 27% (95% CI: 22-33%), respectively. On a time-varying multivariable analysis, PFS (hazard ratio [HR]: 2.41; 95% confidence interval [CI]: 1.41, 4.24; P<0.001) was associated with OS. The development of PFS at 6 months, 1, 2, 3 or 5 year was associated with worse OS compared to those who did not develop any disease progression. The most informative ICE for predicting OS (C-Index: 0.88) was PFS at 5 years at multivariable analysis adjusting for major predictors according to landmark time points. These results require prospective validation and specifically should be validated by use of data form RCTs on adjuvant therapies.

CONCLUSIONS: In the light of the renewed interest on perioperative treatments for intermediate/high risk ccRCC, 5-year PFS appears the best proxy of long-term OS.

SC147
The current role of renal tumor biopsy in the management of small renal masses: long-term results from a prospective, single-institutional database

G. Baiamonte, G. Rosiello, F. Cei, N. Tenace, G. Musso, G. Basile, C. Re, G. Fallara, F. Belladelli, M. Colecchia, I. Rowe, F. De Cobelli, R. Pennella, A. Della Corte, G. Brembilla, R. Bertini, A. Briganti, A. Necchi, F. Montorsi, A. Salonia, R. Lucianò, A. Larcher, U. Capitanio (Milan)

BACKGROUND: Incidence of small renal masses (SRM) increased over the last decade. In this setting, renal tumor biopsy (RTB) may guide clinicians to identify the optimal management. However, controversial data are available regarding the impact of RTB in changing management strategies.

METHODS: Within a prospective maintained database, patients with indeterminate SRM (<4 cm) who underwent RTB between 2015 and 2019 at a single tertiary center were identified. All biopsies were performed using US or a CT-guided system. Clavien-Dindo classification identified postprocedural complications. Multivariable logistic regression analyses were used to assess predictors of surgical management after RTB in patients with pathologically confirmed renal cell carcinoma (RCC). Finally, a local polynomial smoother weighted function was used to graphically depict the effect of clinical size on the probability of undergoing surgical management, after accounting for tumor and patient characteristics.

RESULTS: Overall, 124 patients underwent US/CT-guided renal tumor biopsy. Median tumor size was 2.5 (2-3.3) cm. No grade III- IV complications were reported. At histopathological examination, RCC was found in 87 (70%) patients and 28 (22%) had benign histology. The rate of benign disease decreased from 30% in <2 cm to 20% in 3.5-4 cm SRM. Only 1.6% (N.=2) of biopsies were non-informative. After a median follow-up of 48 (15-68) months, 27 (21.7%) patients underwent kidney surgery. Concordance rates between RTB and final pathology were 90% and 89% for histology and tumor grade, respectively. At multivariable analyses, clinical size [Odds ratio (OR): 1.2, 95% CI 1.1-1.4; P=0.03] and age at biopsy (OR: 0.96, 95% CI 0.93-0.99; P=0.03) were associated with surgical management in patients with RCC.

CONCLUSIONS: Percutaneous RTB is a safe procedure, which is rarely associated with major complications. Moreover, its accuracy in detecting tumor aggressiveness (*i.e.,* tumor histology and grade) is very high, reaching a concordance rate of roughly 90%. Importantly, despite clinical size still represents a predictor of surgical management, the risk of undergoing kidney surgery after RTB in RCC patients suitable for surgery ranges from 30 to 40%.

SC148
Surgical counseling in the 3RD millennium: the hologram project

S. Resca, P.M. Oltolina, S. Ferretti, S. Puliatti, M.C. Sighinolfi, B.C.M. Rocco, F. Ferraguti, C. Secchi, S. Di Bari, M. Amato, M. Ticonosco, R. Ferrari, S. Micali (Modena)

BACKGROUND: In the past few years many things are changing in urology. The advent of new technologies, such as 3D reconstruction, augmented reality, and artificial intelligence, seems increasingly more crucial to offer the better standard of healthcare and to reach the best possible surgical outcomes. In this study, we wanted to evaluate the possible advantages obtained in counselling patients, undergoing partial nephrectomy procedures, with the aid of 3D reconstruction holograms.

METHODS: We enrolled patients from 18 to 80 years old, with a new diagnosis of renal tumor. All the patients executed a contrast enhanced CT scan. Then, the biomedical engineers of our University (UNIMORE), provided us the 3D reconstruction of those clinical cases. Starting from the 3D reconstruction they also prepared holograms. We standardized the counseling as follows: 1) we showed to each single patient the CT scan, explaining the anatomy and the surgical procedure programmed. 2) we showed to the patients the 3D reconstruction on the computer screen (HD 2D monitor) 3) we showed the 3D reconstruction in a 3D fashion with the support of Hololens (Microsoft Corp., Redmond, WA, USA); and 4) we showed the patients the 3D reconstruction with the support of a hologram projector (3D led fan Garsentx). All the patients completed a survey, based on a five grade Likert Scale (from 1 to 5), validated with a modified Delphi consensus, for the evaluation of their understanding of the anatomy, the surgical procedure planned, and the possible complications.

RESULTS: In the questionnaire, 14 questions were constructed to assess the level of understanding of the anatomy, of the planned surgery and the possible complications. The pos-

sible results ranged from 14 to 70. The first 10 patients who submitted the surveys showed a better understanding with the holograms than with the CT scans only. The average result of understanding with the CT was 35±2.7, with the 3D reconstruction it was 51±2.4, with the Hololens it was 56±1.6 and with the hologram projector it was 65±1.4. All the patients felt more relieved and underwent the surgery with less anxiety.

CONCLUSIONS: With this study we demonstrated that the hologram is a very promising tool to allow patients to understanding better the anatomy, the surgical procedure, and the possible complications. A better counselling and a better patients' understanding can have possible implications also from the medicolegal point of view.

SC149
Outcomes in robotic assisted partial nephrectomy and microwave ablation of renal masses according to the RCC Guidelines panel novel TNM proposal

A. Piccolini, P. Diana, A. Uleri, F. Dagnino, C. Saitta, G. Garofano, G. Lughezzani, M. Lazzeri, R. Hurle, A. Saita, P. Casale, V. Pedicini, N. Buffi (Pieve Emanuele, Milan)

BACKGROUND: The European Association of Urology Guidelines Panel proposed a new of the (renal cell carcinoma) RCC-TNM staging setting 3cm as cutoff between cT1a/b. This proposal complies with the current decision-making advances reserving active surveillance and TA for cT1a masses and as secondary options in cT1b patients if unfit for surgery. Despite microwave ablation (MWA) conveys more thermal energy compared to radiofrequency allowing a more effective ablation zone, no evidence and outcomes using the new proposal are available. On the other hand, partial nephrectomy (PN), while it is still an option under discussion for cT1a, it is considered as primary treatment in cT1b. The aim our study is to provide the clinical picture of treatment outcomes of patients undergoing MWA/RAPN according to the novel TNM.

METHODS: This study retrospectively analyzes a single center prospective database of patients diagnosed with cT1 renal masses subjected to either robotic-assisted PN (RAPN) or MWA from 04/2018 to 09/2021. Primary outcomes the comparison of the two population and point out the differences in population up to now and evaluate the surgical and early oncological outcomes. The χ^2 test was used to compare the populations of cT1a and cT1b patients undergoing either MWA or RAPN.

RESULTS: One hundred sixty-eight and 120 patients that underwent RAPN and MWA were analyzed. 95 and 97 patients presented with a cT1a mass and 47 and 18 patients with a cT1b mass and underwent either RAPN or MWA, respectively. Main population variables were compared. Clinical tumor size, as well as, PADUA risk classification, was statistically higher in cT1a patients and undergoing RAPN compared to those that underwent MWA [P=0.002 and P=0.019]. Positive margins for patients undergoing RAPN were 4% (4/95) and 3% (2/73) in cT1a and cT1b. Disease persistence at 2 months was 9% (6/68) and 35% (8/23) disease persistency in cT1a/cT1b. No patients undergoing RAPN reported a positive CT scan at 2-month follow-up.

CONCLUSIONS: The novel classification is an interesting proposal to modernize the decision making. Despite an acceptable and comparable treatment safety profile is seen, this is not true for early oncological outcome where disease persistence in both cT1a and cT1b should not be underestimated in MWA treatment, thus, careful patient selection should be encouraged.

SC150
Robot-assisted radical nephrectomy and inferior vena cava level I-III thrombectomy: perioperative and mid-term oncologic outcomes

U. Anceschi, A. Brassetti, L. Misuraca, G. Cacciamani, A.M. Bove, G. Tuderti, M.C. Ferriero, M. Costantini, R. Mastroianni, R.S. Flammia, S. Guaglianone, S. D'Annunzio, M. Desai, M. Aron, I.S. Gill, M. Gallucci, G. Simone (Rome)

BACKGROUND: Few series of robot-assisted radical nephrectomy (RARN) with inferior vena cava tumor thrombectomy (IVCT) for renal cell carcinoma (RCC) with venous tumor thrombus (VTT) are available in literature, all with short-term oncologic outcomes. The aim of this study was to describe perioperative and long-term oncologic outcomes of RARN and IVCT performed at a single, high-volume center.

METHODS: Between January 2014 and October 2022, 37 consecutive patients underwent RARN-IVCT for RCC and VTT at a single tertiary-care center for VTT Mayo level I (N.=8; 21.6%), level II (N.=11; 29.7%), level III (N.=18; 48.7%), respectively. Baseline, demographic and perioperative data were collected. A descriptive statistical analysis was performed. Frequencies and proportions were reported for categorical variables while medians and interquartile ranges (IQRs) were reported for continuously coded variables. Overall survival (OS), disease-free survival (DFS) and metastasis-free (MFS) were computed with Kaplan-Meier method.

RESULTS: All cases were successfully completed without any conversion to open surgery. Median operative time was 360 minutes (IQR 232.5-382.5). Median estimated blood loss was 550 mL (IQR 275-1500). Median hospital stay was 7 days (IQR 4-12.2). Overall, 19 patients (51.3%) had perioperative complications, 15 Clavien grade 2 (40.5%, all blood transfusions) and 4 grade 3-5 (10.8%), respectively. At a median follow-up of 32 months (IQR 17.2-62.5), MFS, DFS and OS were 37.8%, 59.4%, and 59.4%, respectively. The small series, the high rate of adjuvant targeted therapies (32.4%) as the extreme surgical complexity may affect reproducibility of outcomes.

CONCLUSIONS: RARN-IVCT represents a feasible and safe surgical option in tertiary referral centers; mid-term oncologic results seem to be comparable to those reported in open surgery literature. Our results support RARN-IVCT as a feasible and safe surgical option in tertiary referral centers even in the most advanced setting.

SMART (SC151-SC163)

Luts/benign prostatic hyperplasia 3

SC151
Results from a large single surgeon series of patients treated with Rezum water vapor thermal therapy for LUTS/BPH

SC152
Maximizing the local anesthesia protocol during Rezum treatment of the prostate with Schelin catheter

SC153
Convective radiofrequency water vapor thermal therapy (Rezum): perioperative and functional results from a 3-year follow-up. A retrospective analysis

SC154
The role of irrigation fluid in TURP outcomes and surgeon performance

SC155
A novel outcomes categorization for current minimally invasive ejaculation-sparing treatments of benign prostatic hyperplasia: results of a multicentric series

SC156
Rezum and Urolift mini-invasive procedures for BPH: differences in endoscopic room setting up

SC157
Trans-urethral resection *versus* thulium laser enucleation or photo-selective vaporization of the prostate: a prospective comparison of early postoperative functional results

SC158
Laparoscopic simple prostatectomy *versus* thulium laser endoscopic enucleation of the prostate (THULEP): a prospective comparison

SC159
Comparison of outcomes of HoLEP as treatment for small-medium and large prostate

SC160
Morcellation rate setting related to prostate volume after two lobes HoLEP technique: a prospective multicenter study to investigate the impact on efficacy, safety and operative time

SC161
Assessment of bladder wall thickness (DWT) on MRI depends on bladder volume

SC162
Ejaculation preservation in patients treated with transperineal interstitial laser ablation (TPLA) for LUTS due to benign prostatic obstruction

SC163
Ejaculation-sparing enucleation of the prostate with thulium:YAG laser (ES-THULEP) *versus* thulium fiber laser (ES-THUFLEP): outcomes on sexual function

SC151
Results from a large single surgeon series of patients treated with Rezum water vapor thermal therapy for LUTS/BPH

D. Piccolotti, M. Rizzo, O. Gordeeva, A. Bocchino, L. Ongaro, G. Rossin, A. Ioana, A. Biasatti, M. Barbiero, A. Cocci, C. Trombetta, G. Liguori (Schiavonia, Padua)

BACKGROUND: The aim of this study was to analyze the results of a large series of patients treated with Rezum (Boston Scientific, Marlborough, MA, USA) Water Vapor Thermal Therapy for LUTS/BPH.

METHODS: The present single surgeon, single center series is based on prospectively collected data of patients who underwent Rezum Water Vapor Thermal Therapy for LUTS due to BPH between July 2021 and December 2023. The following data were collected and analyzed: prostate dimensions, procedure durations, in-hospital stay length, the incidence of postoperative complications according to the Clavien Dindo classification, and variations of IPSS and QoL scores at 3, 6, and 12 months.

RESULTS: During the study period, 163 men underwent 166 Rezum Water Vapor Thermal Therapy for LUTS/BPH. The median prostate size was 52mL (IQR: 40-70). The median number of injections was 4 (IQR: 4 - 6). The median operative time was 7 minutes (IQR: 5-10). After 5 procedures, patients remained hospitalized, while after all other procedures, patients were discharged the same day of the Rezum treatment. No patients required blood transfusion for hematuria. One case of sepsis occurred. No other Clavien-Dindo Grade >2 was reported. The median catheterization length was 7 days (IQR 6-10). After 7 procedures, patients had acute urinary retention after catheter removal that resolved with a period of catheter in 6 cases. One patient had an indwelling catheter at the last follow-up. IPSS improved by 61%, 58%, and 67% at 3, 6, and 12 months, respectively ($P<0.05$). QoL scores improved by 60%, 75%, and 75% at these same timepoints ($P<0.05$). At three months, 15 patients reported the absence of ejaculation.

CONCLUSIONS: According to our results, Rezum is a safe procedure that can be performed without the need of a hospital in stay, and because of the short time needed for one procedure, up to 8 patients could be treated within 6 hours. Patients in the study population reported a significant increase in IPSS and QoL scores lasting up to 12 months.

SC152
Maximizing the local anesthesia protocol during Rezum treatment of the prostate with Schelin catheter

S. Secco, G. Siena, F. Sessa, L. Cindolo (Milan)

BACKGROUND: Rezum (Boston Scientific, Marlborough, MA, USA) is one of the most versatile and effective minimally invasive techniques nowadays available for the treatment of LUTS due to BPE. The anesthesia is performed according to surgeons' preference, ranging from general anesthesia or mild sedation to prostatic block or local anesthesia. Recently, the Schelin Catheter (SC; ProstaLund AB, Scheelevägen, Sweden) has been presented as a tool to transurethrally deliver local intraprostatic anesthesia (TUIA). In the attempt to maximize the minimal invasiveness of Rezum, we have evaluated the advantages and feasibility of performing the procedure using TUIA via the SC.

METHODS: SC is an innovative device with an operational channel equipped with a retractile needle and the standard drainage and balloon port. At first, the SC is inserted, and the balloon is filled with 10 cc of saline solution; the catheter is then stretched so the balloon rests against the bladder neck, allowing bladder voiding. Rotating the catheter, a 20 mL of 1% anesthetic solution of mepivacaine or lidocaine is injected transurethrally into the prostate, according to the following scheme: 3-2-2 mL at 8 and 4 o'clock position; 3 mL at 10 and 2 o'clock position. After injections, the balloon can be deflated, and SC removed to introduce the Rezum device. We have prospectively evaluated 25 patients treated with Rezum with previous TUIA delivered with SC. Prior to the procedure, patients were asked to rate their pain on a Numeric Rating Scale (NRS). Pain scores were assessed at nine timepoints: 1) preoperatively; 2) Schelin Catheter insertion; 3) LA infiltration; 4) Rezum probe insertion; 5) water vapor treatment (WVT); 6) catheter insertion; 7) on day 1; 8) day 7 catheter removal; and 9) day 30 – follow-up visit questionnaires were administered on the day of surgery as well as on 1st, 7th and 30th postoperative days to rate NRS of pain.

RESULTS: We enrolled 25 patients, with a median age of 67 (5-74) years. All patients except one had alfa-blocker therapy; all were in an outpatient setting. The median (IQR) prostate size was 73 mL (60-100), with a median Q_{max} 9.1 mL/s, median IPSS 25 (19-26) and QoL 4 (3-4). Median TUIA plus Rezum operative time was 30 min. All patients were discharged 4-6 h after the procedure. Median NRS reported was 0, 2, 2, 1, 3, 1, 1, 1, and 1, respectively, for the 9 different timepoints. Three out of 25 patients reported a NRS of 6 during WVT. No perioperative anesthesiologic and procedure-related complications were reported. Median catheterization time was 7 days. One cases of AUR, and 2 cases of mild dysuria were postoperatively recorded.

CONCLUSIONS: To our knowledge, this is the first series presented using SC to improve pain control during Rezum treatment. Our data suggest the procedure is feasible, safe, and well tolerated. Procedures performed in an office/day case setting can have several advantages (such as shortening of hospitalization and treatment time, possibility to treat patients not suitable for general or spinal anesthesia).

SC153
Convective radiofrequency water vapor thermal therapy (Rezum): perioperative and functional results from a 3-year follow-up. A retrospective analysis

M. Tallè, F. Mengoni, D. Dente, A. Cafarelli (Ancona)

BACKGROUND: Rezum is a new minimally invasive treatment (MIST) for benign prostate enlargement using thermal transurethral water vapor therapy, that allows to spare the ejaculatory function up to 95% of the cases (Rezum; Boston Scientific, Marlborough, MA, USA). The aim of the study was to evaluate the efficacy and feasibility of Rezum as a minimally invasive surgical technique (MIST) for BPH symptoms; to evaluate his efficacy in sparing the ejaculation and in median lobes treating.

METHODS: Clinical data were collected in a dedicated database. Intraoperative variables, postoperative complications, and functional outcomes. Patients with prostates large between 30-80 cc with or without median lobe were eligible for Rezum. Patients with prostate >80 cc, with urinary retention, urethral strictures, bladder stones o severe symptoms (International Prostate Symptoms Score [IPSS] >25) or without follow-up data were excluded. Validated questionnaire (IPSS, Men Sexual Health Questionnarie Ejaculation Disorder [MSHQ-EjD], International Index of Erectile Function [IIEF]) were used to assess lower urinary tract symptoms, ejaculation disorders and erectile function before surgery and at 1 month, three months and 1 year, when possible. Surgical technique: The length of the prostatic urethra determines the number of treatments. We used the McVary formula to do 1 injection per 9 mL of prostate volume.

RESULTS: We collected retrospectively data of 58 consecutive male patients who underwent Rezum from September 2020 to April 2023 (32 months). The median operative time was 10.5 (IQR 8.7-15) min. All patients were dismissed in few hours (average 4 hours) after surgery with indwelling urinary catheter that was removed after a median of 5 (IQR 3-8) days. A significantly decrease of IPSS from baseline (P=0.001) at 1 and 3 months after surgery was reported (mean – 5 points IPSS). No case of urinary incontinence reported. Postoperatively results: 14 cases of dysuria and mild hematuria reported that did not require any intervention. On MSHQ-EjD no statistically significant difference (P= 0,567) were observed with a slight improvement of IIEF-5 with not statistically significance (+ 3 points; P=0.1). A slight positive correlation between numbers of injections and postoperative symptom was observed (r= 0,126; P= 0,3) with not statistically significance. We then divided the cohort in two groups, with median lobe (group 1 = 21 patients) and without median lobe (group 2 = 37 patients) and we observed that there is no statistically significant difference on IPSS scores (group 1 *vs.* group 2; P= 0.67) at 3 months and 1 year from surgery.

CONCLUSIONS: Rezum treatment is a feasible minimally invasive option to spare the ejaculation for patients with BPH symptoms and showed good outcomes at 20 months of follow-up. These data support the feasibility of Rezum regardless the presence of median lobe. Longer follow-up is still needed to prove whether these results will stay stable through years or not.

SC154
The role of irrigation fluid in TURP outcomes and surgeon performance

F. Romantini, D. Biferi, L. Topazio, G. Maselli, F. Narcisi, F. Tana, M. Ranieri (Teramo)

BACKGROUND: TURP is the gold-standard for the treatment of BPE associated with LUTS, after failure of conservative therapy. At present, only resection-rate (grams of prostate resected over time) is regarded as an efficiency parameter to evaluate the skill of the operator and to assess the procedure.

METHODS: One hundred twenty-three patients with BPE/LUTS who came to our observation, from June 2016 to December 2021. 5 randomized surgeons performed TURP using a Gyrus-type bipolar system. The amount of irrigation fluid used during the procedure was registered and correlated to the operating time, resection-rate, prostate adenoma weight, postoperative bladder irrigation time and days of catheterization.

RESULTS: We found an inverse correlation between the amount of irrigation fluid used during TURP and the resection-rate recorded for all operators, according to Spearman's Correlation; (r= -0.78, P=0.002); a direct correlation between the amount of irrigation fluid and the adenoma weight, according to the Spearman correlation (r=0.61575; P= 0.005). Direct correlation was found with intraoperative bleeding and hemoglobin loss (average loss 0.9 g/dL). We also found a direct correlation, statistically significant, with the duration of bladder irrigation after TURP (r=0.2498; P=0.004) and bladder catheterization time.

CONCLUSIONS: The amount of irrigation fluid used is proposed as a reliable parameter to estimate the efficiency of the endoscopic procedure as well to assess the skill of the operator and short-term results (intraoperative bleeding, bladder catheterization after surgery and hospital stay). The observed data encourage the possibility of applying this new efficiency indicator to all endoscopic maneuvers.

SC155
A novel outcomes categorization for current minimally invasive ejaculation-sparing treatments of benign prostatic hyperplasia: results of a multicentric series

U. Anceschi, D. Amparore, G. Siena, A. Cocci, E. Checcucci, F. Prata, S. De Cillis, A. Iannuzzi, A. Quarà, M. Ortenzi, A. Ragusa, L. Misuraca, A.M. Bove, S. D'Annunzio, A. Brassetti, M.C. Ferriero, G. Tuderti, L. Viola, F. Sessa, P. Spatafora, C. Fiori, F. Varvello, A. Minervini, G. Ferrari, F. Porpiglia, L. Cindolo, G. Simone (Rome)

BACKGROUND: Simultaneous achievement of obstruction relief and ejaculatory function preservation represents the main goal for any surgical technique currently available for the management of benign prostatic hyperplasia (BPH). In this scenario, there is paucity of outcomes reporting systems as lack of predictors of clinical results. In this study we proposed a novel scoring system that summarizes composite outcomes for BPH treatment, and we sought to identify its predictors on a large multicentric dataset of minimally invasive techniques.

METHODS: Seven institutional BPH datasets were merged and queried for "urethral-sparing robotic simple prostatectomy" (usRASP; N.=94; group A), "waterjet ablation" (WA; N.=95; group B) and Rezum (Boston Scientific, Marlborough, MA, USA) (N.=308; group C). Patients with a follow-up <12 months (N.=32) or missing data (N.=28) were excluded from the analysis. "Complete clinical success" (CS) was defined as the coexistence of: 1) reduction of ≥30% in IPSS at 12 months compared to baseline IPSS; 2) response to MSHQ-EjD question 3 indicating emission of semen within 12 months during follow-up; and 3) no perioperative complications greater than grade III on the Clavien-Dindo classification. Simultaneous achievement of only two of the presented criteria was considered a "partial clinical" (PS) success. Baseline and perioperative data were reported for the whole cohort, while functional data according to clinical success were compared between groups. A logistic binary regression model was built to iden-

tify predictors of CS. For all statistical analyses, a two-sided P<0.05 was considered significant.

RESULTS: The median follow-up of the overall cohort was 39.8 months (IQR 27.1-46.8). In the A group a complete, partial, absent clinical success was observed in 66%, 28.7%, 5.3% of cases, respectively. In the B group the complete clinical, partial, and absent rates were 73.6%, 14.7%, 3.5% while in the C group were 68.8%, 20.1%, 11%, respectively. No significative difference was found between groups for any of the CS endpoint considered (30% IPSS reduction; P=0.455, ejaculation rates; P=0.07, perioperative complications rates; P=0.445). On multivariable logistic regression analysis, prostate volume <110 mL (OR 0.52; 95% CI 0.29-0.95; P=0.034), higher preoperative SHIM Score (OR 1.07; 95% CI 1.03-1.11; P<0.001) and reduced catheterization time (OR 0.91; 95% CI 0.86-0.96; P=0.02) were independent predictors of complete clinical success.

CONCLUSIONS: We suggested a novel, comprehensive metric to assess 1-year composite outcomes, safety, and efficacy for any of minimally invasive treatments currently available for BPH management. Irrespectively of the surgical technique considered, a preoperative prostate volume <110 mL and unimpaired sexual function are necessary conditions for expecting a complete clinical success.

SC156
Rezum and Urolift mini-invasive procedures for BPH: differences in endoscopic room setting up

M. Boldini, L. Dal Corso, F. Saccà, A. Princiotta, G. Puccio, P.D. Roccaro, V. Gilioli, E. Rubilotta (Verona)

BACKGROUND: The aim of this study was to assess nurse setting of endoscopic room (ER) for mini-invasive bladder outlet obstruction (BOO) endoscopic treatments: Rezum (Boston Scientific, Marlborough, MA, USA) and Urolift (Pleasanton, CA, USA).

METHODS: This was a pilot prospective study on nurse experience of ER setting for Rezum and Urolift procedures in a tertiary urological center (May/December 2022). Data recorded were surgical kit components, number of components and serving tables, preparation times of material used for the endoscopic procedures and ER, patient change times, nurse perceived complexity of ER setting and in helping surgeon during procedure, critical issues in ER setting/helping surgeon. VAS Scale for complexity evaluation was: 0 no complexity, 10 max complexities. A skilled surgeon was involved, and 3 nurses: 1 of high level of experience (HLE) in urological endoscopic procedures (>6 years), 1 of mild level (MLE) (1-6 years), 1 of low level (<1 year). All nurses had a preliminary teaching session before the first procedure.

RESULTS: Data were collected on 6 procedures of Urolift, 6 of Rezum. Mean surgical time was 8 min for Rezum, 14 min for Urolift. No intra- and postoperative complications occurred. Overall nursing time needed for each patient (mean preparation components and ER, mean patient change time) was 34.3 min for Urolift and 36.9 min for Rezum. An explanation of this result could be that both treatments had only slight differences in number of components and need of serving tables, and that critical issues reported by nurses were similar for both devices. Interestingly, great differences in time of ER setting were found comparing HLE nurse and LLN, highlighting doubled preparation time in the latter. Only slight difference was documented between HLE and MLE, while fair difference between MLE and LLE. These findings emphasize the relevance of nurse's experience in endoscopic procedures. Overall, less than 40 min were nursing time needed for each patient undergoing procedures. Therefore, considering also surgical procedure duration, approximately one hour of ER use should be considered for each patient.

CONCLUSIONS: Nurses time duration and complexity grade were comparable for mini-invasive treatments of BOO. Nurse experience in endoscopic procedures was the most important characteristic in reducing ER setting time.

SC157
Trans-urethral resection *versus* thulium laser enucleation or photo-selective vaporization of the prostate: a prospective comparison of early postoperative functional results

L. Micai, M. Sibona, P. Destefanis, E. Vercelli, C. Mangione, G. Montefusco, F. Colucci, F. Bracco, A. Bosio, A. Bisconti, P. Gontero (Turin)

BACKGROUND: According to current international guidelines, endoscopic prostatic resection, vaporization, or enucleation are considered viable surgical options for patients suffering from benign prostatic obstruction (BPO). These techniques have all been proven effective and safe in the long term, but fewer data were available to investigate earlier functional results after surgery. Particularly, a lack of knowledge about the amount and type of urinary symptoms in the first month after surgery must be underlined. The aim of our study was to investigate the early (1 and 3 months) functional results after transurethral resection (TUR-P) *versus* photoselective vaporization (PVP) or thulium laser enucleation (ThuLEP) of the prostate in BPO patients.

METHODS: Our study was conceived as a single center, prospective, non-randomized cohort analysis (EC n. 643/2018). From 06/2022 to 01/2023, we included male patients with indication to endoscopic BPH surgery, which were subsequently divided into three groups, according to the surgical technique adopted: bipolar TUR-P *vs.* ThuLEP *vs.* LBO laser PVP. Baseline, 1-month and 3-month follow-up data were recorded. Validated questionnaires were administered, including the International Consultation on Incontinence Questionnaire (ICIQ), to investigate postoperative urinary incontinence. Statistics: Kruskal-Wallis's H Test; Pearson's χ^2 test.

RESULTS: Globally, 105 patients were considered. Thirty-five patients underwent a bipolar TUR-P, 43 a ThuLEP and 27 an LBO laser PVP. Median age was 70 *vs.* 73 *vs.* 71 years (P=0.187). Median prostate volume was 54 *vs.* 87 *vs.* 84 cc (P=0.003). No significant differences were detected at baseline in the IPSS, IPSS Bother Score or IIEF5 scores among the three groups. ThuLEP was characterized by a longer operation time (107.5 *vs.* 85 *vs.* 80 minutes, P=0.018). Compared to TUR-P, laser procedures were characterized by shorter catheterization and hospital stay (1 *vs.* 1 *vs.* 3 days, respectively; P<0.001). 1 month after surgery, a higher incidence of residual symptoms was recorded in patients undergoing a PVP procedure (median IPSS 8 *vs.* 9 *vs.* 11.5; P=0.018), while no differences were reported

about IIEF5 values. Moreover, a slightly higher incidence of transient urinary incontinence was recorded in the PVP group, as testified by median ICIQ values: 0 *vs.* 0 *vs.* 6 points (P=0.002). After 3 months, no more significant differences were recorded among the groups in all questionnaire scores. Particularly, 3-months median IPSS values were 4 *vs.* 5.5 *vs.* 8 (P=0.237), while ICIQ scored 0 *vs.* 0 *vs.* 0 (P=0.171).

CONCLUSIONS: TUR-P, ThuLEP or LBO laser PVP are effective techniques, which can all lead to optimal LUTS relief in the short to medium term. Anyway, patients could experience different symptoms in the earliest postoperative phase. In our experience, PVP patients could be affected by a higher amount of residual symptoms and mild, transient urinary incontinence in the first month after surgery, probably due to local inflammatory processes.

SC158
Laparoscopic simple prostatectomy *versus* thulium laser endoscopic enucleation of the prostate (THULEP): a prospective comparison

E. Vercelli, P. Destefanis, M. Sibona, G. Montefusco, L. Micai, F. Bracco, C. Mangione, A. Bosio, A. Bisconti, P. Gontero (Turin)

BACKGROUND: Within the wide range of treatments available for Benign Prostatic Obstruction (BPO), Minimally Invasive Simple Prostatectomy (MISP) is still considered "investigational" by international guidelines, due to a lack of prospective data. Whether performed with the laparoscopic (LSP) or robotic technique (RSP), MISP could represent an interesting alternative to the classical Open Prostatectomy or the Endoscopic Enucleation of the Prostate (EEP), to approach large prostates. The aim of our study was to prospectively compare the surgical and functional outcomes of LSP *versus* thulium laser EEP (ThuLEP).

METHODS: We prospectively compared BPO patients undergoing LSP *versus* ThuLEP in a single center analysis performed at Molinette Hospital, Turin (ethics committee n. 643/2018). We included male patients undergoing BPO surgery between September 2020 and January 2023. Patients were divided into two groups, according to their surgical indication: LSP *versus* ThuLEP. No randomization was performed. Baseline, perioperative and 3-month follow-up data were recorded. Validated questionnaires were administered before and after surgery.

RESULTS: Globally, 82 patients were considered (42 ThuLEP *vs.* 40 LSP). Median (IQR) age for ThuLEP *vs.* LSP patients was 73 (66-77) *vs.* 69.5 (63.5-74) years (P=0.040). Median (IQR) prostate volume was 86.5 (59-100.5) *vs.* 147.5 (122-190) years (P<0.001). An indwelling catheter was carried by 13 (31%) and 16 (40%) patients. Median preoperative IPSS was 18 (12-20) *vs.* 16.5 (10-18.5), P=0.227. Time of surgery was significantly longer for LSP: 107.5 (70-157.5) *vs.* 207.5 (180-235) min, P<0.001. The surgical catheter was removed in median postoperative day 1 for thuLEP *vs.* day 5 for LSP. Patients were discharged in postoperative day 1 after thuLEP *vs.* day 6 after LSP. For both techniques, we registered 1 case of Clavien ≥3 complications, due to hematuria requiring endoscopic clot removal and hemostasis. Blood transfusions were required in 4 cases (10%) after LSP *vs.* 0 (0%) after thuLEP, P=0.055. We recorded 1 urethral stenosis after ThuLEP *vs.* none after LSP. A clinically significant, but transient urinary incontinence was reported by 3 (7.1%) patients *vs.* 1 (2.5%) patient. After 3 months, median IPSS was 5 (3-8) *vs.* 3 (1-3), P<0.001.

CONCLUSIONS: When performed in experienced centers, LSP could represent a viable option for BPO patients presenting with larger prostates. Compared to ThuLEP, it seemed to guarantee comparable improvement of the urinary symptoms and a limited incidence of high-grade surgical complications. On the contrary, longer catheter and hospitalization times must be considered for LSP, together with an improved risk of blood transfusions.

SC159
Comparison of outcomes of HoLEP as treatment for small-medium and large prostate

A. Tancredi, G. Cochetti, A. Paladini, A. Vitale, F. Pastore, M. Russo, R. La Mura, S. Tagliaferri, E. Mearini (Perugia)

BACKGROUND: Holmium Laser Enucleation of the Prostate (HoLEP) is the recommended treatment for benign prostatic hyperplasia (BPH) larger than 80 mL. However, many studies showed efficacy of HoLEP also in the treatment of prostate smaller than 80 mL, but currently it is debated if it could become the reference treatment in small and medium BPH too. The aim of the study was to compare perioperative and short-term functional outcomes for patients underwent HoLEP for small prostates (≤80 cc) and large ones (>80 cc).

METHODS: From January 2016 to December 2022, we collected retrospectively data from 133 patients underwent HoLEP. The study population was divided into 2 groups according to prostate volume (PV) revealed by transrectal ultrasound scan: group 1 included 62 patients with PV ≤80 mL (range 32-80 cc) and group 2 included 71 patients with PV >80 mL (range 80-272 cc). We compared perioperative outcomes, including operative time (OT), delivered amount of energy (DaE), estimated blood loss evaluated as difference between preoperative and 24 hours postoperative hemoglobin (ΔHb) values, length of catheterization (LOC), length of stay (LOS), intra- and postoperative complications according to Intraoperative Adverse Incident Classification (EAUiaiC) and Clavien-Dindo classification, respectively. Functional outcomes in terms of IPSS, maximum flow rate (Q max), urgency and urinary incontinence at 1 and 3 months after surgery, were compared between the two groups. A χ^2 test and Student's *t*-test were used for statistical analysis. Statistical significance was set at P<0.05.

RESULTS: The groups were comparable in terms of age, BMI, Hb level, PSA, comorbidities, preoperative IPSS and QoL Index (P>0.05). Statistically difference was founded between the two groups in terms of PV (60,6±20,3 *vs.* 110,2±30,7 cc; P=0.0007), Q max (10,2±4,5 *vs.* 12,4±5,1; P=0.03) and indwelling catheter prior to surgery (12 *vs.* 25; P=0.02). OT and total laser energy were lower in Group 1 than in Group 2 (85±57,8 *vs.* 112±52,3, P=0.0001: 126,5±37,6 *vs.* 179,7±54,1, P=0.002). LOC was significantly lower in HoLEP for small-medium prostate (1,5±0,5 *vs.* 2±1,2, P=0.03), even if clinically this difference was poorly relevant. Estimated blood loss, postoperative complications, LOS, and urinary incontinence were not statistically different between the two groups. No statistically

significant difference was found in functional outcomes at 1 month (IPSS P=0.52; Q_{max} P=0.2) and 3 month (IPSS P=0.7; Q_{max} P=0.6).

CONCLUSIONS: Our findings showed HoLEP as safe and effective treatment for both prostates ≤80cc and >80 cc, with no relevant difference in functional and perioperative outcomes between two groups.

SC160
Morcellation rate setting related to prostate volume after two lobes HoLEP technique: a prospective multicenter study to investigate the impact on efficacy, safety and operative time

O.A. Rera, A.L. Pastore, Y. Al Salhi, A. Fuschi, A. Martoccia, A. Antonioni, F.M. Valenzi, S. Scalzo, P.P. Suraci, D. Graziani, M.B. Sequi, G. Martino, G. Candita, G. Tema, A. Cicione, C. De Nunzio, A. Carbone (Latina)

BACKGROUND: Holmium laser enucleation of prostate (HoLEP) with tissue morcellation is one of the most effective surgical modalities for the treatment of symptomatic BPH. The goal of morcellation is to safely remove the enucleated prostate tissue. The morcellator (Versacut by Lumenis, Yokneam, Israel) allows you to set four suction and morcellation levels. The aim of this study was to optimize morcellation times by modulating the rate of morcellation according to the volume of prostate tissue estimated at the preoperative multiparameter MRI.

METHODS: Two hundred forty patients underwent HoLEP between May 2019 and November 2022. The procedures were performed by the same surgeon using the same surgical technique (2-lobes technique). All patients were studied with multiparameter prostate 3T MRI preoperatively. All patients with a prostate volume between 50 and 150 mL were enrolled. The exclusion criteria were presence of third lobe, presence of PIRADS lesions ≥3/5, positive prostate biopsy, previous interventions on prostate. The subjects were divided into three groups according to the estimated glandular volume at MRI: 83 patients in group A with a prostatic volume between 50 and 80 mL; 81 patients in group B with a prostatic volume between 81 and 110 mL; and 76 patients in group C with a prostate volume between 111 and 150 mL. Each group has been subdivided into 4 subgroups subjected to morcellation with 4 different morcellation speeds: 1, 2, 3, and 4, respectively. The latter is considered our control subgroup. For each procedure, the required morcellation time has been evaluated. The mean morcellation time in the various subgroups was compared with the control subgroup (morcellation at level 4).

RESULTS: In group A the mean morcellation time was 17,8 min at V1, 20,6 min at V2, 21 min at V3, 21 min at V4. In group B the mean morcellation time was 24 min at V1, 25 min at V2, 25,5 min at V3, 25 min at V4. In group C, the mean morcellation time was 36,3 min at V1, 34,65 min at V2, 33,3 at V3, 33 min at V4. Comparing the mean morcellation times of the various subgroups with group V4, we notice that for prostates between 50 and 80 mL (group A), there is a saving of 15% of time at V1, 2% at V2, while there are no differences at V3. For prostates between 81 and 110 mL (group B), there is a time saving of 4% at V1, while there is no time difference at V2, whereas we reported a higher morcellation time of 2% at V3. For prostate volumes between 111 and 150 mL (group C) we observed prolonged morcellation extra-time of 10% at V1, 5% at V2 and 1% at V3, respectively.

CONCLUSIONS: The study aims to advice the surgeon, who approaches HoLEP, towards an optimal setting of morcellation. Prostates with a volume between 50 and 80 mL are morcellated at the first speed level (V1) with a significant saving of operating time, when compared to the maximum level. This setting allows the operator to have greater control of the tissue to morcellate, with a significant reducing the rate of bladder injury.

SC161
Assessment of bladder wall thickness (DWT) on MRI depends on bladder volume

A. Cicione, R. Lombardo, L. Rovesti, S. Riolo, G. Argento, A. Tubaro, A. Franco, C. Gravina, B. Turchi, J. Stira, A. Guercio, G. Gallo, O.A. Voglino, V. Baldassarri, G. Guarnotta, E. Mancini, S. D'annunzio, D. Fiasconaro, C. De Nunzio (Rome)

BACKGROUND: MRI has gained popularity in the field of prostate cancer (PCA) management. Ultrasound DWT measurement has been standardized over the years showing to be related to bladder volume (BV). No data have been published regarding DWT on MR images. We evaluated DWT on MRI at several bladder volumes (BV) to establish the right one.

METHODS: MRI images of patients evaluated for clinical suspicious of PCA were reviewed by one urology-dedicated radiologist. A 3-tesla MRI was used, BWT was computed as mean of three measurements performed at anterior, posterior and dome of bladder wall. The bladder was physiologically filled. Prostate and bladder volume were measured by using the conventional prolate ellipsoid formula. Univariate Analysis and Pearson coefficient were computed to establish the association between e BV and DWT. Patient's stratification in accordance with BV was used to assess the most stable BV value to measure BWT.

RESULTS: MRI features from thirty-eight patients aged 61.9±25.2 years were analyzed. Overall, mean DWT was 3.83±3.43 mm, mean BV was 228.31±126.12 mL and mean prostate volume was 64.16±31.6 mL. Due to normal distribution of BV, patients were categorized as less than 120 mL (6 patients), between 121-272 mL (21 patients) and ≥273 mL (11 patients) with a mean BWT of 6.05±3, 3.75±2.4 and 2.77±2 mm, respectively. DWT showed an inverse correlation with BV (R2=0.22; P=0.003; ρ=-483; P=0.002) and a direct correlation with prostate volume (R2=0.29; P=0.30; ρ=17; P=0.30).

CONCLUSIONS: Like ultrasound exam, measurement of DWT depends on bladder volume. To compute BWT on MRI, a 121-270 mL urine inside the bladder showed to be the proper volume. That finding is in accordance with previous knowledge based on ultrasound exam.

SC162
Ejaculation preservation in patients treated with transperineal interstitial laser ablation (TPLA) for LUTS due to benign prostatic obstruction

P. Polverino, M. Lo Re, M. Saladino, C. Bisegna, A. Pecoraro,

L. Moscardi, G.R. Resta, R. Mariottini, A. Rivetti, R. Nicoletti, V. Li Marzi, G. Siena, A. Cocci, M. Gacci, A. Minervini, S. Serni, R. Campi, F. Sessa (Florence)

BACKGROUND: Ejaculatory disorders (EjD) are prominent postoperative side effects in men who are treated for benign prostatic obstruction (BPO) with traditional prostate surgeries, such as transurethral resection of the prostate (TURP). Recent surgical techniques were developed to preserve antegrade ejaculation with promising short-term results. Among these, transperineal interstitial laser ablation (TPLA) of prostate adenoma seems to play a relevant role. Herein, we report perioperative and short-term sexual outcomes of patients treated with TPLA for LUTS due to BPO.

METHODS: Data from consecutive patients with moderate to severe LUTS and a prostate volume ranging from 30 to 100 mL undergoing TPLA at our institution between April 2021 and February 2023, were prospectively collected in a dedicated database. Procedures were performed in an outpatient setting using local anesthesia and oral benzodiazepine administration, using EchoLaser (Elesta SpA, Calenzano, Florence, Italy) multisource diode laser generator. The International Index of Erectile Function (IIEF-5), Male Sexual Health Questionnaire-Ejaculatory Dysfunction Short Form 3-items (MSHQ-EjD SF 3-items) and patient management (catheterization, medications, PSA) data were recorded pre- and postoperatively at 1-, 3-months and last follow-up (LF-UP) for descriptive analyses.

RESULTS: Overall, 95 patients were enrolled. Median follow-up time was 9 months (IQR 4 - 14). Median prostate volume was 50 mL (IQR 40-70); median preoperative IIEF-5 and MSHQ-EjD SF 3-items were 20 (IQR 13.5-40) and 5 (IQR 2-11), respectively. All patients except one were discharged on the same day as the procedure, recording no Clavien-Dindo Grade ≥2 perioperative complications. Median catheterization time was 7 days (IQR 7-8). Median IIEF-5 and MSHQ-EjD SF 3-items were 21 (IQR 12-25) and 10 (IQR 6-13), 21 (IQR 12-25) and 9 (IQR 4-13), 22 (IQR 12-25) and 11.5 (IQR 5-13) at 1-, 3-months and LF-UP, respectively. In all patients, ejaculation and sexual function were preserved. 12 (12.6%) patients required re-introduction of alpha blocker therapy at 6 months, with a potential a significant negative impact on ejaculatory function.

CONCLUSIONS: According to our experience, TPLA appears to be a safe and feasible option in the treatment landscape for LUTS due to BPO in carefully selected patients, ensuring the preservation of ejaculatory function.

SC163

Ejaculation-sparing enucleation of the prostate with thulium:YAG laser (ES-THULEP) *versus* thulium fiber laser (ES-THUFLEP): outcomes on sexual function

A. Pacchetti, D. Perri, F. Mazzoleni, U. Besana, A. Paulesu, E. Morini, L. Berti, M.C. Sighinolfi, B. Rocco, E. Liatsikos, S. Micali, J. Romero-Otero, G. Bozzini (San Fermo della Battaglia, Como)

BACKGROUND: The aim of this study was to compare the effect on sexual function of ejaculation-sparing thulium laser enucleation of the prostate using thulium:YAG laser (ES-ThuLEP) *versus* continuous-wave thulium fiber laser (ES-ThuFLEP).

METHODS: One hundred twelve patients with lower urinary tract symptoms secondary to benign prostatic hyperplasia who wished to preserve ejaculation were treated by the same surgeon. 58 patients underwent ES-ThuLEP (group A, 51.8%) using the Cyber TM laser generator (Quanta System S.p.A., Milan, Italy). 54 patients underwent ES-ThuFLEP (group B, 48.2%) using the Fiber Dust laser generator. Sexual function was evaluated through the International Index of Erectile Function 5 (IIEF-5) Score preoperatively, and 3 and 6 months after surgery to assess changes in ejaculation and erectile function.

RESULTS: Mean age of patients was 65.8 years in group A and 66.7 years in group B. Groups were comparable according to preoperative features. Mean preoperative IIEF-5 Score was 18.8 in group A and 17.9 in group B (P=0.14). In all cases and ejaculation-sparing procedure was performed sparing the tissue around the *veru montanum* and near the prostate apex. A satisfactory ejaculation was subjectively reported by 42 patients after ES-ThuLEP (72.4%) and 40 patients after ES-ThuFLEP (74.1%) with no significant difference (P=0.11). Three months after surgery IIEF-5 Score was 16.9 in group A and 17.7 in group B (P=0.12) respectively. Six months after surgery IIEF-5 Score was 17.8 in group A and 18.1 in group B (P=0.09), respectively.

CONCLUSIONS: Ejaculation-sparing laser enucleation of the prostate effectively preserved sexual function in most patients, with high subjective satisfaction and no significant differences on erectile function and ejaculation before and after surgery. No significant differences were observed between ES-ThuLEP and ES-ThuFLEP. These treatments are equally effective alternatives for young and sexually active patients.

SMART (SC164-SC174)

Muscle invasive bladder cancer 2

SC164
Do all patients equally benefit from the enhanced recovery after surgery (ERAS) protocol after radical cystectomy?
SC165
Prospective evaluation of early and late complication of robot-assisted radical cystectomy with intracorporeal urinary diversion performed by mechanical stapler
SC166
Laparoscopic *vs.* robotic staplers for intestinal anastomosis in robotic radical cystectomy with urinary diversion: a comparative study
SC167
The Italian Radical Cystectomy Registry: intraoperative outcomes from more than 1000 robotic-assisted, laparoscopic, and open surgeries
SC168
Age represents the main driver of surgical decision making in patients candidate to radical cystectomy
SC169
Ileal conduit *versus* orthotopic neobladder urinary diversion in robot-assisted radical cystectomy: results from a multi-institutional series
SC170
Is YouTube a reliable source of information on urostomy? A contemporary analysis
SC171
How to deal with ileal segment during robot-assisted neobladder reconstruction? Opinions and suggestions of robotic experts from Agile and ERUS scientific working group
SC172
Impairment in activities of daily living assessed by the Barthel Index predicts adverse oncological outcomes after radical cystectomy for bladder cancer
SC173
Minimally invasive *vs.* open radical cystectomy in Northern Italy: a decadal analysis of population-based trends and outcomes
SC174
Stentless Florence robotic intracorporeal neobladder (FloRIN): a feasibility prospective randomized clinical trial

SC164
Do all patients equally benefit from the enhanced recovery after surgery (ERAS) protocol after radical cystectomy?

G. Avesani, G. Basile, R. Leni, C. Re, F. Pellegrino, P. Scilipoti, M. Longoni, D. Cannoletta, G. Gandaglia, A. Necchi, A. Salonia, A. Briganti, F. Montorsi, M. Moschini (Milan)

BACKGROUND: Enhanced recovery after surgery (ERAS) has been proposed as a multimodal perioperative care pathway after radical cystectomy (RC). Despite the clear benefits of ERAS, it is possible that not every patient will equally benefit from its application. Thus, we evaluated the impact of patients' comorbidity on postoperative recovery outcomes after RC in patients managed according to ERAS.

METHODS: We relied on a prospectively maintained database of patients treated with RC following ERAS recommendations between 2015-2022 at our tertiary referral center. A total of 21 ERAS items were evaluated for each patient. Comorbidity was assessed by the Age-Adjusted Charlson Comorbidity Index (ACCI). ACCI³6 identified patients with high preoperative comorbidity status. Patients who exceeded the median of time to autonomous liquid intake, oral diet, alvus recovery and deambulation were considered having a late recovery. Multivariable logistic regression (MLR) analyses assessed the impact of ACCI on postoperative patients' late recovery after adjusting for gender, type of urinary diversion, surgical approach, intraoperative complications and cT stage.

RESULTS: Overall, 573 patients were treated with RC. Overall median number of applied ERAS items was 14, while median ACCI was 6 (IQR: 5-7). A total of 210 (36.6%) and 363 (63.4%) patients had low and high comorbidity status according to ACCI, respectively. Patients with high ACCI were less frequently treated with neoadjuvant therapy and robot-assisted approach and had higher cT stage (all P<0.05). Furthermore, patients with high ACCI received more frequently ureterocutaneostomy (P<0.001) and ileal conduit (P=0.001) diversions rather than neobladder (P<0.001). Patients with high ACCI had more intraoperative complications (P<0.001), while no difference emerged in terms of overall postoperative complication and length of hospital stay (all P>0.05). Overall, median time to autonomous liquid intake was 2 (IQR 1-3) days, median time to oral diet was 4 (IQR: 3-5) days, median time to alvus recovery was 4 (IQR 4-5) days and median time to deambulation was 4 (IQR 3-4) days. No difference emerged among the aforementioned postoperative recovery outcomes among patients with low *vs.* high ACCI (all P>0.05). At MLR analyses, ACCI³6 was not a predictor of late autonomous liquid intake, oral diet, alvus recovery and deambulation (all P>0.05).

CONCLUSIONS: Among all patients following the ERAS protocol, those presenting higher preoperative comorbidity status do not have a higher risk of delayed postoperative recovery compared to healthier counterparts. ERAS protocol can be applied safely to this cohort of patients.

SC165
Prospective evaluation of early and late complication of robot-assisted radical cystectomy with intracorporeal urinary diversion performed by mechanical stapler

G. Cochetti, P. Alessio, S. Ciarletti, F. Pastore, G. Massa, M. Del Zingaro, L. De Angelis, E. Mearini (Perugia)

BACKGROUND: Radical cystectomy with pelvic lymph node dissection is the gold standard treatment for non-metastatic muscle invasive bladder cancer and recurrent high risk non muscle invasive one. For years, the traditional open approach was the only viable option. The widespread of robotic surgery led to its employment also in radical cystectomy to reduce complication rate and to improve the functional outcomes. Regardless of type of approach, radical cystectomy is a procedure with high morbidity and not negligible mortality. Data available in literature show the use of stapler seems to offer good functional and perioperative outcomes with acceptable rate of complications at 30 and 90 days after surgery and lower operative time. The aim of the study was to describe perioperative outcomes and complications associated with robotic radical cystectomy (RARC) with intracorporeal urinary diversion (ICUD) using mechanical stapler.

METHODS: From January 2015 to May 2021, 146 patients with muscle invasive or recurrent high risk non muscle invasive bladder cancer underwent RARC with lymph node dissection in our high-volume center. ICUD (ileal conduit or ileal Y-shaped neobladder according to the Perugia ileal neobladder) was performed in 126 patients. Patients with previous pelvic surgery for cancer, abdominal and pelvic radiation therapy, those without minimum follow-up of 12 months were excluded. Demographic features, perioperative outcomes (operative time [OT], estimated blood loss [EBL], length of stay [LOS]), early (≤30 days) and late (>90 days) postoperative complications according to Clavien□Dindo classification were prospectively recorded and then retrospectively analyzed. We also assessed the potential linear correlation between demographic, preoperative as well as perioperative features and the risk of postoperative complications.

RESULTS: Overall, 112 patients were enrolled. Intracorporeal orthotopic Perugia ileal neobladder was performed in 74.1% of cases while ileal conduit was performed in 25.9%. Mean OT, estimated intraoperative EBL, and LOS were 289 and 159.7 minutes, 390.6 and 186.2 mL and 17 and 9.8 days, for both techniques, respectively. Altogether, early minor, and major complications accounted for 26.7% and 10.8% according to Clavien-Dindo classification, respectively. Overall, late complications were 40.2%. Late major complications occurred in 5.4%. Late most common complications were hydronephrosis (11.6%) and urinary tract infections (20.5%). Stone reservoirs formation occurred in 2.7% of ileal neobladder. In the sub-analysis mean OT and EBL improved significantly after first 56 procedures. According to the statistical analysis, no demographic, preoperative and operative data correlated with the risk of complications.

CONCLUSIONS: RARC with stapled ICUD is safe and effective technique. Stapled Y-shaped neobladder did not increase complication rate. Our results could encourage the use of stapler to perform an intracorporeal ileal neobladder.

SC166
Laparoscopic *vs.* robotic staplers for intestinal anastomosis in robotic radical cystectomy with urinary diversion: a comparative study

E. Panio, C. Sighinolfi, T. Calcagnile, S. Assumma, M. Petix, A. Grasso, M. Sangalli, L. Sarchi, F. Turri, G. Bozzini, S. Micali, P. Dell'Orto, B. Rocco (Milan)

BACKGROUND: During robotic assisted radical cystectomy (RARC), latero-lateral intestinal anastomoses are perfor-

med to realize ileal conduit or neobladder as urinary diversions. To this purpose, conventional laparoscopic staplers have been used so far. Sureform™ staplers were recently developed as robotic instruments to fit the da Vinci Xi (Intuitive Surgical, Inc., Sunnyvale, CA, USA). They are provided with SmartFire technology, which makes automatic adjustments to the firing process to optimize the staple line, and a 120° degree of articulation able to reduce the need to pull the tissue towards the stapler. The aim of the study is to evaluate the effectiveness and ease-of-use of Sureform™ Xi (Intuitive Surgical, Inc.) compared to conventional laparoscopic staplers for ileal anastomosis during urinary diversion reconstruction.

METHODS: From June 2022 to February 2023, a total of 24 patients undergoing RARC with ileal diversion (20 males and 4 females) were retrospectively analyzed. For the robotic staplers, a 60-mm cutline length was used to divide the bowel, realize the first step of the latero-lateral anastomosis, and close the edge of the bowel anastomosis. A 45-mm cutline length was used to increase the depth of the latero-lateral approximation and anastomosis. Blue reloads (3.6 mm) were used in all cases. The series was compared with the last 11 procedures in which Ethicon's Echelon staplers were used, following the same characteristics of the robotic group (60- and 45-mm cutline length, blue reload 3.5 mm). To compare the effectiveness of robotic and laparoscopic staplers, we collected data about: 1) mean time to complete the intestinal step; 2) number of assistants required; 3) mean time dedicated to hemostasis of the cut lines; and 4) mean number of times the monopolar scissors should be introduced to enhance the hemostasis. All variables were compared trough parametric test (*t*-test for unpaired variables).

RESULTS: The characteristics of the patients were similar between the two groups. All surgeries were completed without intraoperative adverse events; bowel vascularization was tested through the infusion of indocyanine green and resulted adequate. No intestinal leak was recorded. Mean time of the intestinal step was significantly lower for robotic staplers (27 minutes *versus* 34 of the laparoscopic ones; P=0.03); hemostasis time was lower as well (42 and 96 seconds for robotic and laparoscopic staplers, respectively; P=0.07). Mean number of time a monopolar cauterization was required was lower for Sureform™ (0.2 +/-0.4 and 1 +/-0.7 for robotic and laparoscopic stapler, respectively; P=0.06). The support of an expert assistant was required in all cases of laparoscopic stapling whereas a resident assistant to change robotic instruments was enough for all the Sureform™ cases.

CONCLUSIONS: Despite the small sample size, the use of Sureform™ seems to improve the overall time and ease of intestinal anastomosis. Further studies are required to confirm these outcomes and to definitely state the stapling performance of this novel technology.

SC167
The Italian Radical Cystectomy Registry: intraoperative outcomes from more than 1000 robotic-assisted, laparoscopic, and open surgeries

D. De Marchi, L. Di Gianfrancesco, A. Crestani, A. Amodeo, P. Corsi, E. Miglioranza, G. Lista, C.G. Cargnel, F. Simonetti, A. Porreca (Castelfranco Veneto, Treviso)

BACKGROUND: The Italian Radical Cystectomy Registry (Registro Italiano Cistectomie – RIC) is based on a multicenter series of patients treated with radical cystectomy (RC) for bladder cancer to analyse outcomes.

METHODS: Data on RC and urinary diversion via open (ORC), laparoscopic (LRC), or robotic assisted (RARC) techniques from 28 Italian urological departments were collected in an observational, prospective, multicenter, cohort study. From January 2017 to June 2020 were included 1425 patients, despite the pre-established inclusion goal of 1000 patients. Categorical and continuous variables were analyzed with χ^2 test and t-test, respectively. All tests were two-sided, with a significance level set at P<0.05.

RESULTS: In RARCs, the overall median operative time was 390 minutes (IQR 335-465), while in ORCs (250, 217-309) and LRCs (292, 228-350) was 250 and 292 minutes, respectively (P<0.001). In RARCs, the Lymph node dissection (LND) was performed in 97.1% of cases, while in LRCs and ORCs was performed in 93.5% and 85.6%, respectively (P<0.001); moreover, in RARCs the extended-LND was performed in 61.6% of cases (2-fold more frequent compared to the other two approaches) (P<0.001). In RARCs, the neobladder was performed in more than one-half of cases. In RARCs, the median estimated blood loss (EBL) rate was 250 mL (IQR 165-400), while in LRCs and ORCs was 330 (200-600) and 400 (250-600), respectively (P<0.001); the intraoperative blood transfusion rates were 11.4%, 21.7% and 35.6% for RARCs, LRCs and ORCs, respectively (P<0.001). In 6.8% of RARCs there was the need of conversion to open surgery, while in LRCs the rate was 4.3%. We did not report statistically significant differences in the rate of intraoperative complications among the approaches (1.3%).

CONCLUSIONS: RARC approach is feasible, and the rate of perioperative complication is not differ compared to the other approaches. It is mandatory to continue in the collection of data in a multicenter manner.

SC168
Age represents the main driver of surgical decision making in patients candidate to radical cystectomy

P. Dell'Oglio, S. Tappero, A. Panunzio, A. Antonelli, G. Simone, C. Lonati, A. Olivero, F. Soria, P. Umari, C. Terrone, M. Moschini, E. Di Trapani (Milan)

BACKGROUND: Age might influence the choice of surgical approach, type of urinary diversion (UD) and lymph node dissection (LND) in patients' candidate to radical cystectomy (RC) for urothelial bladder cancer (UBC). Similarly, age may enhance surgical morbidity and worsen perioperative outcomes. The aim of this study was to test the impact of age (octogenarian *vs.* younger patients) on surgical decision making and peri- and postoperative outcomes of RC.

METHODS: Non-metastatic muscle invasive UBC patients treated with RC at 18 high-volume European institutions between 2006 and 2021 were identified and stratified according to age (≥80 *vs.* <80 years). ICARUS and EAU guidelines recommendations were accomplished in collection and reporting of, respectively, intraoperative, and postoperative complications. Multivariable logistic regression models (MVA) tested the impact of age on outcomes of interest. Sensitivity analyses after 1:3 Propensity Score Matching were performed.

RESULTS: Of 1955 overall patients, 251 (13%) were ≥80 years old. Minimally invasive RC was performed in 18 and 40% of octogenarian and younger patients, respectively

(P<0.001). UD without bowel manipulation (ureterocutaneostomy [UCS]) was performed in 31 and 7% of octogenarian and younger patients (P<0.001). LND was delivered to 81 and 93% of octogenarian and younger patients (P<0.001). At MVA, age ≥80 years independently predicted open approach (odds ratio [OR] 1.55), UCS (OR 3.70), and omission of LND (OR 0.41; all P≤0.02). Compared to their younger counterparts, octogenarian patients experienced higher rates of intraoperative (8 *vs.* 4%, P=0.04), but not of postoperative complications (64 *vs.* 61%, P=0.07). At MVA, age ≥80 years was not an independent predictor of length of stay, intraoperative or postoperative transfusions and complications, and readmissions (all P values >0.1). These results were replicated in sensitivity analyses.

CONCLUSIONS: Age ≥80 years does not independently portend worse surgical outcomes for RC. However, octogenarians are unreasonably more likely to receive open approach and UCS diversion, and less likely to undergo LND.

SC169
Ileal conduit *versus* orthotopic neobladder urinary diversion in robot-assisted radical cystectomy: results from a multi-institutional series

E. Vecchio, S. Tappero, P. Dell'Oglio, M.A. Cerruto, G. Simone, F. Soria, A. Antonelli, A. Briganti, F. Montorsi, O. de Cobelli, C. Terrone, A. Galfano, M. Moschini, E. Di Trapani (Genoa)

BACKGROUND: Head-to-head comparisons between ileal conduit (IC) *vs.* orthotopic neobladder (ONB) – in terms of peri- and postoperative outcomes and complications, in the specific setting of robot-assisted radical cystectomy (RARC) – are not available. In this study, we addressed the impact of type of urinary diversion (UD, IC *vs.* ONB) on RARC morbidity, as well as operative time (OT), length of stay (LOS), and readmissions.

METHODS: Urothelial bladder cancer patients treated with RARC at 9 high-volume European institutions between 2008 and 2020 were identified. Intraoperative and postoperative complications were collected and reported according to ICARUS recommendations and EAU guidelines, respectively. Multivariable logistic regression models (MVA) tested the impact of UD on outcomes, after adjustment for clustering at single hospital level. Covariates included UD reconstruction (intra- *vs.* extra-corporeal), age, Body Mass Index, Charlson Comorbidity Index, ASA Score, previous abdominal surgery, antiplatelet/ anticoagulant therapy, enhanced recovery after surgery (ERAS) protocol, clinical stage, and neoadjuvant chemotherapy.

RESULTS: Overall, 555 non-metastatic RARC patients were identified. In 280 (51%) and 275 (49%) patients, an IC and an ONB was performed, respectively. Eighteen intraoperative complications were recorded. According to EAU Intraoperative Adverse Events Classification (EAUiaiC), 11 (61%) intraoperative complications were of grade 1, and 5 (39%) of grade 2. Rates of intraoperative complications were 4% in IC patients and 3% in ONB patients (P=0.4). Median LOS and readmission rate were 10 *vs.* 12 days (P<0.001) and 20 *vs.* 21% (P=0.8) in IC *vs.* ONB patients, respectively. At MVA, type of UD (IC *vs.* ONB) reached the independent predictor status for prolonged OT (odds ratio [OR]: 0.61, P=0.03), and prolonged LOS (OR: 0.34, P<0.001), but not readmission (OR: 0.92, P=0.7). Overall, 513 postoperative complications were experienced by 324 patients (58%). At least one postoperative complication was experienced by 160 (57%) IC patients *vs.* 164 (60%) ONB patients (P=0.6). Type of UD (IC *vs.* ONB) reached the status of independent predictor of UD-related complications (OR: 0.64, P=0.03). Conversely, type of UD did not independently predict overall, early, and late postoperative complications (all P values >0.1).

CONCLUSIONS: RARC with IC seem to be associated with a reduction in the risk of UD-related postoperative complications, prolonged OT, and LOS relative to RARC with ONB.

SC170
Is YouTube a reliable source of information on urostomy? A contemporary analysis

G. Pezone, A. Fraia, S. Morra, C. Colla Ruvolo, L. Napolitano, R. La Rocca, G. Celentano, G. Califano, E. Di Mauro, M. Creta, F. Di Bello, C. Turco, S. Cili, A. Melchionna, F. Mangiapia, N. Longo, V. Mirone (Naples)

BACKGROUND: To evaluate the quality of YouTube (San Bruno, CA, USA) videos on urostomy and to investigate if they can be used as a reliable source of information.

METHODS: Six keyword combinations were searched on YouTube platform. The first 50 videos for each combination were selected. Patient Education Materials Assessment Tool for audio-visual content (PEMAT A/V), Global Quality Score (GQS) and DISCERN Score were used to assess videos' quality content. Pearson's test was used to assess potential correlations between variables.

RESULTS: Of all 300 videos, 89 were suitable for the analyses. The median PEMAT A/V Understandability Score and PEMAT A/V Actionability Score were 82% (interquartile range [IQR]: 67-92) and 100% (IQR: 67-100), respectively. According to GQS, 20 (22%), 47 (53%), 17 (19%), 3 (3%), and 2 (2%) videos were excellent, good, moderate, generally poor, and poor, respectively. The overall median Total DISCERN Score was 52 (IQR: 46-60). A positive statistically significant correlation was found between video length and video length and DISCERN Section 2 (r=0.31, P<0.05) and video length and Total DISCERN Score (r=0.22, P<0.05).

CONCLUSIONS: To date, the overall quality of YouTube videos on urostomy have been evaluated good according to PEMAT A/V. Moreover, most of the videos were evaluated excellent or good according to GQS. However, the DISCERN Score, exploring the treatment choices, recorded a non-optimal quality of YouTube videos on urostomy. Therefore, our observations suggest that YouTubevideos quality is good, but nevertheless they may not be considered as a reliable tool of information for patients, as they lack information to guide the patient in choosing the treatment.

SC171
How to deal with ileal segment during robot-assisted neobladder reconstruction? Opinions and suggestions of robotic experts from Agile and ERUS scientific working group

M.C. Sighinolfi, P. Wiklund, A. Minervini, A.E. Canda, J. Hubert, F. Annino, S. Terzoni, A. Celia, R. Bertolo, A. Crestani, R. Falabella, A. Galfano, F. Greco, C. Leonardo, A. Porreca, A. Kumar, R. Coelho, M. Sangalli, F. Turri, P. Dell'Orto, G. Bozzini, S. Micali, R. Gaston, S. Assumma, T. Calcagnile, B. Rocco (Milan)

BACKGROUND: Neobladder reconstruction after robotic-assisted radical cystectomy (RARC) is one of the most challenging steps, especially the choice of the best bowel segment, its reconfiguration and the approximation between ileal segment and urethral stump. The aim of the study was to describe tips and tricks to facilitate the drop down of the bowel toward the pelvis and to rate their importance according to experts' opinions.

METHODS: Questions about baseline demographics, annual caseload, approaches to RARC and opinions about how to overcome a difficult ileum-urethral stump approximation were collected and a cross-sectional survey were sent to 15 expert robotic surgeons (Agile Group and ERUS Scientific Working Group were addressed). With a 5-point Likert Scale, the experts evaluated the importance of each trick proposed (1 = very unimportant; 5 = very important). The online questionnaire was developed according to the Checklist for Reporting Results of Internet E-surveys. A descriptive analysis was then performed with the R 4.0 software (R Foundation for Statistical Computing, Vienna, Austria) with frequencies and percentages.

RESULTS: All questionnaires were completed. Cronbach's alpha (0.724) suggested high reliability and reproducibility of the answers under similar casuistry. Annual caseload for RARC was >21 procedure/year for 68% of responders. Six out of 15 surgeons (40%) have performed >100 robotic neobladders in their own career. The Studer reconfiguration was used by 7 surgeons (47%), the Bordeaux technique by 6 (40%), followed by VIP, Florence robotic intracorporeal neobladder (FloRIN) and Pitcher pot reconstruction. Twelve surgeons (80%) indicated ileo-urethral approximation with a tension-free anastomosis as the most challenging step. Among tricks to improve the drop down of the ileum, a posterior reconstruction is considered important (4-5 Likert point) by 60% (9/15) of the surveyed, followed by reduction of Trendelenburg (7/15, 47%) and performing small incisions in ileal mesentery to increase its length (7/15, 47%). Role of the bedside operator (4/15, 27%), opening the ileal segment before ileo-urethral anastomosis (3/15, 20%) and use of vessel loops around the ileum to facilitate the traction (1/15, 7%) are considered less important.

CONCLUSIONS: There are different tricks to improve ileum's descent toward the pelvis, and posterior reconstruction is the most quoted strategy to perform an easy, tension-free neobladder-urethral anastomosis. The standardization of the whole procedure is the key – according to experts' suggestions – to fix some issues and overcome those challenging steps emerging along with this complex surgical procedure.

SC172
Impairment in activities of daily living assessed by the Barthel Index predicts adverse oncological outcomes after radical cystectomy for bladder cancer

A. Panunzio, A. Gozzo, G. Mazzucato, P.I. Ornaghi, A. Soldano, N. De Maria, F. Cianflone, M. Boldini, G. Pettenuzzo, F. Montanaro, A.B. Porcaro, W. Artibani, V. Pagliarulo, M.A. Cerruto, A. Antonelli, A. Tafuri (Verona)

BACKGROUND: With the rapid aging of the population, frailty has become a challenging issue in healthcare, especially among patients with cancer, who are less prone to receive medical or surgical therapies, and more frequently develop postoperative adverse events as complications and early mortality. Among existing tools to screen patients for frailty, the Barthel Index (BI) is a validated aid to assess functional status through the measurement of patient level of independence in activities of daily living (ADL). In this study, we aimed to test whether an association between preoperative BI and oncological outcomes following radical cystectomy (RC) for bladder cancer (BCa) existed.

METHODS: We retrospectively analyzed data of patients with clinically non-metastatic BCa, who underwent RC between 2015 and 2022 at a single tertiary referral center, with available follow-up. The BI was preoperatively assessed by trained nurses; accordingly, patients were divided in two groups: BI≤90 (moderate/severe/total dependency in ADL) *vs.* BI=95-100 (slight dependency/independency in ADL). Kaplan-Meier plots depicted disease recurrence (DR)-, cancer-specific mortality (CSM)-, and overall mortality (OM)-free survival according to established categories. Multivariable Cox regression models tested the BI as an independent predictor of adverse oncological outcomes.

RESULTS: Overall, 262 patients were included. Median age was 70 years (interquartile range: 63-77). According to the BI, the patient cohort was distributed as follows: 19% (N.=50) BI≤90 *vs.* 81% (N.=212) BI=95-100. Compared to patients with BI=95-100, patients with BI≤90 were less likely to receive intravesical immunotherapy or chemotherapy (18% *vs.* 34%; P=0.028), and more frequently underwent less complex urinary diversion as ureterocutaneostomy (36% *vs.* 9%; P<0.001), or harbored muscle invasive BCa at final pathology (72% *vs.* 56%, P=0.043). At two-year, DR-free survival rates were 50% *vs.* 72% in respectively BI≤90 and BI 95-100 patient categories; corresponding CSM- and OM-free survival rates were 65% *vs.* 86%, and 56% *vs.* 77%, respectively (P<0.05 for all comparisons). In multivariable Cox regression models that also adjusted for age, American Society of Anesthesiologist' physical status score, urinary diversion type, major postoperative complications, pathological tumor and nodal stage, and surgical margin status, BI≤90 independently predicted higher DR (hazard ratio [HR]: 2.00; 95% confidence interval [CI]: 1.21-3.30; P=0.007), CSM (HR: 2.12; 95% CI: 1.12-3.99; P=0.021), and OM (HR: 1.72; 95% CI: 1.04-2.86; P=0.037).

CONCLUSIONS: Preoperative impairment in ADL was associated with adverse oncological outcomes following RC for BCa. Less access to care and delayed diagnosis due to functional disability and impaired antitumor response to cancer can be hypothesized among possible explanations and related mechanisms. The integration of the BI into clinical practice may improve the risk assessment of BCa patients' candidates to RC.

SC173
Minimally invasive *vs.* open radical cystectomy in Northern Italy: a decadal analysis of population-based trends and outcomes

E. Bonacina, C. Silvani, A. Li Puma, R. Di Benedetto, S. Guzzo, D. Vizziello, E. Finkelberg, P. Acquati, L.F. Carmignani (San Donato Milanese, Milan)

BACKGROUND: Despite the introduction of bladder-preserving treatment, radical cystectomy (RC) still represents the standard of care of muscle-invasive bladder cancer (MIBC). A significant interest in minimally invasive surgery (MIS) has arisen in the last two decades with an increase rate of robotic

and laparoscopic radical cystectomy. It has been suggested that in comparison with open radical cystectomy, MIS results in less blood loss, shorter length of stay (LOS) and fewer complications with equivalent short-term oncological outcomes; however, benefits of these techniques remain still uncertain. The aim of this study was to describe trends of radical cystectomy – including both laparotomic and minimally invasive surgery – in Lombardy (Northern Italy).

METHODS: Discharge records of patients undergoing radical cystectomy for bladder cancer in 2012-2021 were extracted from the regional archives of hospital discharges. Data on RC, surgical technique (open *vs*. laparoscopic or robotic) and type of urinary diversion were collected from intervention codes. For every procedure we also recorded age, sex, year of intervention, in-hospital mortality, and LOS.

RESULTS: Overall, 8487 cystectomies were performed in Lombardy from 2012 to 2021. Among patients 81.38% were male; median age was 72 (65-78) years. 663 procedures (7.81%) were performed with MIS (robotic or laparoscopic), with an increase of 11% from 2012-13 to 2020-21 (P<0.001). MIS rate gradually decreases from 14.97% in patients younger than 55 years to 4.65% in patients older than 80 years (P<0.001). MIS is associated with lower age at surgery (68 *vs.* 72; P<0.001), shorter LOS (12 *vs.* 16; P<0.001) and a higher rate of continent diversion choice (27.15% *vs.* 15.40%; P<0.001). In-hospital mortality rate in patient treated with open surgery appears higher than MIS (2.02% *vs.* 0.45%; P=0.0045). At the univariate analyses, increasing age, ileal conduit *vs.* continent diversion and ureterocutaneostomy *vs.* continent diversion were associated with MIS with an OR of 0.96/year (P<0.001), 0.44 (P<0.001) and 0.53 (P<0.001), respectively. At the multivariate analyses, after adjusting for age, all the variables previously described remain associated with open technique choice.

CONCLUSIONS: RC's number in northern Italy remains stable over last 10 years. MIS in Italy is increasing its weight and Lombardy represents the Italian region with the highest density of robotic platforms. Despite this, MIS appears to be still reserved to young patients with less comorbidities which obtain better outcomes. Nevertheless, given the aging of the population, traditional open RC continues to play a major role, particularly in elderly patients who are more likely to receive simpler urinary diversion. In the future, advancements in minimally invasive surgery technology, such as robotic platforms, may allow even older patients to benefit from these approaches with reduced complications and shorter hospital stays.

SC174
Stentless florence robotic intracorporeal neobladder (FloRIN): a feasibility prospective randomized clinical trial

L. Lambertini, F. Di Maida, A. Cadenar, S. Nardoni, A.A. Grosso, D. Paganelli, S. Coco, F. Valastro, A. Tuccio, G. Vittori, R. Fantechi, A. Mari, A. Minervini (Florence)

BACKGROUND: Several intracorporeal neobladders (ICNs) features transposed from the open surgery to the robotic experience still require an evidence-based validation. In this light, the benefits, and harms of stent placement duing the ICN configuration are still debated. The aim of our study was to evaluate the safety and the efficacy of stentless Florence robotic intracorporeal neobladder (FloRIN) compared to the stented procedure in a prospective randomized trial.

METHODS: Clinical and surgical data of all consecutive patients treated at our Institution from January 2021 to November 2022 with RARC, lymph node dissection (LND) and FloRIN reconfiguration were gathered in this single institution randomized 1:1 prospective series. For the present study, only patients with a minimum 6 month-follow-up were evaluated.

RESULTS: Overall, 93 patients were enrolled. Among these, 46 (49.5%) and 47 (50.5%) had RARC and stentless or stent FloRIN, respectively. No differences were found in terms of baseline characteristics between the two groups. Median reported age was 68 (IQR 59-77) and 67 (IQR 57-78) years while median BMI was 28 (IQR 24-33) and 27 (IQR 24-28) kg/m^2 in the stentless and stent group, respectively. Stentless group had significant shorter console time 314 (IQR 284-345) *vs.* 345 (IQR 321-387) minutes (P=0.04) as compared to the stent group. Moreover, a shorter LOS stay was found in stentless group, 9 (IQR 7-13) *vs.* 13 (IQR 12-15) days (P=0.04). Conversely, no significant differences emerged in terms of time to canalization (P=0.51) and time to drainage removal (P=0.23). Regarding postoperative symptoms occurrence, no differences were recorded between the two groups with VAS≥3 flank pain recorded in the 14.2% and 15.1% of patients within the stentless and the stent group, respectively (P=0.23). Similarly, the ureteral management did not affect the early and delayed postoperative complications rate. In particular, early postoperative complications Clavien ≥3a occurred in 5 (11.1%) and 7 (13.8%) patients among the stentless and the stent placement group, respectively (P=0.28). Similarly, at a median follow-up of 13 (IQR 7-17) months, major delayed complications were recorded in 4 (8.2%) and 7 (14.8%) patients, respectively (P=0.07) with no differences recorded in term of changes in renal function between baseline and 3-, 6- and 12-month evaluation (P=0.15, P=0.18, and P=0.24, respectively). Regarding the early and delayed readmission rate, no differences emerged among groups with a 30-days rate of 6.2% and 9.6% (P=0.66) and a 90-days rate of 3.1% and 3.2% (P=0.65) in the stentless and stent groups, respectively.

CONCLUSIONS: In conclusion, FloRIN stentless configuration confirmed worthy perioperative and mid-term functional outcomes compared to the stented procedure. Further series with longer functional follow-up assessment are still needed to confirm our preliminary results.

SMART (SC175-SC181)

Testicular cancer

SC175
Sexual complications following post chemotherapy unilateral robot-assisted retroperitoneal lymph node dissection for non-seminomatous germ cell tumors
SC176
Overall survival of stage III non-seminoma testicular germ-cell tumor patients *vs.* simulated age-matched male population-based controls, according to race/ethnicity
SC177
Differences in future life expectancy of testicular germ-cell tumor patients *vs.* age-matched male population-based controls
SC178
Clinical evaluation of the role of 371 miRNA in stage I small testicular masses: preliminary results of the "S1STEM 371" trial
SC179
Is it unilateral minimally invasive retroperitoneal lymph node dissection the best option for upfront surgery in stage II germ cell tumors?
SC180
Higher testosterone serum levels are associated with a higher childbirth in patients treated for testicular cancer
SC181
Unilateral postchemotherapy robot-assisted retroperitoneal lymph node dissection in stage II non-seminoma testicular tumors: a tertiary care experience

SC175
Sexual complications following post chemotherapy unilateral robot-assisted retroperitoneal lymph node dissection for non-seminomatous germ cell tumors

A. Tufano, D. Franzese, A. Izzo, R. Muscariello, L. Castaldo, G. Quarto, F. Passaro, G. Grimaldi, G. Spena, P. Del Prete, S. Perdonà (Naples)

BACKGROUND: The aim of our study was to report sexual and reproductive outcomes following unilateral postchemotherapy robot-assisted retroperitoneal lymph node dissection (PC-rRPLND) for non-seminomatous germ cell tumors (NSGCT) at a high-volume cancer center.

METHODS: From January 2018 to November 2021, we obtained information regarding sexual and reproductive outcomes of patients following unilateral PC-rRPLND for stage II NSGCT. A unilateral lymph node dissection template was used for all patients according to those previously described. Preoperative and postoperative (12 months) erectile function of each patient was assessed basing on the International Index of Erectile Function-5 (IIEF-5) and Erection Hardness Score (EHS). Only patients with a preoperative International Erectile Function Score-Erectile Function (IIEF-EF) of ≥22 and Erection Hardness Score (EHS) of ≥3 were included in this analysis.

RESULTS: Overall, 22 patients undergoing unilateral PC-rRPLND met the inclusion criteria. Of those, 7 (31.8%) patients presented an andrological disorder of any type after PC-rRPLND. Specifically, retrograde ejaculation was present in 3 (13.6%) patients and hypospermia was present in 1 (4.5%) patient. Moreover, 3 (13.6%) patients yielded erectile disfunction ED (IIEF-5<22 and/or EHS<3). Lastly, 2 (9.1%) attempted to have a child after PC-rRPLND and all had successfully fathered children.

CONCLUSIONS: In our series retrograde ejaculation confirms to be one of the most common complications of PC-rRPLND. Moreover, a non- negligible number of patients experienced ED. In consideration of curability rate of testicular cancer and the life expectancy of testicular cancer survivors the identification and the prevention of andrological complications is of upmost importance.

SC176
Overall survival of stage III non-seminoma testicular germ-cell tumor patients *vs.* simulated age-matched male population-based controls, according to race/ethnicity

S. Morra, C. Cano Garcia, M.L. Piccinelli, S. Tappero, F. Barletta, R. Incesu, L. Scheipner, A. Baudo, Z. Tian, V. Mirone, G. Califano, G. Celentano, F. Saad, N. Longo, P. Karakiewicz (Naples)

BACKGROUND: It is unknown whether five-year overall survival (OS) differs and to what extent between the American Joint Committee on Cancer stage III non-seminoma testicular germ-cell tumor (NS-TGCT) patients and simulated age-matched male population- based controls, according to race/ethnicity groups.

METHODS: We identified newly diagnosed (2004-2014) stage III NS-TGCT patients within Surveillance Epidemiology and End Results database 2004-2019. For each case, we simulated an age- and sex-matched control (Monte Carlo simulation), relying on Social Security Administration (SSA) Life Tables with five years of follow-up. We compared OS rate between stage III NS- TGCT patients and simulated age-matched male population-based controls, according to race/ethnicity groups (Caucasian, Hispanic, Asian/Pacific Islander, and African American). Both, cancer-specific mortality (CSM) and other-cause mortality (OCM) were computed.

RESULTS: Of 2054 stage III NS-TGCT patients, 60% were Caucasians *vs.* 33% Hispanics *vs.* 4% Asians/Pacific Islanders *vs.* 3% African Americans. Five-year OS difference between stage III NS-TGCT patients *vs.* simulated age-matched male population- based controls was highest in Asians/Pacific Islanders (64 *vs.* 99%, Δ=35%), followed by African Americans (66 *vs.* 97%, Δ=31%), Hispanics (72 *vs.* 99%, Δ=27%), and Caucasians (76 *vs.* 98%, Δ=22%). Five-year CSM rate was highest in Asians/ Pacific Islanders (32%), followed by African Americans (26%), Hispanics (25%) and Caucasians (20%). Five-year OCM rate was highest in African Americans (8%), followed by Caucasians (4%), Asians/Pacific Islanders (4%), and Hispanics (2%).

CONCLUSIONS: Relative to SSA Life Tables, the highest five-year OS disadvantage applied to stage III NS-TGCT Asian/Pacific Islander race/ethnicity group, followed by African American, Hispanic, and Caucasian, in that order.

SC177
Differences in future life expectancy of testicular germ-cell tumor patients *vs.* age-matched male population-based controls

S. Morra, M.L. Piccinelli, C. Cano Garcia, S. Tappero, F. Barletta, R. Incesu, L. Scheipner, A. Baudo, Z. Tian, V. Mirone, G. Califano, C. Colla' Ruvolo, S. Shariat, O. De Cobelli, G. Musi, F. Chun, C. Terrone, A. Briganti, D. Tilki, S. Ahyai, L. Carmignani, N. Longo, P. Karakiewicz (Naples)

BACKGROUND: It is unknown whether five-year overall survival (OS) differs and to what extent between testicular germ-cell tumor (TGCT) patients and age-matched male population-based controls.

METHODS: We identified newly diagnosed (2004-2014) TGCT patients within Surveillance Epidemiology and End Results database 2004-2019. We compared OS between non-seminoma (NS-TGCT) and seminoma (S-TGCT) patients relative to age- matched male population-based controls based on social security administration lifetables. Smoothed cumulative incidence plots displayed cancer-specific mortality (CSM) *vs.* other-cause mortality (OCM).

RESULTS: Of all 20,935 TGCT patients, 43% had NS-TGCT and 57% had S-TGCT. Of NS-TGCT patients, 63% were stage I *vs.* 16% stage II *vs.* 21% stage III. Of S-TGCT patients, 86% were stage I *vs.* 8% were stage II *vs.* 6% stage III. Five-year OS differences between NS-TGCT patients *vs.* age-matched male population-based controls were 97 *vs.* 99% (Δ=2%) for stage I, 96 *vs.*99% (Δ=3%) for stage II, 76 *vs.* 98% (Δ=22%) for stage III. Five-year OS differences between S-TGCT patients *vs.* age-matched male population-based controls were 97 *vs.* 98%(Δ=1%) for stage I, 95 *vs.* 97%(Δ=2%) for stage II, 87 *vs.* 98%(Δ=11%) for stage III. OCM rates ranged from 1 to 3% in NS-TGCT patients and from 2 to 4% in S-TGCT patients.

CONCLUSIONS: The OS difference between NS-TGCT patients *vs.* age-matched male population-based controls was invariably higher across all stages (2 to 22%) than for S-TGCT patients (1 to 11%). Reassuringly, OCM rates were marginal in stage I and stage II patients. Conversely, higher OCM rates were recorded in stage III patients.

SC178
Clinical evaluation of the role of 371 miRNA in stage I small testicular masses: preliminary results of the "S1STEM 371" trial

S. Nazzani, B. Valentina, A. Macchi, S. Stagni, T. Torelli, A. Tesone, L. Cattaneo, E. Tamborini, F. Perrone, I. Capone, E. Conca, A. Busico, D. Biasoni, M. Catanzaro, E. Montanari, N. Nicolai (Milan)

BACKGROUND: The primary aim of the study was to test the ability of 371 miRNA kit (M371-test, CE approved) to predict the presence or not of germ cells tumors (GCTs) in patients with small testicular lesions.

METHODS: This is a prospective study that explores if 371 miRNA blood testing with Mir-detect predicts presence of GCTs in small testicular masses. We recruited 9 patients with small testicular masses ranging between 5 and 20 mms. Patients with presence of distant disease or previous diagnosis of cancer were excluded. All patients had 371 miRNA blood testing before surgical exploration. The results of presurgery 371 miRNA were compared to definitive pathological specimen to test the role of 371 miRNA kit in diagnosing GCTs in this specific setting.

RESULTS: Median age was 39 years old (interquartile range [IQR]: 27-56) and number of lesions were 1 in six (66.7%) patients, 2 in two patients (22.2%) and 3 in one patient (11.1%). Median lesion size was 15 mm (IQR: 9-16). Six patients had left testicular lesions (66.7%) and 3 had right testicular lesions (33.3%), respectively. At definitive pathology 6 patients (66.7%) had seminoma, one had leyomioma, one fibrosis and one capillary hemangioma. In case of seminoma, pT stage was pT1a in 4 patients and pT1b or pT2 in one patient each. Median 371 miRNA relative expression was 280.50 (IQR: 211.00-737.75) in patient with GCTs and 2.00 (IQR: 1.50-9.00) in patients without GCTs. Of note, pT2 (1857) and pT1b (858) patients had the highest 371 miRNA relative expression. Finally, capillary hemangioma patients had a miRNA relative expression of 16 that is considered indicative of GCTs according to previous data. However, all patients with GCTs in our preliminary experience had a miRNA relative expression higher than 100.

CONCLUSIONS: According to our preliminary experience the miRNA 371 kit showed promising result in detecting GCTs in small testicular lesions.

SC179
Is it unilateral minimally invasive retroperitoneal lymph node dissection the best option for upfront surgery in stage II germ cell tumors?

S. Nazzani, V. Bernasconi, D. Sessa, A. Macchi, S. Stagni, A. Tesone, T. Torelli, L. Cattaneo, R. Lanocita, T. Cascella, B. Avuzzi, M. Claps, P. Giannatempo, D. Biasoni, M. Catanzaro, N. Nicolai (Milan)

BACKGROUND: Primary retroperitoneal lymph node dissection (RPLND) is an option for negative marker stage IIA non-seminomatous germ cell tumors (NSGCTs). In low volume (<3 cm) negative marker stage IIB NSGCTs and in stage IIA-B (<3 cm) seminomatous GCTs it should be also considered within institutional studies or prospective trials. Evidence supporting approach and extent of dissection are lacking. According to institutional therapeutic and diagnostic pathways we can evaluate perioperative and oncological outcomes of minimally invasive primary unilateral RPLND in stage II A/B NSGCTs and SGCTs.

METHODS: Between 2008 and 2023 included, 46 selected stage II germ cell tumors (GCTs) patients underwent primary unilateral laparoscopic (L-)RPLND. Node count, histology, hospital stay, complications (according to Clavien-Dindo), administration of chemotherapy, relapse and site of relapse were evaluated.

RESULTS: Eight (17.4%) patients had pure seminoma, 4 (8.7%) had moderately elevated markers prior to RPLND. Thirty-eight (82.6%) and eight (17.4%) were clinical stage IIA and IIB, respectively. Median clinical nodal size was 16 mms (interquartile range [IQR] 12-20 mms). Overall median operative time was 180 minutes (IQR 160-225). Median number of removed nodes was 17 (IQR: 12-23) and median number of positive nodes was 1 (IQR: 1-2). Median hospital stay was 3 days (IQR: 3-4). Out of 6 complications (12%), we recorded two grade III complications according to Clavien-Dindo classification (lymphocele requiring drainage). Definitive histology revealed viable non-seminoma in 26 (56.5%), viable seminoma in 8 (17.4%) and postpubertal teratoma in 2 (4.3%). Pathological stage was I in 9 cases (all clinical stage marker negative) (19.6%), IIA in 24 (52.2%), IIB in 11 (23.9%) and IIC in 2 (4.3%). Three patients underwent immediate adjuvant chemotherapy consisting of 2 courses of BEP. After a median follow-up of 29 months, 36 (78.3%) of 46 patients undergoing L-RPLND alone remained recurrence-free; one patient had an in-field recurrence following a left dissection. All relapsed patients were rescued with first-line chemotherapy and all patients are currently alive and disease-free.

CONCLUSIONS: These findings pertain a high-volume center and are consistent with the emerging thought that unilateral primary L-RPLND is effective and safe in relatively selected stage II NSGCT and SGCT. More data are needed to assess formal applicability of this choice as an alternative within a referral center.

SC180
Higher testosterone serum levels are associated with a higher childbirth in patients treated for testicular cancer

L.M. Rovesti, R. Lombardo, L. Sarcinelli, G. Guarnotta, C. Gravina, A. Tubaro, A.L. Pastore, A. Carbone, Y. Al Salhi, G. Tuderti, A. Brassetti, G. Simone, C. De Nunzio (Rome)

BACKGROUND: The aim of our study was to assess fertility in patients treated with orchifunicolectomy for testicular cancer.

METHODS: A retrospective analysis of patients undergoing orchifunicolectomy for testicular cancer was conducted in 3 centers from 2000 to 2019. Demographic, clinical, and histological characteristics of the patients were recorded. Adjuvant treatments were recorded. Number of pregnancies, number of children, cryopreservation, *in-vitro* fertilization

was recorded as well as postoperative testosterone serum level. Risk factors for pregnancy were evaluated. Univariate and multivariate analysis were performed to evaluate factors influencing pregnancy rates.

RESULTS: Overall, 271 patients were enrolled with a median age of 31 (25/35) years and a median BMI of 25 (23/28 kg/m²). Overall, 187 of 271 (69%) presented a seminoma, 61 of 271 (22%) presented advanced stage (≥pT2), 4 of 271 (1%) presented metastasis, 13 of 271 (5%) underwent lymphadenectomy. 112 of 271 (41%) underwent adjuvant chemotherapy and 35 of 271 (13%) underwent adjuvant radiotherapy. 71 of 271 (26%) patients had at least one child, 165 of 271 (60%) performed cryopreservation, 9 of 271 (3%) performed fertilization *in vitro* and out of them 8 of 9 (89%) had at least 1 child. Patients with at least 1 child presented higher levels of testosterone and performed more often *in-vitro* fertilization. On multivariate analysis testosterone levels (OR=1.94; 95% CI:1.35-2.80, P=0.001) were associated with a higher probability of having a child after testicular cancer surgery.

CONCLUSIONS: In our experience, patients undergoing testicular cancer surgery have 25% probability of having a child. Higher testosterone levels increase the probability of having a child in patients treated for testicular cancer.

SC181
Unilateral postchemotherapy robot-assisted retroperitoneal lymph node dissection in stage II non-seminoma testicular tumors: a tertiary care experience

D. Franzese, A. Tufano, A. Izzo, G. Grimaldi, P. Del Prete, R. Muscariello, G. Quarto, L. Castaldo, G. Spena, R. Autorino, G. Pezone, S. Perdonà (Naples)

BACKGROUND: Postchemotherapy retroperitoneal lymph node dissection (PC-RPLND) represents an integral component of the management of patients with non-seminomatous germ cell tumor (NSGCT). Modified templates have been proposed to minimize the surgical morbidity of the procedure. Moreover, the implementation of robotic surgery in this setting has been explored. The aim of this study was to report our experience with unilateral template robot-assisted PC-RPLND (PC-rRPLND) for clinical stage IIA/B NSGCT.

METHODS: A retrospective single-institution review was performed including 33 patients undergoing PC-rRPLND for stage IIA/B NSGCT between January 2015 and February 2019. Descriptive statistics were provided for demographics, clinical characteristics, intraoperative and postoperative parameters. Perioperative, oncological, and functional outcomes were recorded.

RESULTS: Overall, 7 patients (21.2%) exhibited necrosis/fibrosis, 14 (42.4%) had mature teratoma, and 12 (36.4%) had viable tumor at final histology. The median operative time was 180 min (IQR: 165-215) and no major postoperative complications were documented. Anterograde ejaculation was preserved in 78.1% of patients. Median follow-up was 26 months (IQR: 19-30). A total of two lung recurrences were identified, and one death was recorded.

CONCLUSIONS: PC-rRPLND is a reliable and technically reproducible procedure with safe oncological outcomes and acceptable postoperative ejaculatory function in well-selected patients with NSGCT.

SMART (SC182-SC193)

Upper tract urothelial cancer

SC182
Follow-up intensity scheme for patients with upper tract urothelial carcinoma after endoscopic conservative management

SC183
The importance of second look ureteroscopy implementation in the conservative management of upper tract urothelial carcinoma

SC184
Assessing postoperative morbidity after retrograde/anterograde ureteroscopy for upper tract urinary cancer management using the EAU quality criteria for standardized reporting

SC185
Does endoscopic kidney sparing management of UTUC affect long-term renal function? Results from a large single center series

SC186
Role of inflammatory markers and Frailty Index as predictors of adverse pathological stage and complications in patients with upper urinary tract urothelial cancer: a multicenter analysis

SC187
The added value of systematic biopsies in the diagnosis and characterization of upper tract urothelial cancer

SC188
Urological follow-up and mutational patterns in Lynch Syndrome patients: a single center experience

SC189
Role of upper urinary tract urothelial cell carcinoma localization in bladder carcinoma

SC190
Prognostic impact of variant histologies in patients with clinical localized upper urinary tract urothelial carcinoma

SC191
Holmium:YAG *versus* thulium:YAG laser in endoscopic ablation of upper tract urothelial carcinoma: a comparison on perioperative outcomes and short-term follow-up

SC192
Machine learning and upper tract urothelial cancer: proposal and validation of prediction model of prognosis after nephroureterectomy

SC193
Complications predictive analysis following robot-assisted or pure laparoscopic nephroureterectomy in patients with upper urinary tract urothelial carcinoma

SC182
Follow-up intensity scheme for patients with upper tract urothelial carcinoma after endoscopic conservative management

G. Basile, A. Gallioli, A. Martini, A. Territo, P. Verri, F. Sanguedolce, A. Tedde, J.M. Gaya, A. Uleri, P. Gavrilov, F. Algaba, J. Palou, A. Breda (Barcelona)

BACKGROUND: The EAU Guidelines on upper tract urothelial carcinoma (UTUC) have been implemented to provide separate recommendations on oncologic surveillance for low- and high-risk UTUC after endoscopic conservative management. This study aimed to investigate the most appropriate oncologic surveillance scheme in both low- and high-risk UTUC after conservative treatment.

METHODS: We relied on a prospectively maintained database of patients who underwent endoscopic conservative management for UTUC between 2015-2021. Patients were followed up in compliance with the EAU guidelines. The crude risks of bladder cancer (BCa) and UTUC recurrences over time were evaluated against time from primary endoscopic treatment with the Locally Weighted Scatterplot Smoothing method. The risk of recurrence at the time points when imaging should be de- intensified according to the EAU guidelines was estimated. Kaplan-Meier method was used to investigate the difference in BCa recurrence-free survival (BCa-RFS) and UTUC-RFS between patients with previous BCa *vs.* no previous BCa in both low- and high-risk patients.

RESULTS: Overall, 54 and 55 patients had low- and high-risk diseases, respectively. In low-risk cohort, after a median follow-up of 46.9 (IQR 28.7-68.7) months, 11 (20.4%) and 9 (16.7%) patients experienced BCa and UTUC recurrence, respectively in low-risk group. Furthermore, 1 (1.8%) and 5 (9.2%) patients underwent RC and radical nephroureterectomy (RNU), respectively, while 3 (5.6%) patients had UTUC-related death. In high-risk cohort, after a median follow-up of 36.9 (19.8- 60.1) months, 18 out of 49 (36.7%) patients and 21 (38.1%) patients experienced BCa and UTUC recurrence, respectively. Furthermore, 3/49 (6.1%) and 24 (43.6%) patients underwent RC and RNU, respectively, while 5 (9%) patients experienced UTUC-related death. In low-risk patients, BCa recurrence risk was more than 20% at 24-month follow-up. At 60 months, time point after which cystoscopy and imaging should be interrupted, the risk of BCa recurrence and UTUC recurrence were 14% and 7%, respectively. In high-risk patients, the risk of BCa and UTUC recurrence at 36 months was approximately 40% and 10%, respectively. Conversely, at 60 months, the risk of bladder recurrence and UTUC recurrence was 28% and 8%, respectively. Finally, no statistically significant difference emerged in terms of BCa-RFS and UTUC-RFS in both low- and high-risk patients according to previous history of BCa (all P>0.05).

CONCLUSIONS: According to our results, for low-risk patients, cystoscopy should be performed semi-annually until 24 months, while upper tract assessment should be obtained up to 60 months, as per current EAU guidelines recommendations. For high-risk patients, upper tract assessment should be intensified to semi-annually up to 36 months after surgery, then obtained yearly. Conversely, cystoscopy should be ideally performed semi-annually until 60 months and yearly thereafter.

SC183
The importance of second look ureteroscopy implementation in the conservative management of upper tract urothelial carcinoma

A. Gallioli, G. Basile, A. Territo, P. Verri, J.M. Gaya, F. Sanguedolce, J. Aumatell, A. Tedde, A. Uleri, P. Diana, J. Huguet, F. Algaba, J. Palou, A. Breda (Barcelona)

BACKGROUND: Second-look ureteroscopy (SU) has been investigated in the endoscopic work-up of patients with upper-tract urothelial carcinoma (UTUC) elected for conservative treatment. However, its effect on oncological outcomes is still uncharted. The aim of this study was to investigate the effect of SU on the oncological outcomes of patients diagnosed with UTUC, possibly identifying the appropriate timing for its execution.

METHODS: We retrospectively analyzed single-center data of patients who underwent SU between 2016-2021. First, we assessed the cancer detection rate (CDR) at SU, which was defined as the endoscopic visualization of a tumor. Second, the effect of positive vs. negative SU on recurrence-free survival (RFS), radical nephroureterectomy-free survival (RNU-FS), and cancer-specific survival (CSS) was estimated using the Kaplan-Meier method and compared using log-rank tests. Third, multivariable Cox-regression analyses (MVA) were used to identify factors independently associated with UTUC recurrence, the need for RNU, and cancer-specific mortality (CSM). Fourth, multivariable logistic regression (MLR) analysis tested for predictors of negative SU between age and tumor characteristics at first treatment. The secondary objective was the identification of the appropriate timing of SU execution after classifying SUs as "early" (£8 weeks) and late (>8 weeks).

RESULTS: Overall, 85 patients underwent SU. The CDR at SU was 44.7% and 78.9% had tumor recurrence in the same location as the primary treatment. After a median follow-up was 35 (IQR: 15-56) months, patients with positive SU had a higher rate of ipsilateral UTUC recurrence (47.4% *vs.* 19.1%; P=0.01) and were more frequently treated with RNU (34.2% *vs.* 8.5%, P=0.007), without significant difference in tumor-related mortality (10.5% *vs.* 4.3%; P=0.5). Accordingly, Kaplan-Meier survival analysis among patients with positive and negative SU revealed a statistically significant difference in 2-year RFS (P=0.001) and RNU-FS (P=0.002), while no difference emerged in terms of 2-year CSS (P=0.32). Patients with high-grade disease (hazard ratio [HR]: 3.14, 95% CI 1.18-8.31; P=0.02) had a higher risk of upper tract recurrence, while high-grade tumor (HR: 3.87; 95% CI1.08-13.77; P=0.04) and positive SU (HR: 4.56; 95% CI: 1.05-22.81; P=0.04) were both predictors of radical treatment. Low-grade tumors (odds ratio [OR]: 5.26; 95% CI: 1.81-17.07; P=0.003) and tumor dimension <20 mm (OR: 5.69; 95% CI: 1.48-28.31; P=0.01) were predictors of negative SU. Finally, no significant difference emerged regarding UTUC recurrence, RNU, and CSM between early *vs.* late SU (all P>0.05).

CONCLUSIONS: SU may help in selecting candidates for timely radical treatment in patients elected for conservative treatment of UTUC, guaranteeing the oncological safety of endoscopic management. SU can be safely performed within 3 months after primary treatment.

SC184

Assessing postoperative morbidity after retrograde/anterograde ureteroscopy for upper tract urinary cancer management using the EAU quality criteria for standardized reporting

P. Verri, G. Basile, A. Uleri, A. Tedde, A. Gallioli, A. Territo, F. Sanguedolce, J. Aumatell, J.M. Gaya, J. Palou, A. Breda (Barcelona)

BACKGROUND: Since the EAU panel on complications claimed a standardized methodology for complication reporting, it has never been adopted for ureteroscopy (URS) for upper tract urinary cancer (UTUC). We aimed to conduct a rigorous assessment of 30 days (30-d) complications according to the EAU guidelines and evaluate possible predictors of overall and specific types of complications and readmission.

METHODS: We relied on a prospectively maintained database of patients who underwent URS for UTUC suspicion at our tertiary care institution, between 2015-2021. Complications were graded with the Clavien-Dindo (CD) classification. Complications were classified as bleeding, infectious and genitourinary. Multivariable logistic regression (MLR) analyses tested for predictors of 30-d complications and for each of the different complication types among age, gender, ASA Score, tumor characteristics (dimension, focality, localization), treatment of UTUC and approach (retrograde *vs.* anterograde). Finally, MLR analysis tested for predictors of readmission after 30-d among different types of complication, tumor treatment and surgical approach.

RESULTS: Overall, we identified 575 cases of URS, of which 139 (24.2%) were operative. In 86 (14.9%) and 18 (3.1%) cases, patients experienced at least one complication and a major complication (CD≥3a), respectively. 26 (4.5%), 27 (4.6%) and 23 (4%) cases developed postoperative bleeding, infectious, and genitourinary complications, respectively. Patients developing 30-d complications were older (P<0.01), while no difference emerged in terms of preoperative morbidity status according to ASA Score, tumor characteristics, and treatment among those cases who developed complication *vs.* no-complication. At MLR analyses, tumor multifocality was the strongest predictor of overall 30-d (odds ratio [OR]: 1.86; 95% confidence interval [CI]: 1.05-3.38; P=0.04), bleeding (OR: 3.13; 95% CI: 1.19-7.66; P=0.01) and infectious (OR: 2.53; 95% CI: 1.14-6.08; P= 0.04) complications. Anterograde approach was a predictor of major complication (OR: 4.86; 95% CI: 1.30-14.74; P=0.008). Age was predictor of bleeding (OR: 1.08; 95% CI: 1.03-1.13; P=0.0001) and genitourinary complication (OR: 1.08; 95% CI: 1.02-1.15; P=0.006). Finally, bleeding (OR: 11.07; 95% CI: 1.78-57.92; P=0.005), infectious (OR: 9.46; 95% CI: 1.23-51.30; P=0.01) and anterograde approach (OR: 10.2; 95% CI: 2.12-44.93; P=0.002) were all predictors of patient readmission.

CONCLUSIONS: Complications after URS are not common events and rarely with severe sequelae (CD≥3a). Tumor multifocality and anterograde approach are the strongest predictors of complication development. The application of the EAU recommendations allowed the identification of a higher number of complications after URS if compared with previous reports based on unsupervised charts review.

SC185

Does endoscopic kidney sparing management of UTUC affect long-term renal function? Results from a large single center series

J. Aumatell, A. Uleri, P. Verri, G. Basile, A. Gallioli, A. Territo, P. Gavrilov, F. Sanguedolce, S. Fontanet, J. Huguet, J. Palou, A. Breda (Barcelona)

BACKGROUND: The relation between renal function and radical nephroureterectomy is extensively studied while the impact of multiple ureteroscopies in the contest of an endoscopic kidney sparing treatment of the upper tract urothelial carcinoma (UTUC) remains an unstudied topic. The aim of this study was to investigate 3-year renal function outcomes in patients affected by UTUC treated with repeated ureteroscopies (≥2 procedures)

METHODS: Clinical and pathological data of patients underwent ureteroscopy (URS) at our institution were prospectively collected from 2015 to 2020 at our institution. CKD-EPI formula was used to estimate glomerular filtration rate (eGFR). The postoperative complications were reported and classified according to Clavien-Dindo classification. Chronic kidney disease (CK) upstaging was defined as stage migration starting from stage 2 CKD (*i.e.*, 1-2 to 3, 3 to 4, 4 to 5)

RESULTS: One hundred twelve patients were treated with 2 or more URS for a total of 322 URS. Of these, 54 (48%) patients were submitted to three or more URS. Median age was 74 (65-80) and age adjusted Charlson Comorbidity Index 6 (4-7). Twenty-four (7%) experienced postoperative complications and 6 (1.8%) Clavien-Dindo >2 occurred. 63 (56%) patients had a high-risk UTUC. Twenty- two (20%) patients underwent nephroureterectomy during follow-up. The median baseline eGFR was 65 (44-84) mL/min. Twenty-eight (26%) patients had a CKD upstage at last follow-up and the risk of CKD upstaging did not appear to be affected by the previous CKD stage >2 (P=0.13). The median eGFR at 5 years was 65 (44-85) mL/min with a median follow- up of 39 months (20-55). Six (5%) patients developed an end-stage renal disease. 2/66 (3%) and 4/46 (9%) patients had prior CKD stage ≤2 and ≥3, respectively (P=0.2). At Cox regression analysis the number of procedures did not appear to affect the risk of CKD upstaging (HR=0.89; 95% CI:0.65-1.22; P=0.48), conversely the age, ACCI, solitary kidney and a baseline CKD stage ≥3 were associated to the risk of developing CKD upstaging (P<0.05).

CONCLUSIONS: Endoscopic kidney sparing treatment of the UTUC does not significantly affect renal function at 3-year follow-up. A minority of patients (5%) developed de novo end-stage renal disease.

SC186

Role of inflammatory markers and Frailty Index as predictors of adverse pathological stage and complications in patients with upper urinary tract urothelial cancer: a multicenter analysis

C. De Nunzio, R. Lombardo, A.A. Cicione, G. Guarnotta, L. Sarcinelli, E. Mancini, O. Voglino, S. D'annunzio, A. Tufano, L. Costantino, S.R. Flammia, R. Papalia, F. Esperto, A. Brassetti, G. Simone, A. Claudio, R. Mastroianni, A. Cantiani, S. Signore, A. Tubaro (Rome)

BACKGROUND: The aim of this study was to assess patient frailty and inflammatory state as predictors of adverse pathological outcomes after nephroureterectomy for upper urinary tract cancer.

METHODS: We performed an analysis of prospectively collected data of consecutive patients undergoing nephroureterectomy or patrial nephrectomy in 5 primary care Italian urology centers. Charlson Comorbidity Score and Frailty Index was measured using a Simplified Frailty Index (sFI) with a 5-item score including: 1) diabetes mellitus; 2) functional status; 3) chronic obstructive pulmonary disease; 4) congestive cardiac failure; and 5) hypertension, with a maximum 5-item score meaning high level of frailty. Inflammatory status was evaluated with neutrophil/ lymphocyte ratio (NLR), monocyte to lymphocyte ratio (MLR), fibrinogen and albumin levels. Frailty and inflammatory markers were evaluated as risk factors of advanced pathological stage and complications using binary logistic regression.

RESULTS: A total of 128 patients was enrolled. Overall, 47/128 (37%) presented advanced disease (≥3a) and 28/128 (22%) presented a postoperative complication. Age (OR: 1.05; 95% CI: 1.00-1.07; P=0.045), PLR (OR: 1.48; 95% CI: 1.02-2.13; P=0.035) and fibrinogen levels (OR: 1.01; 95% CI 1.00-1.01; P=0.010) were predictors of adverse pathological outcomes. PLR (OR: 1.54; 95% CI: 1.05-2.25; P=0.026; P=0.035) and fibrinogen levels (OR: 1.01; 95% CI 1.00-1.01; P=0.002) were predictors of complications. However, Frailty Index, NLR, MLR and albumin were not predictors of adverse pathological outcomes nor complications.

CONCLUSIONS: In patients undergoing surgery for UTUC, fibrinogen and PLR are predictors of adverse pathological outcomes and complications. Further studies should assess the role of these markers in the management of patients with UTUC.

SC187
The added value of systematic biopsies in the diagnosis and characterization of upper tract urothelial cancer

A. Gallioli, G. Basile, A. Territo, P. Verri, J.M. Gaya, F. Sanguedolce, J. Aumatell, A. Tedde, A. Uleri, J. Huguet, F. Algaba, J. Palou, A. Breda (Barcelona)

BACKGROUND: An accurate diagnosis of upper tract urothelial tumor (UTUC) is crucial. In this regard, the employment of ureteral systematic biopsies (USB) has never been considered. The aim of this study was to investigate the safety and clinical usefulness of USB in the diagnosis of UTUC and its impact on disease management.

METHODS: We relied on a prospectively maintained database of patients who underwent diagnostic ureteroscopy (URS) for a suspicious UTUC at our tertiary care institution, between 2015-2021. USB consisted of at least 2 biopsies in each of the upper tract portion: pelvis, proximal, medium, and distal ureter. Perioperative complications were graded using the Clavien-Dindo (CD) classification. First, we assessed the surgical safety of USB compared with those who no underwent USB. Second, the diagnostic impact of USB was assessed, and Kaplan-Meir method estimated the 2-year nephroureterectomy free-survival (NFU-FS) according to USB results. Third, Cox regression model investigated the added value of USB over the variables depicting a high-risk tumor according to EAU prognostic model. Finally, uni- and multivariable logistic regression (MLR) analyses investigated preoperative predictors of positive USB.

RESULTS: Overall, 91 out of 360 (25.3%) patients underwent USB. Compared to patients who did not undergo USB, USB does not increase the risk of overall perioperative and major (CD >3a) complications, nor the risk of readmission (all P>0.05). USB resulted positive in 43 (47.25%) cases, while negative in 30 (33%) patients. Overall, we 58 out of 300 (19.3%) biopsies were not diagnostic. In 36 (39.5%) patients were performed both USB and biopsy of a suspicious lesion. In 7 (19.4%) cases, USB outperformed the biopsy of the lesion in detecting UTUC. 11 (12%) patients were diagnosed with a distal ureter tumor. In 5 (45.4%) cases USB detected UTUC in other upper tract portions. The 2-year NFU-FS rates were 87.7% (95 CI%: 78.1-98.5) *vs.* 53% (95% CI: 39.4-71.2) (P=0.001) for negative USB *vs.* positive USB patients. At Cox regression model accounting for predefined variables, patients with positive USB (*vs.* negative) had a higher risk of being treated with NFU (hazard ratio [HR]: 3.38; 95% CI: 1.46-7.80; P=0.004]). At MLR analysis, after adjusting for age, preoperative positive cytology, smoking status, previous bladder cancer and previous UTUC, patients with negative preoperative CT scan had a higher probability of having a positive USB (odds ratio: 8.36; 95% CI: 1.57-71.18; P=0.02).

CONCLUSIONS: The addition of USB in the diagnostic pathway of UTUC is a safe procedure and in one out of five patients detected a non- visible tumor at URS. The presence of positive USB strongly increases the risk of radical treatment for UTUC and possibly changing the treatment algorithm in almost half of the candidates for distal ureterectomy. In case of suspicious UTUC, patients with preoperative negative CT scan could benefit the most from this procedure.

SC188
Urological follow-up and mutational patterns in Lynch Syndrome patients: a single center experience

P. Scilipoti, M. Longoni, C. Re, G. Rosiello, A. Bertini, M. de Angelis, G. Gandaglia, E. Ventimiglia, U. Capitanio, A. Salonia, F. Montorsi, A. Briganti, M. Moschini (Milan)

BACKGROUND: Lynch Syndrome (LS) is a genetic dominant autosomal disease that predisposes to a broad spectrum of tumors, among which upper tract urothelial carcinoma (UTUC) is the third most common manifestation. We present the first results of our LS dedicated outpatient clinic with the aim of evaluating the incidence of UTUC, patterns of mutation and individuate the optimal follow-up schemes among patients affected by LS.

METHODS: We observed 23 LS patients from December 2021 to October 2022 at a tertiary referral center. We collected prospectively data regarding LS mutations, medical and family history and simultaneously started a strict follow-up strategy. Genetic diagnosis was obtained both by Immunohistochemistry (IHC) and by genetic test (DNA sequencing). For each patient we applied Bethesda, EAU Guidelines, Amsterdam I and II criteria. Follow-up stra-

tegy was based on ultrasound (US), urinalysis and urinary cytology every two years. In high-risk cases (age >50 years, MSH2 mutation carriers and family history of UTUC) CT-scans where alternated with US every year in addition to urinary cytology.

RESULTS: Among this court 52.2% of patients (N.=12) had a LS diagnosis after cancer manifestation, meanwhile 47.8% (N.=11) through genetic counseling due to investigation in first degree relatives. Among our patient population, 8 patients (34.8%) had a diagnosis of colorectal cancer, 4 (17.4%) UTUC, 1 (4.3%) endometrial, 1 (4.3%) gastric, 1 (4.34%) skin cancer and 2 rare LS related cancer (Renal Clear Cell Carcinoma and Lung Cancer). MSH2 mutation was detected in 39.1% of cases (N.=9), while MLH1 was found in 34.8% of cases (N.=8). In subgroup analysis colorectal cancer's most common mutation was MSH2 (50%) followed by MLH1 (25%) and MSH6 (25%), while among UTUC cases, MSH2 was the most common (75%) and MLH1 was reported in 25% of cases. Median age at UTUC diagnosis was 60, while median age at colorectal cancer diagnosis was 49 (P=0.007). Bethesda and EAU guidelines criteria were more accurate (91% *vs.* 90%) compared to Amsterdam I and II criteria (74%). No tumor diagnosis was made during the observational time.

CONCLUSIONS: The current study is a first attempt to establish a dedicated LS outpatient clinic. This will let us observe the most frequent mutations, thus potentially in the future allow us to diagnose UTUC earlier and provide a refined follow-up to LS patients.

SC189
Role of upper urinary tract urothelial cell carcinoma localization in bladder carcinoma

D.F. Colatorti, S. Marzio, D. Mizio, S. Forte, A.M. Capurso, G. Lippolis, S. Soldano, L. Rella, P. Ditonno, G. Lucarelli (Bari)

BACKGROUND: The aim of this study was to analyze the relationship between the ureteral tract involved by Upper urinary tract urothelial cell carcinoma (UUT- UCC) and concomitant bladder cancer (BC) or bladder recurrence. UUT-UCC is a pan-urothelial disease of the transitional epithelial cells that may involve the lower and the upper urinary tract. Although several studies have shown the association of bladder recurrence following UUT-UCC, little is known about the association between the different site of upper urinary tract involved by UUT-UCC and concomitant BC or bladder recurrence in patients with UCC in different site of upper urinary tract.

METHODS: A retrospective study of patients diagnosed and treated for UUT-UCC was per- formed. We investigated age, sex, location of the upper tract tumor (calyx-renal pelvis, upper ureter, lower ureter), multifocality, stage and tumor grade. Contingency tables and χ^2 test were used for categorical variables and analysis of variance (ANOVA) for quantitative variables. Multivariate analysis was performed using logistic regression.

RESULTS: One hundred fifty-one patients eligible for inclusion were identified. Of these, 84 (55.6%) presented primary UUT-UCC with no story of BC, 67 (44.4%) presented UUT-UCC with concomitant and/or recurrent oBC. Location of primary UUT-UCC was in calyx and/or renal pelvis in 46 patients (54.8 %), upper ureter 25 (29.7 %) and lower ureter 13 (15.5 %). Location of UUT-UCC in patient with concomitant or recurrent BC was found in 18 (26.9%), 23 (34.3%), and 26 (38.8%) patients with primary caliceal/renal pelvis, upper ureter, and lower ureter UUT-UCC, respectively. On multivariate analysis, the location of UUT-UCC in the distal ureter was the only predictive factor for the presence of concomitant or recurrent bladder tumor (OR=2.27; 95% CI: 1.47- 3.51; P=0.0002).

CONCLUSIONS: Our findings suggest that the probability of concomitant and/or recurrent BC in primary diagnosed patient with UUT-UCC is in strictly associated with the UUT localization, becoming progressively higher as the upper tract tumor involves the distal tract of ureter.

SC190
Prognostic impact of variant histologies in patients with clinical localized upper urinary tract urothelial carcinoma

I.A. Iachimovs.ky, C. Bignù, O. Runti, G. Rossin, L. Ongaro, F. Traunero, A. Piasentin, A. Biasatti, M. Barbiero, F. Vedovo, G. Liguori, C. Trombetta, R. Bussani, F. Claps (Trieste)

BACKGROUND: The presence of variant histology (VH) in upper tract urothelial carcinoma (UTUC) is recognized as high-risk feature by the European Association of Urology (EAU) Guidelines. Treatment options for UTUC are represented by radical nephroureterectomy (RNU) or kidney-sparing surgery (KSS) if feasible in well-selected cases. The aim of this study was to evaluate the incidence, clinical and pathological characteristics of VH UTUC after the stable introduction of the novel World Health Organization (WHO) classification and to determine the prognostic effect on survival outcomes in patients who underwent RNU or KSS.

METHODS: We relied on a prospectively maintained database of 101 patients with clinical-localized UTUC who underwent surgical resection from January 2016 to June 2022 in a tertiary referral center. VHs were defined according to the WHO 2016 criteria. Pathology review was conducted by a single dedicated uropathologist. We included data from patients treated with RNU or KSS as per distal or segmental ureterectomy. We compared patients with pure urothelial carcinoma (UC) and patients with VH regarding their preoperative data, clinicopathological findings and oncological outcomes. Cox' regression models were developed to analyze the impact of VH compared to pure UC on oncological outcomes in terms of hazard ratio (HR) with 95% confidence interval (CI). The Kaplan-Meier method was used to estimate cancer-specific survival (CSS), recurrence-free survival (RFS) and overall survival (OS) stratified by histological pattern.

RESULTS: Of all UTUC cases, 71 had pure UC (70.3%), whereas 30 (29.7%) harbored a VH. A trend towards a growing incidence of VHs was described. VH entities were 12 squamous (40% of VH cases), 1 (3.3%) micropapillary, 4 (13.2%) microcystic, 2 (6.6%) clear-cell, and 11 (36.7%) poorly differentiated. VHs were associated with advanced tumor-stage (pT2 16.7%, pT3 33.3%, pT4 30%) and adverse features compared to pure UC such as high-grade disease (76.7% *vs.* 16.9%), tumor multifocality (23.3% *vs.* 19.7%), tumor necrosis (23.3% *vs.* 2.8%), lymphovascular invasion (46.7% *vs.* 9.9%), lymph-node metastasis (29.9% *vs.* 5.6%)

and positive surgical margins (6.6% *vs.* 2.8%) (all P<0.05). Development of bladder cancer recurrence was higher in the VH group compared to pure UC (13.2% *vs.* 7%). At Cox' regression analyses VHs were associated with poor survival outcomes considering CSS (HR: 3.95; 95% CI: 1.55-10.1; P=0.004), RFS (HR: 2.93; 95% CI: 1.30-6.59; P=0.01), and OS (HR: 2.44; 95% CI: 1.24-4.79; P=0.009).

CONCLUSIONS: In this single-center pilot experience, almost one out of three cases of UTUC harbored a VH. Compared to pure UC, VHs were associated with worse CSS, RFS, and OS in patients with UTUC treated with either RNU or KSS. Accurate pathological detection of VH is a mandatory step that may ensure a tailored counselling and adequate risk-stratification by improving both an individualized treatment and follow-up algorithm.

SC191
Holmium:YAG *versus* thulium:YAG laser in endoscopic ablation of upper tract urothelial carcinoma: a comparison on perioperative outcomes and short-term follow-up

E. Morini, D. Perri, U. Besana, F. Mazzoleni, A. Pacchetti, L. Berti, M. Corinti, M.C. Sighinolfi, B. Rocco, S. Micali, J. Romeno-Otero, J.B. Roche, A.L. Pastore, G. Bozzini (Como)

BACKGROUND: The holmium-YAG (Ho:YAG) laser is the most widely used laser in urology for both the treatment of stones and soft tissues. However, the thulium-YAG (Tm:YAG) laser has become a reliable alternative for soft tissue treatment. The aim of our study was to increase evidence on the safety and efficacy of endoscopic management of upper tract urothelial carcinoma (UTUC) with the Ho:YAG and Tm:YAG lasers.

METHODS: One hundred eleven patients with a diagnosis of low-risk UTUC were enrolled. Exclusion criteria comprised patients with a bilateral or multifocal disease and use of antiplatelet/anticoagulant therapy. In all cases a preoperative computed tomography (CT) scan was performed with evidence of contrast-enhanced solid tissue inside the upper urinary tract. In all cases indication to ureteroscopy was given to confirm diagnosis and to perform biopsy. Endoscopic laser ablation was decided with respect to EAU guidelines recommendations: unifocal disease, tumor size <2 cm, negative or low-grade cytology, low-grade biopsy and no invasive aspect on CT. Laser ablation was performed with Tm:YAG and Ho:YAG in 62 (group A, 55.9%) and 49 (group B, 44.1%) patients respectively. Three months after surgery CT scan and ureteroscopy were performed. Afterwards, CT scan was performed every 6 months.

RESULTS: Mean tumor size was 18.1 mm. Tumor was localized in the renal calyxes in 30 cases (27.0%), in the renal pelvis in 41 cases (37.0%) and inside the ureter in 40 cases (36.0%). Preoperative features were comparable between the two groups. Mean operative time was 18.2 min and 21.7 min in groups A and B respectively (P=0.09). Mean hemoglobin drop at first postoperative day was 0.8 g/dL and 0.6 g/dL in groups A and B (P=0.10). However, despite hemoglobin drop was not significantly different between the two treatments, a more consistent bleeding and a lower visibility were subjectively reported with the use of holmium laser. At a median follow-up of 42.3 months, we observed a local recurrence in 12 patients (19.3%) in group A and 18 (36.7%) patients in group B (P=0.02).

CONCLUSIONS: Despite perioperative outcomes were comparable between groups, a higher recurrence rate was observed after UTUC ablation with Ho:YAG laser. Lower intraoperative bleeding and better intraoperative vision were subjectively reported during surgery. These features along with a higher vaporization effect with Tm:YAG laser may explain our results.

SC192
Machine learning and upper tract urothelial cancer: proposal and validation of prediction model of prognosis after nephroreterectomy

R. Nicoletti, N. Ho Cho-lik, L. Hsiang-Ying, W. Wu, E. Laukhtina, P. Spatafora, R. Campi, M. Gacci, G. Giannarini, P. Gontero, N. Vasdev, C.A. Ng, C. Li, W. Li, H. Ke, H. Yeh, S. Shariat, T. Choi, J. Teoh (Florence)

BACKGROUND: The European association of Urology (EAU) suggests a prognostic stratification of UTUC based on high and low risk patients, with Radical nephroureterectomy (RNU) and bladder cuff resection being the gold standard for the treatment of non-metastatic High risk UTUC. However, no consensus on postoperative patient management or tools that predict who would benefit the most from a close follow-up rather than a cisplatin-based postoperative adjuvant chemotherapy regimen exist. Machine learning (ML) is gaining interest in urology providing models for prognostic prediction purpose; Its role in upper tract urothelial cancer (UTUC) has not yet been investigated. The aim of our study was to develop and validate multiple supervised machine-learning models based on patient- and tumor-related features to predict prognosis in patients with preoperative Histological or Imaging proved UTUC treated with RNU.

METHODS: A total of 3129 patients with histologically proven UTUC underwent NFU were enrolled, and data collected in two multicenter international datasets: 637 Asian Patients were used as training cohort and 2492 European patients as validation cohort. We built 20 predictive models using supervised learning algorithms to predict overall survival (OS), cancer specific survival (CSS) and disease-free survival (DFS) at 3 and 5 years using both patient-related (age and gender) and tumor related (grading according to WHO 1973 classification for patient enrolled before 2004 and to the WHO 2004 classification for patients enrolled after 2004, pT, pN, presence of CIS, multifocality and lymphovascular invasion) features. We evaluated and compared the performance of each prediction model using Area-under-curve (AUC) of receiver-operating characteristics (ROC).

RESULTS: LR models achieved the best results, being the best model for prediction of 4/6 outcomes, with better result in CSS both at 3 and 5 years, with a AOUC of 0,8495 (95% CI 0.7839-0.9159) and 0.0,8375 (95% CI 0.7680-0.9070). Overall, LR models seems to achieve the best results, being the number 1 model for prediction of 4/6 outcomes (5-year OS, 3- and 5-year CSS and 3-year DFS) and number 2 on the other 2/6 outcomes (3-year OS and 5-year DFS).

CONCLUSIONS: ML is a promising technology also in the field of UTUC. Our model performs better than all existing nomograms in terms of prediction of CSS: further clinical validation is needed for its use in clinical practice.

SC193
Complications predictive analysis following robot-assisted or pure laparoscopic nephroureterectomy in patients with upper urinary tract urothelial carcinoma

S.D. Pandolfo, M. Ferro, M. Tozzi, G. Simone, G. Tuderti, V. Mirone, E. Checcucci, A. Minervini, A. Mari, A. Antonelli, A. Veccia, A. Aveta, G. Spena, C. Massimiliano, L. Napolitano, N. Longo, C. Imbimbo, A. Franco, P. Verze, G. Lucarelli, C. Cerrato, Z. Wu, F. Fusco, C. Manfredi, F. Porpiglia, R. Autorino (Naples)

BACKGROUND: The aim of this study was to identify predictive complication risk factors of upper tract urothelial carcinoma (UTUC) after minimally invasive (laparoscopic or robotic assisted) nephroureterectomy (MIRNU).

METHODS: We performed a multicenter, retrospective analysis of 1492 patients with UTUC who underwent MIRNU at 13 institutions across the United States, Europe, and Asia. Multivariate regression models were used to identify predictive factors for complication. We considered different risk factors, including patient characteristics (age, Body Mass Index [BMI], American Society of Anesthesiologists [ASA]), tumor related factors (high risk *vs.* low risk), and surgery related factors (operative time, estimated blood loss [EBL]). Three different model for overall, major postoperative complication (≥ Clavien-Dindo III) and 30-days readmission rate, were assessed.

RESULTS: A total of 1492 (821 = robot assisted; 671 = laparoscopic) patients were included in analysis. Overall, 798 (53.5%) of patients developed (any grade) complications. There were 565 (37.9%), 179 (11.9%), 31 (2.1%), 11 (0.7%), and 12 (0.8%) in grade I, II, III, IV, V respectively. On multivariable analysis for overall postoperative complications, age (OR: 1.02; CI: 1-1.03; P=0.015), ASA Score (≤2) (OR: 0.12; CI: 0.03-0.48; P=0.002), BMI (≤30) (OR: 0.93; CI: 0.9-0.96; P<0.001), high risk disease (OR: 3.8; CI: 1.001-1.004; P= 0.013), and EBL (OR: 1.003; CI: 1.001-1.004; P<0.001) were significant. When considering major complication, high risk disease (OR: 6.76; CI: 1.12-40.5; P=0.03) was the only predictor of perioperative complications. Considering 30-day readmission rate, age (OR: 1.02; CI: 1-1.03; P=0.01), ASA (≤2) (OR: 0.2; CI: 0.045-0.9; P=0.03), BMI (<30) (OR: 0.93; CI: 0.8-0.9; P<0.001), and EBL (OR: 1.003; CI: 1.002-1.003; P<0.001) were associated with an increased risk.

CONCLUSIONS: Patient related factors, cancer risk category and surgery related factors can play a role in the risk of complications after MIRNU. When it comes to high grade complications, high risk disease seems to be the most relevant factor. Risk of 30-day readmission seems to be driven by both patient characteristics and surgery related factors (EBL) with a lower BMI and ASA Score having a protective effect against this risk.

SMART (SC194-SC202)

Ureteral stenoses

SC194
Analysis of risk factors for the prediction of postoperative benign uretero-enteric anastomotic strictures following radical cystectomy and ileal conduit

SC195
SIS graft bulbar urethroplasty is a viable technique: results compared to buccal mucosa graft urethroplasty after Propensity Score Matching

SC196
Time for double-J (DJ) indwelling ureteral stent removal following primary or salvage pyeloplasty in us adult patients is affected by demographic and perioperative factors: results from a large population- based cohort analysis

SC197
Feasibility and outcomes of temporary bulbar urethral stents after internal urethrotomy from the largest multicenter series

SC198
Vesical mucosa: new graft for ureteroplasty

SC199
Intra- *vs.* postoperative repair of ureteral lesions secondary to other specialties surgeries: a single center experience

SC200
Complex proximal ureteral stenosis treated by 3D augmented reality robot-assisted segmental ureterectomy and buccal mucosa graft

SC201
Robot-assisted buccal mucosal graft (BMG) ureteroplasty for the treatment of ureteral strictures

SC202
Outcomes of robot-assisted buccal mucosa graft ureteroplasty with the assistance of intraoperative flexible ureteroscopy and indocyanine-green fluorescence

SC194
Analysis of risk factors for the prediction of postoperative benign uretero-enteric anastomotic strictures following radical cystectomy and ileal conduit

M. Campetella, F.P. Bizzarri, F. Gavi, E. Scarciglia, A. Cretì, F. Bellavia, C. Gandi, M. Ragonese, F. Marino, P. Russo, F. Pinto, N. Foschi, A. Totaro, G. Palermo, R. Bientinesi, M. Racioppi, E. Sacco (Rome)

BACKGROUND: Benign uretero-enteric anastomosis stricture (UAS) is a significant complication described in 3-15% of patients undergoing radical cystectomy (RC) and urinary diversion with ileal conduit. In this paper we examined the risk factors predicting the incidence of UAS with the greatest accuracy.

METHODS: All consecutive patients undergoing RC and urinary diversion from October 2018 to December 2020 were retrospectively included in the study. Preoperative, intraoperative and follow-up data were recorded. Follow-up was based on imaging (CT-scan or ultrasound) and blood tests (serum creatinine and principal electrolytes). Patients with hydronephrosis and radiologic evidence of UAS (unilateral or bilateral) on a contrast-study were included in the research. Patients with disease recurrence and malignant UAS were excluded from the study.

RESULTS: In total 115 patients were included in the study. At 24-month mean follow-up, 22 patients (19.1%) were diagnosed with benign UAS, 50% of UAS were on the left side (11 patients). Median time from RC to diagnosis of benign UAS was 6 months. On multivariate analysis, previous abdominal surgery (PAS) had the strongest association with shorter time to stricture development (OR: 3.19; 95% CI: 0.4-1.7; P<0.05) and a 6-fold increased risk to develop UAS (OR: 6.41; 95% CI: 2.16-21.1; P<0.001). Also, male gender, age, Body Mass Index, lower albumin serum level and albumin/fibrinogen ratio were statistically significant in predicting UAS (P<0.05). Neutrophil to lymphocyte ratio was not statistically associated to UAS development (P>0.05).

CONCLUSIONS: The incidence rate of UAS following urinary diversion after radical cystectomy was relatively high. Having a history of PAS significantly increases the risk of strictures formation. Moreover, older patients, obese patients, male patients and patients with preoperative lower albumin serum level and lower albumin/fibrinogen ratio are more likely to develop UAS.

SC195
SIS graft bulbar urethroplasty is a viable technique: results compared to buccal mucosa graft urethroplasty after Propensity Score Matching

E. Palminteri, S. Toso, M. Preto, L. Gatti, O. Sedigh, N.M. Buffi, G. Ferrari, A. Gobbo (Turin)

BACKGROUND: Tissue-engineered grafts have been used as an alternative to conventional grafts to overcome some possible hindrances, such as donor-site morbidity and time-consuming harvesting. SIS graft urethroplasty (SISU) has been employed in humans to decrease buccal mucosa morbidity and facilitate the procedure. Despite some promising reports, the published series suffer from short follow-up (FU), inhomogeneous patients, and a lack of a control group. The aim of this study was to report for the first time the outcomes of bulbar SISU directly compared to a buccal mucosa graft urethroplasty (BMU) Propensity Score matched cohort, using survival analysis.

METHODS: From our institutional database of 1132 bulbar urethroplasties, 25 BMU and 25 SISU cases were selected using Propensity Score Matching with nearest neighbor without replacement. The matching variables were age, stricture length, and history of urethrotomy. Failure was defined as any treatment after urethroplasty, and data were censored at 156 mo. Survival analyses were used to analyze treatment failure occurrence.

RESULTS: Matching resulted in a complete correction of bias between the two samples, except for the FU duration, which was slightly longer in the SIS group (125 *vs.* 156 mo). At a median FU of 156 mo, 8/17 SISU and 4/21 BMU failed. At Kaplan-Meier analysis, the cumulative treatment success probability of BMU and SISU at 156 mo was 83.4% and 68%, respectively. At multivariable Cox regression, SIS graft, previous urethrotomy, stricture length, and lower postoperative Q_{max} (within 2 mo after catheter removal) were predictors of failure. Stricture length had a more remarkable effect on treatment success in patients undergoing SISU, with an estimated survival probability from the Cox model lower than 80% in strictures ≥3 cm. On the contrary, BMU had an estimated success consistently higher than 90%.

CONCLUSIONS: This propensity score-matched study has the longest FU and the greatest sample of bulbar SISU available. Using the first postoperative uroflowmetry result to identify patients at risk of failure is a useful and readily available measure for tailoring FU. Our findings suggest that the best candidates for SISU, with outcomes comparable to BMU, are patients with strictures shorter than 3cm, preferably without a history of DVIU. Overall, SISU is a viable technique in selected patients, particularly when BMU is not feasible.

SC196
Time for double-J (DJ) indwelling ureteral stent removal following primary or salvage pyeloplasty in us adult patients is affected by demographic and perioperative factors: results from a large population- based cohort analysis

V. Asero, C.M. Scornajenghi, P. Dipinto, E. De Berardinis, A. Sciarra, S. Basran, M.L. Eisenebrg, B.I. Chung, F. Del Giudice (Rome)

BACKGROUND: Our study aimed to investigate trends and predictors influencing early *vs.* later DJ stent removal and compare DJ stenting *vs.* stentless pyeloplasty in US adults.

METHODS: Patients aged ≥18 years with primary UPJO undergoing open, or minimally invasive pyeloplasty were identified from the IBM Marketscan (IBM Corp., Armonk, NY, USA) research de-identified databases from 2007 to 2021. Time to DJ stent removal was explored using Kaplan-Meier estimates. Postoperative complications, direct health-related costs, and re-intervention rates between DJ stented *vs.* stentless cohorts were compared. Multivariable models were used to ascertain outcomes.

RESULTS: A total of 3851 (N.=731 open; N.=3120 laparoscopic) primary pyeloplasty procedures were identified, with median DJ stent removal at 1,5 months (IQR: 0.4-256.9). Higher Charlson Comorbidity Index, shorter hospital stays,

and the choice of minimally invasive surgery were independent predictors for shorter DJ stenting time to removal. Postoperative adverse events were rare (N.=218, 4.5%) and not associated with the choice of surgical approach or stenting (odds ratio [OR]: 1,12; 95% confidence interval [CI]: 0.78-1.61; OR 1.19; 95% CI: 0.8-1.78, respectively). However, delayed time for DJ removal was a surrogate for increased risk of urinary non-infectious complications (N.=56, 1.5%; OR: 0.76; 95% CI: 0.50-1.16). Median cost for in-hospital charges was 5796 $ (IQR: 4320-8650 $), with DJ stent placement independently affecting the median aggregate amount (OR: 2.95; 95% CI: 2.35-3.71), but not when greater than the 75th percentile of total expense (OR: 1.10; 95% CI: 0.87-1.39). DJ stenting at the time of primary pyeloplasty found to be protective (OR: 1.40; 95% CI: 1.16-1.69).

CONCLUSIONS: DJ stent placement during pyeloplasty for UPJO in US adults is common but is not reducing 90-day postoperative morbidity or hospital budgets compared to stentless population, yet a median of 36 months of upper tract DJ stenting lowered the risk of any later re-operation, providing the latest evidence on DJ stent timing in the US after pyeloplasty. These results could aid in developing patient-centered risk stratification for future research on adverse events, including UPJO relapse and perioperative outcomes.

SC197
Feasibility and outcomes of temporary bulbar urethral stents after internal urethrotomy from the largest multicenter series

O. Sedigh, F. Sordelli, A. Gobbo, E. Dalmasso, M.H. Dashti, F. Bagheri, A. Shamsodini, Y. Alqattan, F. Soleimanzadeh, N. Buffi, P. Gontero, J. Hosseini (Rozzano, Milan)

BACKGROUND: Permanent urethral stents were developed more than 30 years ago aiming to find an easy solution for urethral strictures. Initial promising experiences were progressively revisited due to a high rate of challenging complications. Years later a new generation of urethral stent was designed but for a temporary adjuvant use. Large series with detailed analysis of adverse events are still lacking, as well as evidence-based indications for stent placement. We report complications and outcomes from the largest case history available of self-expandable, metallic, silicone-covered urethral stents.

METHODS: We performed a retrospective analysis of patients affected by urethral stricture who underwent UVENTA stent placement after direct vision internal urethrotomy (DVIU) for bulbar strictures in 7 different centers from 2016 to 2019. Patients included underwent stent placement as a first treatment or after the failure of previous treatments (urethral dilations, DVIU, urethroplasties, etc.). The indications were patients unwilling to undergo urethroplasty, seeking less invasive treatments before eventually undergoing urethroplasty, or unfit for surgery. All strictures were evaluated by retrograde and voiding cystourethrography. Stents were removed after at least 6 months unless events that required earlier removal occurred. Success was defined as no further urethral procedures after stent removal. All cases were managed according to the principles of the Declaration of Helsinki.

RESULTS: One hundred forty-nine patients underwent bulbar stent placement, 6 were lost during FU and were excluded from the analysis. Overall, 89.5% (N.=128) of the stents were removed after at least 6m while 10.5% (N.=15) were removed earlier due to complications. The median FU was 38.2m (IQR: 30.1-45.8) with an overall success of 76.9% (N.=110/143). Patients who removed the stent earlier than 6m had a higher probability of treatment failure (46.7% *vs.* 20.3%, P=0.022), and the result was confirmed at ULRM (OR=3.43, P=0.028, CI 1.14-10.33). No other factors were predictors of treatment outcome. Kaplan Meier's estimate by the timing of removal showed a significant difference in treatment-success cumulative probability (P=0.026): the success probability was 79.7% in case of removal after at least 6m and 53.3% in case of removal before 6m. Cox regression confirmed a significant HR (removal before *vs.* after 6 m: HR 2.4, P=0.039, CI 1.04-5.57) with a valid proportional hazard assumption.

CONCLUSIONS: Temporary urethral stents may be a safe choice with satisfying results in patients not undergoing urethroplasty. A stent indwelling time shorter than 6 m provides worse outcomes, comparable to DVIU-only.

SC198
Vesical mucosa: new graft for ureteroplasty

E. Dalmasso, A. Giordano, E. Alessandria, R. Aimar, G.F. Oppezzi, P.I. Ornaghi, F. Pini, I. Morra (Cuneo)

BACKGROUND: The aim of this study was to show the use of bladder mucosa graft for robotic ureteroplasty.

METHODS: We present the first two cases in which we used bladder mucosa graft to treat ureteral strictures by robotic ureteroplasty. The first patient – a female who underwent several procedures for urinary stones – presented iatrogenic stricture of the right distal ureter. Furthermore, stricture length was about 2 cm. In this case, ureteroplasty was preferred to reimplantation to keep the orthotopic meatus for future endoscopic procedures. The second patient was a female patient who underwent robotic anterior resection of the rectum and adjuvant chemotherapy for rectal cancer. Seven months later, right hydronephrosis complicated by sepsis was found. Imaging and subsequent ureteroscopy showed a stricture longer than 3 cm on the iliac vessels. Surgical technique: patients and trocars were placed in the standard position for robotic pelvic surgery (Da Vinci Xi; Intuitive Surgical, Inc., Sunnyvale, CA, USA). Ureter was dissected and the stricture was found and measured by mean of ICG and ureteroscopy. Regarding bladder patch harvest, stenotic ureter was measured, and an area of the same size was marked on the posterior aspect of the bladder. Peritoneum was opened and the fat and muscle layers were removed identifying mucosa. Mucosal patch was finally harvested. Bladder defect was closed by running sutures on two layers. As far as ureteral reconstruction is concerned, two stitches were passed to secure the patch to the distal and proximal ends of the defect; the edges of the ureter and the patch were anastomosed in running fashion using 3-0 PDS on a double J catheter.

RESULTS: Surgeries lasted 180 and 171 minutes. Postoperative course of the first patient was uneventful, whereas patient 2 experienced hematuria requiring blood transfusion (Clavien Dindo II). Bladder catheter was removed 5 and 11 days later. Double J was removed 4 and 5 weeks later. Patients 1 underwent successful ureteroscopy for stone removal 4 months later. Patient 2 has no dilatation 2 months after stent removal. Both patients did not report voiding problems

CONCLUSIONS: Bladder mucosa is an interesting graft for ureteral reconstruction due to the excellent urothelial match. Harvest is easy and fast if stricture is located in the medium and distal part of the ureter whereas different port

placements or endoscopic retrieval are necessary in case of upper strictures. During reconstruction bladder patched proved resistant e distensible allowing an easy suture. Further cases are required to show the real efficacy and the long-term functional results.

SC199
Intra- *vs.* postoperative repair of ureteral lesions secondary to other specialties surgeries: a single center experience

F. Montanaro, S. Costantino, P.I. Ornaghi, R. Orlando, G. Pettenuzzo, F. Artoni, A. Bianchi, M. Balzarro, E. Rubilotta, R. Rizzetto, M.A. Cerruto, A. Veccia, A. Antonelli (Verona)

BACKGROUND: The aim of this study was to compare outcomes of intra *vs.* postoperative repair of ureteral lesions performed during other specialties surgeries.

METHODS: The analyzed subjects were patients who underwent intra- *vs.* postoperative ureteral lesions repair secondary to other specialties surgeries between 2017 and 2022. Baseline, intraoperative, postoperative, and functional outcomes were assessed. Median and interquartile range and frequencies and percentages were used for continuous and dichotomous variables, respectively. Mann-Whitney U-Test and Fisher's Exact Test were adopted to compare the two groups. According to the number of events, univariable logistic regression analysis was performed to assess the variables associated to intraoperative ureteral lesions. Statistical significance was set at P value <0.05.

RESULTS: Overall, 13 intraoperative and 13 postoperative ureteral lesion repairs were collected. In terms of baseline features no statistically significant differences were found. In both the groups ureteral repair was performed by the urologist (100% *vs.* 92.3%; P=1). Ureteral lesions happened during open, laparoscopic, and trans-vaginal procedures, but no statistically significant difference was recorded among the two groups. Patients who underwent intraoperative repair were most likely to undergo uretero-uretero anastomosis (60% *vs.* 11.1%; P=0.008), whereas in a postoperative setting ureteroneocystostomy was the preferred approach (P=0.008). In our experience, patients who underwent intraoperative ureteral repair required new postoperative diversion (0% *vs.* 45.4%; P=1). None of the variables assessed at univariable analysis showed to be associated to intraoperative ureteral lesions.

CONCLUSIONS: In our experience, intraoperative ureteral repair showed no statistically significant differences compared to the postoperative one. However, intraoperative repair patients were more likely to require a secondary urinary diversion.

SC200
Complex proximal ureteral stenosis treated by 3D augmented reality robot-assisted segmental ureterectomy and buccal mucosa graft

A. Piana, D. Amparore, G. Busacca, P. Alessio, E. Checcucci, F. Piramide, S. De Cillis, G. Volpi, P. Verri, M. Sica, A. Bellin, M. Manfredi, C. Fiori, F. Porpiglia (Rocca di Neto, Crotone)

BACKGROUND: The surgical treatment of ureteral strictures represents a challenging procedure, related to a high rate of postoperative complication. In case of 2-/3-cm proximal strictures, robot-assisted segmental ureteral resection with end-to-end anastomosis with a buccal mucosa graft is a suitable option. Normally, during the procedure, aiming to clearly identify the stenosis, a concomitant ureteroscopy is performed. Nevertheless, the addition of ureteroscopy increases both surgical complexity and its costs. In order to enhance the accuracy of stenosis' identification during ureteral's dissection, our group investigated the potential role of 3D augmented reality (AR) surgical navigation during the procedure.

METHODS: AR surgical navigation was carried out with the aid of a dedicated ICON rack connected to the da Vinci surgical console (Intuitive Surgical, Inc., Sunnyvale, CA, USA). Thanks to a 3D mouse, an assistant was able to overlap the 3D reconstruction over the real anatomy. The surgeon could then observe the overlayed images in real time *via* the Tile Pro (Intuitive Surgical, Inc.). In the video, three cases of ureteral stenosis located upstream to the iliac vessels crossing determined by stones embedded in the mucosa are shown. AR technology was exploited to overlap the 3D reconstruction of the ureter and the stone to the endoscopic vision, allowing an accurate identification and subsequent resection of the stenosis. During the reconstructive phase, the buccal mucosa was inserted in the abdominal cavity once the posterior plate of the anastomosis was completed with an end-to-end suture, reducing the tension.

RESULTS: In all the cases, AR ensured an accurate location of the stenotic tract. All the procedures were successful and uneventful. Postoperative investigations confirmed the accuracy of the procedures.

CONCLUSIONS: AR guidance demonstrated to be an effective and precise tool, able to accurately locate the ureteral stenosis even when not identifiable on the ureteral surface, allowing to extremize peri-structural healthy tissue's preservation.

SC201
Robot-assisted buccal mucosal graft (BMG) ureteroplasty for the treatment of ureteral strictures

F. Tanese, L. Rella, G. Torre, S. Liguigli, M. Spilotros, G. Lucarelli, P. Ditonno, M. Battaglia (Bari)

BACKGROUND: The aim of this study was to describe our initial experience with robot-assisted buccal mucosal graft (BMG) ureteroplasty for the management of ureteral strictures.

METHODS: Two stone former patients who underwent multiple lithotripsy procedures resulting in the development of a middle-ureteral stenosis (3 and 4 centimeters) were treated with robot-assisted BMG ureteroplasty. To identify the margins of the stricture in one case flexible ureteroscopy and near-infrared fluorescence (NIRF) imaging were combined while in the other the indocyanine green (ICG) was intraureteral injected (under NIRF, the ureteral tissue fluoresced green until the ureteral stricture area). After ureteral stricture dissection, the narrow segment was cut longitudinally, and a buccal mucosal graft (BMG) of the required length was harvested, followed by double-J stent placement and BMG onlay anastomosis. Finally, the anastomotic area was wrapped with omentum.

RESULTS: No urinary leak was reported in both patients

during the hospitalization (creatinine on drainage fluid always negative). Four weeks after surgery in both patients the ureteral stent has been removed and a CT urogram was performed which showed no contrast medium spillage or signs of recurrence of the stenosis.

CONCLUSIONS: Robot-assisted buccal mucosal graft (BMG) ureteroplasty with the utilization of NIRF imaging combined with flexible ureteroscopy/indocyanine green to assist with precise identification of the ureteral stricture margins, provides another treatment option for complex long proximal or middle ureteral strictures, circumventing ileal ureter or renal autotransplantation. This technique is well-suited for ureteral reconstruction as it allows for minimal disruption of the delicate ureteral blood supply and facilitates a tension-free anastomosis. Our preliminary results showed that BMG ureteroplasty for the management of iatrogenic ureteral strictures seems to be safe and feasible.

SC202
Outcomes of robot-assisted buccal mucosa graft ureteroplasty with the assistance of intraoperative flexible ureteroscopy and indocyanine-green fluorescence

F. Mazzoleni, D. Perri, A. Pacchetti, E. Morini, U. Besana, M. Corinti, L. Berti, M.C. Sighinolfi, B. Rocco, J. Romero-Otero, A.L. Pastore, J.B. Roche, F. Bruyere, G. Bozzini (Como)

BACKGROUND: The aim of this study was to describe perioperative and functional outcomes of robot-assisted treatment of ureteral strictures with buccal mucosa graft with the assistance of intraoperative endoscopy and Indocyanine-green (ICG) fluorescence.

METHODS: Twenty-eight patients were treated for a ureteral stricture and were retrospectively revised. All patients underwent preoperative contrast-enhanced CT scan, 99Tc-MAG renal scan, ureteroscopy and retrograde ureteropyelography to assess position and length of the stricture. In all cases the stricture was located in the lumbar tract of the ureter and an indication to robot- assisted buccal mucosa graft ureteroplasty was given. Intraoperative flexible ureteroscopy and ICG fluorescence were used to specifically locate the stricture and to evaluate vascularization of the ureter. Omentum flap was always positioned around the graft. A ureteral stent was left in place at the end of surgery in all cases. Patients were followed-up with a CT scan at 3 and 6 months and a renal scan 6 months after surgery.

RESULTS: All patients developed the stricture after endoscopic treatment for ureteral stones. In 20 cases (71.4%) a nephrostomy tube was positioned before treatment to manage idronephrosis, whereas in the remaining 8 cases (28.6%) a ureteral stent was positioned. Median length of the stenosis was 8.0 mm (IQR 5.0-23.0). Median preoperative function for the affected kidney at renal scan was 32.4%. Median total operative time was 98 minutes and median blood loss 60 mL (IQR 30-120). Median buccal mucosa graft sampling was 18.2 minutes. No high-grade complications occurred. At 6-month follow-up 3 patients (10.7%) still showed hydronephrosis, however without evidence of a recurrent stricture and with a renal function >30% at scintigraphy. Six months after surgery renal scan detected a median renal function of 34.5% for the operated kidney, without a statistically significant difference compared to the preoperative value (P=0.18). At a median follow-up of 11.8 months only 2 stricture recurrences occurred and were managed with an indwelling nephrostomy tube.

CONCLUSIONS: Robot-assisted buccal mucosa graft ureteroplasty is safe and effective for the treatment of ureteral strictures providing good short-term preservation of renal function. Intraoperative flexible ureteroscopy, ICG fluorescence and omentum flap are useful tricks to maximize treatment outcomes.

SMART (SC203-SC218)

Non-muscle-invasive bladder cancer: treatment

SC203
Long-term outcomes of repeated mitomycin C instillation in low-risk and intermediate-risk non-muscle-invasive bladder cancer patients
SC204
Standard intravesical Bacillus Calmette-Guerin (BCG) protocol *versus* sequential intravesical BCG and device-assisted chemo-hyperthermia (mitomycin C delivered by the combat BRS system) for high-grade non-muscle-invasive bladder cancer patients
SC205
Patient selection criteria for an effective and safe TURBT in day hospital regimen
SC206
One-year oncological outcome updated analysis of a single-center prospective, randomized, controlled, non-inferiority trial: *en-bloc vs.* conventional transurethral resection of bladder tumor
SC207
Trans-urethral resection of the bladder (TURB) video consensus: a simple and effective way to improve awareness of patients undergoing TURB
SC208
Trimodal therapy in patients with non-muscle-invasive bladder cancer who refuse radical cystectomy
SC209
Intravesical instillations in octagenerian high grade, non-muscle-invasive bladder cancer patients: could they offer a real survival advantage?
SC210
Clinical validation of the EAU2021 intermediate risk NMIBC definition and implications for adjuvant treatment: a multicenter YAU urothelial collaboration
SC211
Progression-free survival as surrogate endpoint in high-risk non-muscle-invasive bladder cancer studies: results from a machine learning- based analysis of a large multi-institutional database
SC212
The impact of variant histologies in patients with PT1 NON-MUSCLE-invasive bladder cancer undergoing repeated transurethral resection of bladder tumor
SC213
Adequate *vs.* inadequate BCG intravesical therapy in intermediate and high-risk non-muscle-invasive bladder cancer: total number of instillations is what really matters
SC214
Prognosis of patients with t1 low-grade urothelial bladder cancer treated with BCG
SC215
International Bladder Cancer Group intermediate-risk non-muscle-invasive bladder cancer (IBCG IR-NMIBC) scoring system predicts outcomes of patients on active surveillance
SC216
Long-term follow-up and risk of high-grade recurrence in low-grade PTA bladder cancer patients
SC217
Surgical checklist adherence across urology expertise levels impacts transurethral resection of bladder tumor quality indicators
SC218
Effect of intravesical therapy with Bacillus Calmette-Guérin in elderly patients: results of a large, single institution series in elderly patients

SC203

Long-term outcomes of repeated mitomycin C instillation in low-risk and intermediate-risk non-muscle-invasive bladder cancer patients

P. Scilipoti, M. Longoni, M. de Angelis, C. Re, G. Rosiello, A. Bertini, G. Avesani, D. Cannoletta, G. Gandaglia, A. Salonia, F. Montorsi, A. Briganti, M. Moschini (Milan)

BACKGROUND: The use of repeated Mitomycin C (MMC) instillation in low- (LR) and intermediate-risk (IR) non-muscle-invasive bladder cancer (NMIBC) is still a matter of discussion among the urological community. The aim of the current study was to analyze long term outcomes of maintenance regimen of repeated MMC instillations in LR and IR patients.

METHODS: We identified 228 patients diagnosed with NMBIC after transurethral resection of bladder tumor (TURBT) that underwent MMC instillations between 2013 and 2022 at a tertiary referral center. All patients felt within the criteria for LR or IR class according to European Association of Urology Guidelines. Recurrence-free survival (RFS) was analyzed and compared with Cox-derived univariate Kaplan-Meier (KM). A Multivariable Cox-regression analyses (MVA) assessed the impact of MMC maintenance regimen on RFS (covariates: T stage, grade, multifocality, early instillation). Subgroup analysis evaluated the effect of MMC instillations number on RFS in patients who received maintenance.

RESULTS: Overall, 89 (39%) and 139 (61%) patients were diagnosed with LR and IR NMIBC, respectively. Low grade lesions were found in 88% (N.=200) of cases. Pathological Ta tumors were 93% (N.=211) and multifocality was present in 107 cases (47%). Median age at diagnosis and follow-up time were 71 (IQR 62-77) and 44 months (IQR 28-63), respectively. Early instillation was performed in only 21 patients (9.2%). Recurrence occurred in 57 patients (25%). All patients underwent MMC induction with 89% rate of 6-instillations cycle completion; 118 patients (51%) underwent maintenance instillations with a median number of instillations equal to 9.5 (6-11). Overall, RFS at 5-year follow-up was 69.6% (62.7, 77.2). Patients who did or did not receive MMC maintenance had a 5-year RFS of 73.4% *vs.* 65.2%. At MVA, MMC maintenance and number of instillations did not significantly correlate with a better RFS.

CONCLUSIONS: Our study showed that MMC maintenance instillations do not reduce the risk of recurrence in LR and IR NIMBC patients who received MMC induction.

SC204

Standard intravesical Bacillus Calmette-Guerin (BCG) protocol *versus* sequential intravesical BCG and device-assisted chemo-hyperthermia (mitomycin C delivered by the combat BRS system) for high-grade non-muscle-invasive bladder cancer patients

F. Persico, F. Chiancone, R. Giannella, C. Meccariello, M. Fedelini, M. Ferraiuolo, L. Pucci, M. Carrino, P. Fedelini (Naples)

BACKGROUND: Until January 2021, in response to the Bacillus Calmette-Guerin (BCG) shortage, we modified our adjuvant intravesical regimen for high grade (HG) non-muscle-invasive bladder cancer (NMIBC) patients who experienced low grade adverse events (like shiver and facial swelling) during the first two doses of BCG. The aim of this study was to analyze the oncological outcomes and complications of six BCG instillations *versus* a protocol of sequential intravesical BCG and device-assisted chemo-hyperthermia (C-HT) treatment. Mitomycin C was delivered by the COMBAT BRS system.

METHODS: We compared 36 patients (Group A) whose underwent six BCG instillations and 24 patients (Group B) whose underwent the sequential therapy (BCG, BCG, C-HT, C-HT, C-HT, BCG) from January 2021 to June 2022. Six weeks later, a control cystoscopy was performed. All patients with no evidence of disease at the follow-up cystoscopy received a maintenance treatment with C-HT for three months and a subsequent cystoscopy after six weeks. All data were recorded in a prospectively maintained database and retrospectively examined. Yates's χ^2 test and Student's *t*-test were used to compare the statistical significance of differences in proportions and means, respectively. Statistical analyses were performed using SPSS V23.0 (IBM Corp., Armonk, NY, USA), defining statistical significance at $P<0.05$.

RESULTS: There were no significant differences in the demographics and baseline characteristics among the groups (age, BMI, ECOG performance status, gender, smoking status, diabetes, number of tumors, tumor size, recurrence rate, pathologic state, concomitant CIS, tumor on second TURB, prior history of UTUC, previously treated with MMC, BCG failure group; $P>0.05$). No significant differences were found in recurrence (9/36 group A *vs.* 4/24 group B; P=0.6543) and progression (2/36 group A *vs.* 1/24 group B; P=0.7168) rates after induction course between Group A and B. No significant differences were found in recurrence (2/27 group A *vs.* 1/20 group B; P=0.7875) and progression (1/27 group A *vs.* 1/20 group B; P=0.6079) rates after first maintenance course with C-HT. Low-grade adverse events (grade I-II bladder spams and frequency/urgency) occurred in 3 out 36 patients in group A and in 2 out 24 in group B (P=0.6336).

CONCLUSIONS: Our preliminary data in the BCG+ C-HT sequence group show promising results in terms of efficacy and safety potentially representing a viable alternative HG-NMIBC treatment.

SC205

Patient selection criteria for an effective and safe TURBT in day hospital regimen

A. Martoccia, Y. Al Salhi, A. Fuschi, A. Carbone, P.P. Suraci, S. Scalzo, O.A. Rera, A. Antonioni, F.M. Valenzi, M.B. Sequi, D. Graziani, A. Cicione, G. Tema, C. De Nunzio, A.L. Pastore (Latina)

BACKGROUND: The aim of our study was to find valid criteria to include in a system score for the correct choice of the admission regimen in TURBT candidates for bladder cancer. The score comes from the identification of parameters that might expose patients to early postoperative (PO) complications occurrence (within 24-48 h).

METHODS: This retrospective study examined 513 patients underwent to TURBT from July 2020 to July 2022. The variables examined were sex, age, Body Mass Index, type of lesion implant base, number of lesions, size of the largest lesion, preoperative Hb, use of anticoagulant drugs, smoke, relapse, occupational risk factors, familiarity, American Society of Anesthesiologist classification (ASA Score), need

for PO ICU. The investigation focused on PO complications at 24 and 48 h according to Clavien-Dindo Classification. The operative procedure was performed under general or spinal anesthesia and all patients received one-shot antibiotic EV prophylaxis. All procedures were performed with bipolar energy. The association between complications and major risk factors have been investigated through a series of univariate and multivariate logistic regression models according to the appearance of complications requiring hospitalization.

RESULTS: Mean age was 62 years with a slight prevalence of male gender (52%). The mean surgical time was 40.6 min. From the analyzed data, the outcome was not significantly influenced by sex, BMI, smoke, familiarity, occupational risk factors, relapse. On univariate Cox regression analysis, age resulted significantly associated with the risk of developing an adverse event:(≥70 years old; P<0.0001). The number of lesions (>2) and the size (≥3 cm) represented a further significant risk factor (P<0.0001), as the probability of complications increased proportionally to the number and size of lesions (P<0.0001). As well, on multivariate Cox regression confirmed the variables previously investigated at univariate Cox regression, as independent predictors of PO complications within 24-48 h. Starting from these results, we develop a score comprising all the significant variables at the multivariate analysis, assigning to each variable a score from 0 to 2. Our idea is to create a score useful to predict the risk of PO complications at 24-48h (classifiable as Clavien-Dindo >2) to establish beforehand the most suitable hospitalization regimen. A statistically significant correlation has been found between the score and the risk of complications (r+0,711; P<0.0001). The application of this score on patients undergoing TURB showed that 91% did not have complications in 24h and 48h PO.

CONCLUSIONS: Considering the prevalence of patients undergoing TURBT, the use of carefully selected preoperative criteria might suggest the correct choice of hospitalization regimen. The application of the score showed that 91% patients submitted to TURBT did not report complications in PO 24-48h, so we could manage with DH regimen.

SC206
One-year oncological outcome updated analysis of a single-center prospective, randomized, controlled, non-inferiority trial: *en-bloc vs.* conventional transurethral resection of bladder tumor

P. Diana, A. Gallioli, A. Territo, Ó. Rodriguez-Faba, J.M. Gaya, F. Sanguedolce, G. Basile, P. Verri, A. Uleri, F. Algaba, J. Palou, A. Breda (Barcelona)

BACKGROUND: Several randomized controlled trials (RCTs) comparing *en-bloc* resection of bladder tumor (ERBT) *versus* conventional transurethral resection of bladder tumor (cTURBT) were published showing controversial results. In particular, 1-year recurrence rate ranged from 5-40% and 11-31% for ERBT and cTURBT, respectively. We provide an updated analysis of an RCT comparing the oncological outcome of ERBT *vs.* cTURBT at 1-year follow-up.

METHODS: This is an updated analysis of a single-center prospective, randomized, controlled, non-inferiority trial analyzing patients subjected to ERBT *vs.* cTURBT for BC. Inclusion criteria were tumor size of ≤3 cm, and ≤3 lesions, and no sign of muscle invasion and/or ureteral involvement. The trial (NCT04712201) was approved by the Institutional Review Board (2017/09c). Kaplan-Meier curves were used to illustrate recurrence-free survival. The log-rank test was used to assess univariable differences in recurrence-free survival according to the technique employed.

RESULTS: From April 2018 to June 2021, a total of 248 patients were assessed for eligibility. After excluding patients that were diagnosed with cT0 (N.=11), cT2 (N.=11) tumors, benign features (N.=5), and those with variant histology (N.=2), we relied on a cohort of 219 patients: 123 (56.2%) in the ERBT and 96 (43.8%) in the cTURBT group. Patients presenting with low-grade (LG), high-grade (HG), and CIS were 70 (56.9%), 49 (39.8%), and 4 (3.3%) *versus* 56 (58.3%), 37 (38.5%), and 3 (3.1%) for ERBT *versus* cTURBT, respectively. A total of 201 patients reached at least one year of follow-up. The median follow-up of patients without recurrence was 19 months (IQR 14-35). Bladder 1-year recurrence was recorded in 11 (8.9%) and 12 (12.5%) patients after ERBT and cTURBT, respectively. Of which 5/123 (4%) LG and 6/123 (5%) HG in the ERBT group and 7/96 (7%) LG and 5/96 (5%) HG in the cTURBT group. Median time to recurrence was 14 months (IQR 8-22). The Kaplan-Meier curve revealed that recurrence-free survival was similar between the groups (P=0.88).

CONCLUSIONS: No statistical difference was found in the comparison of recurrence rates between ERBT and cTURBT at 1-year follow- up. Compared to other RCTs the heterogeneity observed in terms of bladder recurrence could be explained by the scarce and the heterogenous adoption of tools and techniques that have been proved to lower the recurrence rate of NMIBC, supporting the implementation of a TURBT-checklist.

SC207
Trans-urethral resection of the bladder (TURB) video consensus: a simple and effective way to improve awareness of patients undergoing TURB

F. Esperto, F. Tedesco, L. Cacciatore, F. Prata, N. Deanesi, A. Ragusa, A. Minore, A. Testa, R. Papalia, R.M. Scarpa (Rome)

BACKGROUND: In the age of information technology, new platforms are consulted by patients to acquire their own consciousness about medical treatments, even if often information found are not reliable. The European Association of Urology Patient Information (EAU PI) delivers, with the support of EAU guidelines, high quality video-content about surgical procedures with a language easy to understand for patients. The aim of this study was to assess the level of understanding and feasibility of video consensus administration in patients scheduled for trans-urethral resection of the bladder (TURB) comparing it with standard written informed consensus.

METHODS: The EAU PI video content about TURB was translated in Italian and implemented with possible complication explanation at the end of it. After Ethical Committee approval, from January 2021 to September 2021 all patients who underwent TURB for bladder cancer (BC) at our institution were prospectively included in this study. A print-based traditional consensus was administered to all patients and, after that, a video information about TURB showing poten-

tial complications. After paper-based consensus and video consensus, patients received a preformed Likert 10 Scale questionnaire to evaluate: 1) comprehension; 2) contents; 3) satisfaction; 4) simplicity; 5) details; with a score from 1 to 10. Descriptive and variance analysis was performed through SPSS v27 (IBM Corp., Armonk, NY, USA) with an alpha value of significance set at 0.05, comparing the different types of consensuses.

RESULTS: Ninety patients were included in our study and 90 questionnaires were evaluated. 30% (27) of patients were female and 70% (63) were male, 45% (40) were aged 50-69 years, 55% (50) 70-80 years. Mean score±standard deviation (SD) for different domains analyzed was the following: mean comprehension score±(SD) was 6.5±(0.8) in standard consensus group *versus* 8.6±(0.77) in the video consensus group, P=0.0001. Mean contents score±(SD) was 6.4±(0.6) in standard consensus group *versus* 8.4±(0.69) in the video consensus group (P=0.0001). Mean satisfaction score±(SD) was 6.38±(0.49) in standard consensus group *versus* 9±(0.7) in the video consensus group (P=0.0001). Mean simplicity score±(SD) was 6.3±(0.4) in standard consensus group *versus* 8.4±(0.75) in the video consensus group (P=0.0001). Mean details score±(SD) was 6.15±(0.55) in standard consensus group *versus* 8.8±(0.65) in the video consensus group (P=0.0001 *U Mann-Whitney Test for independent samples).

CONCLUSIONS: All the domains analyzed showed a higher statistically significant appreciation for video consent compared to traditional informed consent. Overall satisfaction, with a mean score of 9 out of 10, showed to our advice the way to chase for the future. Video consent represents a simple and comprehensive tool for patients and can improve their awareness and satisfaction.

SC208
Trimodal therapy in patients with non-muscle-invasive bladder cancer who refuse radical cystectomy

A.M. Capurso, S. Forte, B. Turi, A. Gernone, D.F. Colatorti, S. Soldano, G. Lippolis, L. Rella, G. Lucarelli, P. Ditonno (Bari)

BACKGROUND: According to current guidelines, radical cystectomy is indicated for high grade and very high-grade non-muscle-invasive bladder cancer (NMIBC) unresponsive to BCG therapy. Many patients decline this major surgery especially for worsening of quality of life or because unfit to surgery. Actually, there are not alternative therapies. In our multidisciplinary team (MDT), in according with oncologist and radiotherapist we propose a trimodal therapy approach.

METHODS: From 2020 to 2022 we selected 4 patients with a pT1G3 bladder cancer (BC) unresponsive to BCG therapy. The mean time to recurrence after BCG therapy was 4 months. All patients refused the early cystectomy and underwent a multidisciplinary team (MDT) evaluation. The trimodal approach was proposed as an alternative therapy. The follow-up was based on cystoscopies and TC/ MRI. The average time of the follow-up was 10.7 months (2-21).

RESULTS: The mean age was 76.5 years (73-84). The Charlson Comorbility Index was 5.5 (5-6). All patients were no metastatic, and before radiotherapy and chemotherapy, they underwent cystoscopy to confirm cT0 in the bladder. The chemotherapy of 3 of them was based on Cisplatin (for 1 patient 6 sessions, each session of 80 mg; for 2 patients 5 sessions, each session of 60 mg), for the last patient was based on Gemcitabine (5 sessions, each of 180 mg). The radiotherapy consists of external beam radiation therapy whit VMAT technique, the total dose for 2 of the patients was 60 Gy (divided in 30 fractions each of 2 Gy), for 1 patient was 55 Gy (divided in 20 fractions each of 2.75 Gy) and for 1 patient was 52.25 Gy (divided in 19 fractions each of 2.75 Gy). The last one did not receive the last fraction of radiotherapy because he had a worsening of his clinical conditions not related to his bladder history of tumor. After the MDT decision, the patients begin the trimodal approach in 4.15 months (0.5-8.8). The duration of the treatment based on chemo- and radiotherapy for all the patients was 30 days. No severe side effects were observed, and all patients had a good quality of life. The follow-up was based on cystoscopies every three months and imaging (TC/ MRI) every 6 months. Currently no recurrence or progression was reported.

CONCLUSIONS: According to guideline a cystectomy sparing approach should not be offered in the patients with NMIBC BCG failure or unresponsive. However, the trimodal approach could be a valid alternative to cystectomy in patients who refuse surgery.

SC209
Intravesical instillations in octagenerian high grade, non- muscle-invasive bladder cancer patients: could they offer a real survival advantage?

G. Guano, F. Chierigo, S. Parodi, S. Tappero, S. Rebuffo, F. Ambrosini, F. Vecco, C. Paola, G. Granelli, E. Vecchio, L.L.B. Lo Monaco, B. Col, G. Ragno, G. Mantica, C. Terrone, M. Borghesi (Genoa)

BACKGROUND: The aim of this study was to analyze survival outcomes of octogenarian patients with high grade non-muscle-invasive bladder cancer (HG- NMIBC) treated either with intravesical therapy or surveillance.

METHODS: We retrospectively analyzed patients aged ≥80 treated with transurethral resection of the bladder (TURB) and diagnosed with HG-NMIBC from a single academic institution from 2016 to 2020. Patients were treated with either intravesical instillation or surveillance. Descriptive statistics analyzed differences in perioperative characteristics. Smoothed Poisson regression plots depicted cancer specific mortality (CSM) and other-cause mortality (OCM). Kaplan-Meier plot depicted recurrence free survival according to treatment. We relied on cumulative incidence plots and univariable competing-risks regression models to analyze differences in CSM and OCM among patients managed by surveillance *vs.* intravesical instillations (either mitomycin C [MMC] or Bacillus Calmette-Guerin [BCG]).

RESULTS: We collected 121 patients with a median [interquartile range (IQR)] age of 84 (81-87), of which 15 (12%) were females. Overall, 74 (61%) of patients had a first diagnosis of BCa and 59 (49%) had multifocal disease. At presentation, 33 (27%) had a tumor size ≥3cm. Intermediate, high, and very-high EAU NMIBC risk was present in respectively 17 (14%), 82 (68%), and 22 (18%) patients. After diagnosis of NMIBC, 80 (66%) patients were surveilled, 24 (20%) were treated with BCG, 17 (14%) with MMC. Median follow-up was 60 months. Overall, 5-year CSM rate was 9%

and 5-year OCM rate was 50%. Overall, 44 (36%) patients recurred within 10 months. Recurrence rate for patients under surveillance was 38% (30 patients) *vs.* 38% (9 patients) for BCG *vs.* 29% (5 patients). Cumulative incidence plots and univariable competing-risks regression models revealed no difference in 5-year CSM rates in surveillance *vs.* intravesical instillations (9.6 *vs.* 10%; HR: 1.09; 95% CI: 0.33-3.65; P=0.9), as well as in OCM rates (57 *vs.* 35%; HR: 0.66; 95% CI: 0.39-0.12; P=0.1).

CONCLUSIONS: Mortality in octogenarian patients with HG-NMIBC is mostly attributable to OCM. Our study suggests that, in those patients, intravesical instillations do not seem to provide an oncological survival benefit. Induction and maintenance with BCG and Mitomycin C should therefore be carefully considered as a treatment in elderly patients.

SC210
Clinical validation of the EAU2021 intermediate risk NMIBC definition and implications for adjuvant treatment: a multicenter YAU urothelial collaboration

M. Rosazza, F. Soria, M. Moschini, F. Del Giudice, R. Pichler, R. Hurle, D.M. Carrion Monsalve, W. Krajewski, L.S. Mertens, S. Livoti, D. Dutto, L. Ola, F. Colucci, C. Fiameni, B. Lillaz, P. Gontero (Turin)

BACKGROUND: Recently, a new risk-stratification model for NMIBC has been adopted by EAU Guidelines (EAU2021 scoring model). This model has incorporated the LG/HG definition and was tested in an IPD analysis of 3401 primary NMIBC. Of these, only 54% were treated with adjuvant chemotherapy and may be therefore not representative of current clinical practice. Moreover, there is variation amongst guidelines with respect to the stratification of TaHG disease. Using the EAU2021 model, some TaHG tumors should be classified as intermediate risk (IR). Consequently, the IR group now includes a broad spectrum of disease (Ta and T1 as well as LG and HG tumors) for whom treatment may vary from adjuvant chemotherapy with or without maintenance to intravesical BCG. Based on these considerations, the aim of our study was to externally validate the new EAU2021 scoring model, to validate homogeneity of IR group regarding the inclusion of selected TaHG in this category of risk and, finally, to evaluate the most effective chemotherapy regimen for this subgroup of patients.

METHODS: This was a multicenter collaboration involving 9 European referral centers of the YAU Urothelial working group. Primary or recurrent NMIBC treated with adjuvant intravesical chemotherapy and stratified as having IR disease according to the 2021 scoring model were included. Main endpoint was RFS and PFS rates of the entire group, and of TaHG patients compared to other patients' subgroups. Secondary endpoint was to evaluate the impact of maintenance chemotherapy on RFS and of PFS. KM curves were built to evaluate the risk of disease recurrence and progression and multivariable Cox regression analyses to evaluate the impact of maintenance on RFS and PFS.

RESULTS: Overall, 786 patients were included. Of these, 389 (49%) and 397 (51%) were primary and recurrent NMIBC, respectively. TaHG was found in 109 (14%) patients while TaLG and T1LG were present in 632 (80%) and 45 (6%) of cases. RFS rates varied from 85% at 1 year and 52% at 5 years. PFS rates varied from 99% at 1 year and 95% at 5 years. These results are in line with those provided by the 2021 EAU scoring model. Within a median follow-up time of 36 months (IQR 20-54), oncological outcomes (both RFS and PFS) of TaHG patients did not differ from those of TaLG or T1LG disease, thus demonstrating the homogeneity of the IR group. On multivariable analyses maintenance was associated with improved RFS (HR: 0.60; P<0.001) but not with PFS (HR: 1.09; P=0.8).

CONCLUSIONS: We externally validated the homogeneity of IR disease spectrum regarding oncological outcomes, and we confirmed that selected TaHG patients harbor the same oncological outcomes of other IR subgroups. In IR disease, adjuvant chemotherapy with maintenance should be indicated to lower the risk of disease recurrence.

SC211
Progression-free survival as surrogate endpoint in high-risk non-muscle-invasive bladder cancer studies: results from a machine learning-based analysis of a large multi-institutional database

R. Cicchetti, A. Porreca, M. Di Nicola, D. Ciavarella, G. Lucarelli, V. Mihai Dorin, F. Soria, D. Terracciano, F.A. Mistretta, C. Buonerba, F. Cantiello, A. Mari, A. Minervini, A. Veccia, A. Antonelli, G. Musi, R. Hurle, G.M. Busetto, F. Del Giudice, B.I. Chung, F. Berardinelli, S. Perdonà, P. Del Prete, V. Mirone, M. Borghesi, A. Porreca, P. Bove, R. Autorino, N. Crisan, M. Battaglia, P. Di Tonno, G.I. Russo, M. Muto, R. Damiano, F. Porpiglia, O. De Cobelli, L. Schips, M. Ferro, M. Marchioni (Chieti)

BACKGROUND: Progression-free survival (PFS) is often used as surrogate endpoint in clinical trials investigating treatment effectiveness in patients affected by high-risk non-muscle-invasive bladder cancer patients (HR-NMIBC). However, the goodness of such surrogate endpoint and its association with overall survival (OS) is challenged by conflicting results showing lack of OS advantage, even in presence of PFS improvement. We aimed to test the effect of time-to-progression on OS in a large cohort of HR-NMIBC treated with intravesical BCG.

METHODS: We included patients at first diagnosis of T1 high grade NMIBC after transurethral resection of bladder (TURB). All procedures were performed at 18 different tertiary institutions between January 2002 and December 2012. Progression was defined as the time form HR-NMIBC to muscle invasive bladder cancer development. All patients who experienced a progression underwent radical cystectomy with or without neo-adjuvant chemotherapy according to referral oncologist. Machine learning approach, based on random survival forest (RSF) was used to rank covariates based on OS prediction. Then survival tree data mining technique was used to obtain classes based on time-to-progression. Finally, Cox-regression models including progression as time-dependent covariate were deployed to estimate hazard ratios and their 95% confidence intervals.

RESULTS: Overall, 1510 patients were included. During a median follow-up of 49.0 (IQR: 40.0-73.0) months, 485 (32.1%) patients progressed to muscle-invasive bladder cancer, while 163 (10.8%) patients died. The median time to progression was 82 (95% CI: 78.0-93.0) months. In RSF time-to-progression and age were the most predictive covariates of OS (out of 27 covariates considered). The C-Index

resulted to be 0.814 (0.792-0.842) on the training set and 0.726 (0.696-0.793) on the test set. Survival tree including these two covariates defined 5 groups of risk: PFS≥62.5 months and age <77.5 years (reference), PFS ≥62.5 months and age ≥77.5 years (HR: 9.0; P<0.001), PFS between 10.5 and 62.5 months and age <79.5 years (HR: 14.3; P<0.001), PFS <10.5 months and age <79.5 (HR: 44.9; P<0.001) and PFS <62.5 month and age ≥79.5 years (HR:58.7; P<0.001). In multivariable Cox's regression models accounting for progression status as time- dependent covariate, longer PFS (as continuous covariate) was associated with longer OS (HR: 0.9; P<0.001). Results were virtually the same after PFS stratification (PFS≥10.5 months as reference): PFS between 10.5 and 62.5 months (HR: 0.4; P<0.001) and PFS ≥62.5 months (HR: 0.2; P<0.001).

CONCLUSIONS: Our results suggest that PFS represent a good surrogate endpoint of OS considering its strong independent predictor status and the high accuracy. Future studies evaluating the efficacy of HR-NMIBC treatments can safely rely on PFS as surrogate of OS. Our results are of importance for future clinical studies design.

SC212
The impact of variant histologies in patients with pT1 non-muscle-invasive bladder cancer undergoing repeated transurethral resection of bladder tumor

F. Claps, N. Pavan, L. Ongaro, N. d'Altilia, M. Maggi, E. Checcucci, L. Napolitano, R. Contieri, A. Morlacco, A. Tafuri, C. Palumbo, G. Mazzon, F. Del Giudice, R. Campi, C. Signorini, L. Boeri, G. Giannarini, F. Esperto, G. Tulone, M. Finati, M. Sica, R. La Rocca, C. Bignù, U.G. Falagario, F. Traunero, A. Panunzio, A. Zucchi, A. Sciarra, G.M. Busetto, G. Liguori, R. Bartoletti, A. Simonato, A. Minervini, R. Papalia, R.M. Scarpa, S. Serni, E. Montanari, L. Carmignani, A. Celia, A. Volpe, A. Antonelli, F. Dal Moro, V. Mirone, F. Porpiglia, R. Hurle, A. Tubaro, L. Cormio, G. Carrieri, C. Trombetta (Trieste)

BACKGROUND: Repeated transurethral resection of bladder tumor (re-TURBt) is the gold-standard treatment for patients with pT1 non-muscle-invasive bladder cancer (NMIBC). Urothelial carcinoma (UC) has a remarkable propensity for divergent differentiation and several variant histologies (VHs) have been recognized by the 2016 World Health Organization (WHO) classification as potential drivers of clinical and therapeutic management. Here we evaluated the impact of each VH and other conventional predictors of residual tumor at time of re-TURBt.

METHODS: We relied on our prospectively maintained collaborative database of consecutive patients treated with re-TURBt at sixteen academic centers between January 2016 and March 2022. Re-TURBt was defined as a second resection which involved the site of pT1 NMIBC of the first TURBt performed within 2-6 weeks from the previous resection. Multivariable Binomial Logistic Regression models were used to assess the odds ratio (OR) testing the risk of residual tumor at re-TURBt. The Area Under the Curve (AUC) of the model was calculated. Beyond that, we relied on 1:1 nearest neighbor propensity-score- matching without replacement to account and adjust for potential baseline differences in patients' characteristics.

RESULTS: A total of 1196 patients were included and 446(37.3%) had a residual tumor at re-TURBt. Overall, 175(14.6%) patients harbored a VH. Micropapillary was the most common VH with 51(29.1%) cases followed by 39(22.3%) squamous, 18(10.3%) poorly differentiated, 11(6.3%) nested, 11(6.3%) lymphoepithelioma-like, 11(6.3%) clear-cell, 9(5.1%) glandular, 8(5.6%) giant-cell, 7(4.9%) plasmacytoid, 6(3.4%) sarcomatoid, and 4(2.3%) microcystic cases. On multivariable analysis, residual tumor was independently associated with giant-cell (OR 9.55, P=0.044), glandular (OR 12.5, P=0.004), micropapillary (OR 8.05, P<0.001), plasmacytoid (OR 15.0, P=0.03), poorly-diff. (OR 8.28, P=0.008), sarcomatoid (OR 9.86, P=0.04), and squamous VH (OR 3.33, P=0.002), together with female gender (OR 1.58, P=0.005), preoperative anemia (OR 1.62, P=0.003), multiple lesions (OR 1.70, P<0.001), tumor size ≥30 mm (OR 1.54, P=0.01), bladder neck (OR 2.77, P=0.002) and dome (OR 2.01, P=0.04) location of the index lesion, high grade disease (OR 11.0, P=0.002), presence of concomitant CIS (OR 3.94, P<0.001), presence of LVI (OR 2.96, P<0.001), and the absence of detrusor muscle in the specimen of initial TURBt (OR 1.46, P=0.03). The AUC of the model was 0.82.

CONCLUSIONS: A non-negligible group of patients with pT1 NMIBC undergoing re-TURBt harbored a VH. Compared to pure UC, several VHs were independently associated with an increased risk of residual disease at time of re-TURBt. Accurate pathologic diagnosis of VHs may ensure a tailored counselling to identify patients who require more intensive management.

SC213
Adequate *vs.* inadequate BCG intravesical therapy in intermediate and high-risk non-muscle-invasive bladder cancer: total number of instillations is what really matters

M. de Angelis, F. Pellegrino, M. Longoni, P. Scilipoti, C. Re, A. Bertini, R. Leni, D. Robesti, G. Gandaglia, U. Capitanio, A. Salonia, A. Briganti, F. Montorsi, M. Moschini (Milan)

BACKGROUND: Intravesical immunotherapy with Bacillus Calmette-Guérin (BCG) is currently recommended by EAU guidelines for proper treatment of patients with intermediate (IR) and high risk (HR) non-muscle-invasive bladder cancer (NMIBC). We aimed to verify if complete adherence to BCG therapy relates to better oncological outcomes in terms of risk of recurrence and progression.

METHODS: Overall, we retrospectively identified 250 patients who underwent transurethral resection of primary bladder cancer between 2012 and 2022 at a tertiary referral center. All these patients were diagnosed with IR or HR NMIBC and then were treated with BCG intravesical therapy according to EAU guidelines. We evaluated if intravesical treatment in these patients was adequate, defined as at least 1 year of maintenance in IR patients and 3 years maintenance in HR patients. Multivariable Cox regression analyses (MVA) tested the impact of number of instillations and therapy adequateness on recurrence and progression. Recurrence and progression were compared with the Kaplan-Meier (KM) analysis according to intravesical therapy adequateness.

RESULTS: Median age was 69 years old. Overall, 45 patients (18%) received adequate intravesical therapy according to their class of risk. Patients with adequate treatment received approximately triple the amount of BCG instillations compared with inadequately treated patients (21 *vs.* 9,

respectively). Median FU was 42 months. During follow-up, 75 patients showed disease recurrence, 62 of which belonged to inadequately treated patients (83%). Similarly, progression was found in 29 patients, 27 of which were treated inadequately (93%). At MVA, both total number of instillations and adequate treatments were related with disease progression (HR 0.92, P=0.015 *vs.* HR 0.22, P=0.041, respectively). Conversely, recurrence was only associated with total number of instillation (HR 0.95, P=0.019). KM analysis shows how at 2-year follow-up, progression free survival was higher in patients who received adequate treatment compared with those treat inadequately (96%*vs.* 83%, respectively)

CONCLUSIONS: This study proved that only one-fifth of patients actually receives adequate intravesical therapy. A more intense BCG instillation regime is associated with lower risk of recurrence and progression of bladder cancer. In particular, a higher number of instillations more than the effective adequateness of treatment seems to be more related with tumor recurrence and progression. These results confirm the hypothesis that too often real life differ from guidelines, resulting in an actual undertreatment of these patients and the consequent worsening of the disease.

SC214
Prognosis of patients with t1 low-grade urothelial bladder cancer treated with BCG

L. Gobbi, C.M. Scornajenghi, V. Asero, P. dipinto, E. de berardinis, A. Sciarra, S. Basran, M.L. Eisenberg, B.I. Chung, R. Piszczek, W. Krajewski, Ł. Nowak, T. Szydełko, B. Małkiewicz, F. Del Giudice (Rome)

BACKGROUND: The aim of this study was to analyze recurrence-free survival (RFS) and progression-free survival (PFS) in patients with T1LG bladder cancers treated with BCG immunotherapy.

METHODS: A multi-institutional and retrospective study of 2510 patients with Ta/T1 NMIBC with or without carcinoma in situ (CIS) treated with BCG (205 T1LG patients) was performed. Kaplan-Meier estimates and log-rank test for RFS and PFS to compare the survival between TaLG, TaHG, T1LG, and T1HG NMIBC were used. Also, T1LG tumors were categorized into EAU2021 risk groups and PFS analysis was performed, and Cox multivariate model for both RFS and PFS were constructed.

RESULTS: The median follow-up was 52 months. For the T1LG cohort, the estimated RFS and PFS rates at 5 years were 59.3% and 89.2%, respectively. While there were no differences in RFS between NMIBC subpopulations, a slightly better PFS was found in T1LG NMIBC compared to T1HG (5-year PFS; T1LG *vs.* T1HG: 82% *vs.* 89%; P<0.001). A heterogeneous classification of patients with T1LG NMIBC was observed when EAU2021 prognostic model was applied, finding a statistically significant worse PFS in patients classified as high-risk T1LG (5-year PFS; 81.8%) compared to those in intermediate (5-year PFS; 93.4%), and low-risk T1LG tumors (5-year PFS; 98.1%).

CONCLUSIONS: The RFS of T1LG was comparable to other NMIBC subpopulations. The PFS of T1LG tumors was significantly better than of T1HG NMIBC. The EAU2021 scoring model heterogeneously categorized the risk of progression in T1LG tumors and the high-risk T1LG had the worst PFS.

SC215
International Bladder Cancer Group intermediate-risk non-muscle-invasive bladder cancer (IBCG IR-NMIBC) scoring system predicts outcomes of patients on active surveillance

R. Contieri, W.S. Tan, V. Grajales, A. Finocchiaro, A. Saita, M. Soloway, M. Lazzeri, N. Frego, G. Lughezzani, N.M. Buffi, Casale, A.M. Kamat, R. Hurle (Milan)

BACKGROUND: Although there remains variation in the definition of intermediate risk (IR) NMIBC, recurrent LG NMIBC is considered IR in the current bladder cancer guidelines. To better define patients with IR NMIBC, the IBCG has proposed a scoring system based on five clinical risk factors. We have already reported the efficacy and safety of active surveillance in LG Ta patients (Bladder Italian Active Surveillance, BIAS project). In this analysis, we analyzed the outcomes of patients on the BIAS project using the IBCG IR-NMIBC scoring system to predict outcomes among patients undergoing AS.

METHODS: The BIAS project is a prospectively maintained AS database of patients with a history of LG Ta/T1a NMIBC. The inclusion criteria for BIAS are LG papillary NMIBC, ≤5 lesions, tumor ≤1 cm, absence of hematuria and negative urinary cytology. Follow-up protocol mandated three monthly urinary cytology and cystoscopy for the first 12 months, followed by 6 monthly thereafter. A subsequent transurethral resection (TURBT) was performed following the development of any condition meeting the exclusion criteria during follow-up or voluntary withdrawal. The IBCG IR-NMIBC risk factors were multifocal tumor, early recurrence (<1 year), frequent recurrence (>1/year), tumor size (≥3 cm), and failure of prior intravesical treatment. Survival estimates were calculated using the Kaplan-Meier methods. Multivariable Cox proportional-hazards analysis was used to determine factors associated with subsequent TURBT after active surveillance.

RESULTS: A total of 163 patients from the BIAS database had all IBCG IR-NMIBC scoring factors available and were included for analysis. One hundred and nine (67%) patients received subsequent TURBT after entering AS with a median time on AS of 23 months (IQR: 8-35). A total of 35 patients had 0 risk factors, 91 patients had 1-2 risk factors and 37 patients had ≥3 risk factors. Patients with 0 risk factors was more likely to continue AS compared to patients with ≥3 risk factors at 24-month follow-up (59% *versus* 24%). Patients with 1-2 risk factors (HR: 1.63, 95% CI: 0.94-2.83, P=0.081) and ≥3 risk factors (HR: 3.00, 95% CI: 1.63-5.48, P<0.001) had a higher risk of undergoing a subsequent TURBT. With increasing risk factors, the median time on AS decreased significantly from 28 (IQR: 12-36) months for patients with 0 risk factors to 15 (IQR: 4-18) months for patients with ≥3 risk factors (P=0.002). On multivariable Cox regression, the IBCG IR-NMIBC scoring system was an independent predictor for subsequent TURBT (1-2 risk factors [HR: 1.6, 95% CI: 0.94-2.866, P=0.080], ≥3 risk factors [HR: 3.14, 95% CI: 1.67-5.94, P<0.001)]) after adjusting for age and T stage at entry of AS.

CONCLUSIONS: This study found that the IBCG IR-NMIBC scoring system predicts the likelihood of continued AS among patients in the BIAS study. As such, the scoring system can be used to counsel patients and allow for better informed joint patient- physician decision making before embarking on an AS program.

SC216
Long-term follow-up and risk of high-grade recurrence in low-grade PTA bladder cancer patients

A. Finocchiaro, R. Contieri, P. Casale, G. Lughezzani, N.M. Buffi, A. Saita, M. Lazzeri, P. Diana, N. Frego, A. Gobbo, H. Rodolfo (Milan)

BACKGROUND: Non-muscle-invasive bladder cancer (NMIBC) is a common diagnosis, with approximately 60% of cases being low-grade (LG) tumors that do not invade the lamina propria (Ta). Despite this, contemporary data on TaLG bladder cancer patients is scarce, with historical series comprising patients treated more than two decades ago. Hence, the primary objective of this study was to investigate the recurrence rate and identify factors influencing the risk of upgrade and upstage in a contemporary large series of TaLG bladder cancer patients. The aim of this study was to provide suggestions for follow-up schedules and management options in this setting.

METHODS: This single-center retrospective observational study included patients treated at a high-volume tertiary care hospital from 1999 to 2022, with a diagnosis of pTa LG that experienced at least one recurrence. The follow-up schedule and the disease management were in line with the European Association of Urology (EAU) guidelines. The primary endpoint was high-grade (HG) recurrence. Follow-up was calculated with inverse Kaplan-Meier (KM) methods. The Cox regression model was used to predict HG recurrence. KM curve was applied for time to HG recurrence.

RESULTS: A total of 184 TaLG patients were included. The median age was 68 (IQR 60-74), with a median follow-up of 73 months (IQR 46-114). Of them 52 (28.26%) received at least one course of intravesical therapy during the follow-up. A total of 15 patients developed an HG recurrence. The median number of LG recurrences per patient was 2 (IQR 1-3.5). The median time to HG recurrence was 41 months (IQR 27-102). HG-recurrence-free survival was 98% (IQR 95-99), 94% (IQR 89-97) and 91% (IQR 84-95) at 24, 72 and 96 months. Multivariable Cox regression analyses controlled for smoking, grade, age at TUR, previous instillations, and number of previous LG recurrences revealed that age at TUR (hazard ratio [HR]: 1.09; IQR: 1.03-1.16; P<0.05) and number of previous LG recurrences (HR: 1.69; IQR: 1.30-2.20; P<0.01) emerged to be statistically significantly associated with a higher risk of HG recurrence. Whereas previous intravesical instillations are protective against HG recurrence (HR: 0.15; IQR: 0.03-0.81; P<0.05).

CONCLUSIONS: According to our results, grade progression in pTa LG patients is low, especially within the first 2 years, with 94% of the patients without progression at 24 months. We also highlighted that age at first TUR and the number of previous LG recurrences increase whereas previous intravesical instillation decrease the risk of HG progression, suggesting that is fundamental to accurately distinguish patients, basing on their disease history, in the follow-up scheduling. These findings could be used to guide clinical decision-making and counsel patients with LG NMIBC about their long-term risk of progression. Furthermore, our findings reinforce the concept that conservative approaches, such as active surveillance or in-office fulguration, are reasonable choices in this setting and should be encouraged.

SC217
Surgical checklist adherence across urology expertise levels impacts transurethral resection of bladder tumor quality indicators

C.M. Scornajenghi, V. asero, P. Dipinto, E. De Berardinis, A. Sciarra, S. Basran, M.L. Eisenberg, B.I. Chung, F. Del Giudice (Rome)

BACKGROUND: The aim of this study was to address the association of perioperative surgical checklist across variable surgical expertise with transurethral resection of bladder tumor (TURBT) accuracy and oncological outcomes in non-muscle-invasive bladder cancer.

METHODS: We relied on our prospective collaborative database of patients treated with TURBT between 2012 and 2017. Surgical experience was stratified into three groups: resident *vs.* young *vs.* expert consultants. The association of surgical experience with detrusor muscle (DM) presence and adherence to the standardized peri-procedural 9-item TURBT checklist was evaluated with logistic regression models. A Cox regression model was used to investigate the association of surgical experience with recurrence-free survival (RFS).

RESULTS: A total of 503 patients were available for analysis. TURBT was performed by expert consultants in 265 (52.7%) patients, by young consultants in 149 (29.6%) and by residents in 89 (17.7%). Residents were more likely to have DM in the TURBT specimen than expert consultants (odds ratio [OR] 1.75, 95% confidence interval [CI] 1.03-2.99, P=0.04). Conversely, no differences in DM presence were seen between young *vs.* expert consultants (OR 1.09; 95% CI 0.71-1.70; P=0.69). The median checklist completion rate was higher for both residents and young consultants when compared to experts' counterparts (56% and 56% *vs.* 44%; P=0.009). When focusing on patients receiving a second look TURBT, the persistent disease was associated with resident status (OR 4.24; 95% CI 1.14-17.70; P=0.037) at initial TURBT. Surgical experience was not associated with 5-year RFS.

CONCLUSIONS: Surgeon's experience in the case of adequate perioperative surgical checklist implementation was inversely associated with the presence of DM in the specimen but directly linked to higher probability of persistent disease at re-TURBT, although no 5-year RFS differences were noted.

SC218
Effect of intravesical therapy with Bacillus Calmette-Guérin in elderly patients: results of a large, single institution series in elderly patients

M. de Angelis, F. Pellegrino, M. Longoni, P. Scilipoti, C. Re, R. Leni, D. Robesti, A. Bertini, G. Gandaglia, U. Capitanio, A. Salonia, A. Briganti, F. Montorsi, M. Moschini (Milan)

BACKGROUND: Intravesical immunotherapy with Bacillus Calmette-Guérin (BCG) is currently recommended by EAU guidelines for proper treatment of patients with intermediate (IR) and high risk (HR) non-muscle-invasive bladder cancer (NMIBC). However, sparse data exists regarding the effect of BCG in elderly patients. In this study, we aimed to compare oncological outcomes in younger *vs.* elderly patients treated with BCG in terms of risk of recurrence and progression.

METHODS: Overall, we retrospectively identified 220

patients who underwent transurethral resection of bladder cancer between 2012 and 2022 at a tertiary referral center. All these patients were diagnosed with IR or HG NMIBC and then experienced BCG intravesical therapy according to EAU guidelines. We evaluated the efficacy of intravesical treatment in elderly patients, defined as ≥75 years old. Multivariable Cox regression analyses (MVA) tested the impact of age on recurrence and progression. Recurrence and progression were also compared with the Kaplan-Meier (KM) analysis according to each age group.

RESULTS: Overall, 63 patients (28.6%) were ≥ 75 years old. Among these, median number of instillations was 9 and 14% received the adequate number of instillations according to its risk classification. Similar results were found in younger patients (median 12 instillations, 17% of therapy adequateness). No difference was found in terms of treatment adequateness (P=0.7) or total number of instillations (P=0.1). Final pathology 113 pTa, 82 pT1, (51% and 37%, respectively). In 65 (29%) patients was diagnosed carcinoma in situ (concomitant or alone). 62 patients (28%) showed recurrence during follow-up, whereas progression was estimated in 30 patients (13.6%). At MVA, no differences were found in terms of risk of recurrence between younger *vs.* older patients (P=0.8). Conversely, older age was strongly associated with an improved risk of tumor progression (HR 2.5, P<0.01).

CONCLUSIONS: Our results proved that elderly patients with IR and HR NMIBC treated with BCG have an improved risk of tumor progression during follow-up. Conversely, risk of recurrence seemed to be comparable in this group of patients compared with younger ones. As a consequence, a different intravesical scheme or a more effective therapeutic approach should be evaluated for this class of patients.

SMART (SC219-SC230)

Kidney cancer 4

SC219
Lymphovascular invasion predicts lymph node involvement in patients with renal cell carcinoma
SC220
Off-clamp robotic partial nephrectomy: 10-year survival and functional outcomes from a high-volume single center series
SC221
Nephrometric scores based on 3D virtual modes improve accuracy of predicted surgical complexity during robotic partial nephrectomy: results of a collaborative ERUS validation study
SC222
Surgical planning with 3D virtual models' guidance allows the surgeon to set the most reliable strategy for intraoperative management of RAPN: results of a collaborative ERUS study
SC223
Optimizing the clamping strategy during robot-assisted partial nephrectomy based to 3D virtual models with renal perfusion volumes to minimize the postoperative renal injury
SC224
The complementary role of laparoscopy in the era of robotic-assisted partial nephrectomy: a single center experience
SC225
A new model to predict novel trifecta achievement and validation of its prognostic significance in a large single center series of minimally invasive partial nephrectomy
SC226
Robotic partial nephrectomy using Padua Score assessed via 3D virtual models: preliminary results of functional outcomes prediction of a collaborative ERUS study
SC227
Partial *versus* radical nephrectomy for complex renal mass: multicenter comparative analysis of functional outcomes (ROSULA Collaborative Group)
SC228
Redo partial nephrectomy for local recurrence after previous nephron sparing surgery: surgical insights and oncologic results from a high-volume robotic center
SC229
Level III and IV Inferior vena cava thrombectomy in renal cell carcinoma: beating heart surgery with normothermic cardiopulmonary bypass
SC230
Redo robotic partial nephrectomy for RCC local recurrence: video-description of the technique

SC219
Lymphovascular invasion predicts lymph node involvement in patients with renal cell carcinoma

C. Re, F. Belladelli, F. Cei, N. Tenace, G. Basile, G. Fallara, G. Rosiello, R. Matloob, M. Moschini, D. Cignoli, D. Canibus, Karakiewicz, I. Rowe, R. Lucianò, C. Doglioni, M. Colecchia, R. Bertini, A. Briganti, A. Salonia, A. Larcher, U. Capitanio (Milan)

BACKGROUND: Lymphovascular invasion (LVI) is recognized as an adverse pathological feature in numerous malignancies. However, its role in predicting outcomes in renal cell carcinoma (RCC) is unclear. The aim of this study was to assess the prognostic ability of LVI as a predictor of lymph node involvement (LNI) in RCC.

METHODS: Overall, 3796 patients with RCC who underwent partial (PN) or radical nephrectomy (RN) from 1989 and 2021 at a single tertiary referral center were identified. Multivariable logistic regression models were performed to compare the association between LVI and LNI and the oncologic outcomes in RCC patients.

RESULTS: Among 3796 patients, 1298 (34%) underwent lymph node dissection (LND). In 265 (20%) and 182 (14%) patients LVI and positive lymph nodes (LNs) were observed at final pathology, respectively. At multivariable logistic regression, the presence of any symptom at diagnosis (OR: 1.54; P<0.001) resulted as independent predictors of LVI at final pathology, after accounting for age, CCI, and clinical staging. Age, CCI, number of nodes removed, and number of positive nodes did not differ between patients with and without positive LNs (all P>0.05). At multivariable logistic regression analysis, LVI was associated with higher risk of positive LNs (OR: 1.73; P<0.001) after accounting for age, CCI, histology, pathological tumor stage, number of nodes removed. LVI was associated with higher risk of progression (HR: 1.73; P<0.001) but not of overall mortality (HR 3.46, P=0.09) and cancer specific mortality (HR: 4.56; P=0.2) compared to those without LVI, also when accounting for age, CCI, histology, pathological tumor stage, number of LNs removed and number of positive LNs.

CONCLUSIONS: LVI is an independent predictor of LNI in RCC patients and is associated with a higher risk of tumor progression. Our findings highlight the key importance of LVI in identifying patients at higher risk of recurrence and progression. This has key implications also for identifying patients who might benefit from adjuvant therapy after surgery.

SC220
Off-clamp robotic partial nephrectomy: 10-year survival and functional outcomes from a high-volume single center series

G. Tuderti, R. Mastroianni, U. Anceschi, A.M. Bove, A. Brassetti, S. D'Annunzio, M. Ferriero, L. Misuraca, S. Guaglianone, M. Gallucci, G. Simone (Rome)

BACKGROUND: The adoption of Off-clamp (Off-C) robotic partial nephrectomy (RPN) is led by the intent to maximize renal functional preservation. There is paucity of evidence about long-term functional outcomes of Off-C RPN. The aim of this study was to report perioperative, and long term functional and survival outcomes of a single high-volume center series of Off-C RPN.

METHODS: A prospective renal cancer institutional database was queried, and data of consecutive patients treated with Off-C RPN between 2010 and 2015 in a high-volume center were collected. Baseline, preoperative, perioperative, oncological, and functional outcomes were assessed. Trifecta was defined as the coexistence of negative margins, no Clavien-Dindo ≥3 complications and ≤30% postoperative estimated glomerular filtration rate reduction. Kaplan-Meier analysis was performed to assess survival and renal functional outcomes. Univariable and multivariable analyses were carried out to identify predictors of Trifecta achievement and renal function deterioration over time.

RESULTS: Overall, 530 patients with a mean follow-up of 57.8 months were included. Severe perioperative complications occurred in 1.9% of patients. Trifecta was achieved in 80.9% of cases. The 8-year recurrence-free survival, cancer-specific survival and overall survival rates were 96.8%, 99% and 96.4%, respectively. Patients with baseline eGFR ≥60 mL/min displayed a negligible risk of long term severe renal function deterioration (10-year newly onset chronic kidney disease (CKD) stage 3b risk: 8.1% for patients with preop CKD stage 1, 4.9% for patients with preop CKD stage 2). At multivariable analysis, the increasing tumor complexity (PADUA Score) was the only indipendent predictor of Trifecta achievement reduction. Concerning functional outcomes, age at surgery was the only independent predictor of developing newly-onset CKD stage≥3b (HR: 1.10; 95% CI: 1.009-1.19-0.98; P=0.03).

CONCLUSIONS. Off-C RPN represents a safe surgical approach with a negligible risk of severe perioperative complications occurrence. Regarding functional outcomes, at 10-year evaluation renal function deterioration is mainly driven by patients ageing.

SC221
Nephrometric scores based on 3D virtual modes improve accuracy of predicted surgical complexity during robotic partial nephrectomy: results of a collaborative ERUS validation study

D. Amparore, E. Checcucci, S.T. De Cillis, F. Piramide, A. Piana, G. Volpi, G. Basile, A. Larcher, A. Gallioli, A. Territo, J.M. Gaya, P. Piazza, S. Puliatti, A. Grosso, A. Mari, R. Campi, L. Zuluaga, K. Badani, S. Serni, U. Capitanio, F. Montorsi, A. Mottrie, C. Fiori, A. Minervini, A. Breda, F. Porpiglia (Orbassano, Turin)

BACKGROUND: 3D virtual models (3DVMs) have been already demonstrated as useful tools to evaluate the anatomical features of the renal masses *via* nephrometry scores to establish their surgical complexity. The aim of this prospective observational study was to validate these preliminary data comparing the PADUA Nephrometry Score and risk category (NS/NC) as assessed *via* 2D imaging and 3DVMs in a large multi-institutional cohort of renal masses suitable for robotic-assisted partial nephrectomy (RAPN), evaluating their predictive role on the occurrence of postoperative complications.

METHODS: Six high-volume robotic centers were involved in this validation study. Patients scheduled for RAPN were prospectively enrolled from June 2019 to September 2022, performing a PADUA-NS/NC assessment with 2D-imaging and 3DVMs. The χ^2 test evaluated the different

patient's distribution based on the imaging tool used to assess the NS/NC, while Cohen's k coefficient tested the concordance between classifications. ROC curves have been produced to evaluate sensitivity and specificity of the 3D-NS/NC *vs.* 2D-NS/NC in predicting the occurrence of postoperative complications. Finally, multivariable logistic analyses were built, looking for predictors of overall and major postoperative complications.

RESULTS: Three hundred eighteen patients were included in the study. The PADUA-NS/NC assessed *via* 3DVMs resulted downgraded when compared to the same scores based on 2D imaging in 44% and 12% of the cases. The Cohen's k coefficient demonstrated a low rate of concordance between 3D- and 2D-NS/NC (0.48 and 0.67, respectively). 3D-NS/NC demonstrated better accuracy than their 2D counterparts in predicting overall (AUC 3D-NS 0.66 *vs.* 2D-NS 0.60, P=0.012; AUC 3D-NC 0.64 *vs.* 2D-NC 0.59, P=0.046) and major (AUC NS 0.70 *vs.* 0.63, P=0.0007; AUC 3D-NC 0.69 *vs.* 2D-NC 0.65, P=0.0025) postoperative complications, with significant differences in areas under curves (AUCs) for each NS/NC comparing 3DVMs *vs.* 2D imaging. Multivariable analyses confirmed the 3D-PADUA NS as the only independent predictor of overall and major postoperative complications (OR 1.64, 95% CI: 1.19-2.25, P=0.002; OR 1.80, 95% CI: 1.03-3.15, P=0.039).

CONCLUSIONS: In this multi-institutional validation study, 3DVMs have been confirmed to be superior to 2D standard imaging in assessing the PADUA-NS/NC, often reducing the rate of surgical complexity but being more accurate in rating with higher scores those cases who are more likely to develop postoperative complications.

SC222
Surgical planning with 3D virtual models' guidance allows the surgeon to set the most reliable strategy for intraoperative management of RAPN: results of a collaborative ERUS study

D. Amparore, F. Piramide, A. Piana, E. Checcucci, G. Basile, A. Larcher, A. Gallioli, A. Territo, J.M. Gaya, P. Piazza, S. Puliatti, A. Grosso, A. Mari, R. Campi, S. Serni, U. Capitanio, F. Montorsi, A. Mottrie, C. Fiori, A. Minervini, A. Breda, F. Porpiglia (Orbassano, Turin)

BACKGROUND: 3D virtual models (3DVMs) already demonstrated to be useful for the planning of many different steps of robot-assisted partial nephrectomy (RAPN). The aim of this prospective observational study was to assess their role in driving the surgical strategy of three different steps of the intervention: the pedicle management, the resection of the tumor and the reconstruction of intrarenal structures.

METHODS: Five European tertiary centers took part in the study, enrolling prospectively patients scheduled for RAPN from 06/2019 to 09/2022. For each patient, his/her operating surgeon was asked to indicate the planning strategy, evaluating both 2D-imaging and 3DVMs. For the pedicle management the options considered were global, selective or no clamping, for the tumors' resection pure enucleation or enucleoresection and for the reconstruction of intrarenal structures (*i.e.*, calyceal violation repair) dedicated suture or parenchymal suture. The concordance rate between the two imaging tools-based planning was tested by using the Cohen's k coefficient test. Then, each planning strategy was compared with the real intraoperative management for the three steps of the surgery by using χ^2 test.

RESULTS: Two hundred eighty-nine patients were included in the study. Median age, BMI and lesion size were 65 (55:73) years, 26 (23:29) and 32 (20:48) mm, respectively. Median PADUA scores, as calculated *via* 2D imaging and 3DVMs, resulted significantly different (P<0.001), being 8 (7:10) and 8 (7:9), respectively. Concerning intraoperative variables, median operative time and blood loss were 111 (86:147) min and 150 (100:250) mL. Overall postoperative and major complications were 56/289 (19.3%) and 11/289 (3.8%). The rates of malignant tumors and positive surgical margins were 71.6% and 5.2%. The Cohen's K coefficient calculated between the 2D imaging or the 3DVMs-based plannings for the pedicle management, tumor resection and intrarenal structures reconstruction were 0.37, 0.63, and 0.54, respectively. Looking at the intraoperative management of the different surgical steps, the global clamping was performed according to the preoperative 2D imaging-based or 3DVMs-based planning in 59.3% *vs.* 94.5% of the cases, the pure enucleation in 62.8% *vs.* 89.7% of the cases and the reconstruction of intrarenal structures in 46.2% *vs.* 72.4% of the cases, respectively (all P values<0.001).

CONCLUSIONS: In this multi-institutional prospective study, 3DVMs demonstrated to have a primary role for the planning of the different steps of RAPN. They resulted to be more accurate than 2D images in aiding the surgeon to set the most reliable strategy for the pedicle management, the resection of the tumor and the reconstruction of intrarenal structures.

SC223
Optimizing the clamping strategy during robot-assisted partial nephrectomy based to 3D virtual models with renal perfusion volumes to minimize the postoperative renal injury

F. Piramide, D. Amparore, E. Checcucci, S. De Cillis, A. Piana, G. Volpi, M. Sica, P. Verri, M. Burgio, D. Zamengo, A. Quarà, E. Cisero, G. Busacca, M. Colombo, M. Mandaletti, A.G. Mesterca, B.S. Ribolzi, M. Manfredi, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: The role of 3D virtual models (3DVM) in driving the selective clamping strategy to minimize the renal ischemic injury extension has already been tested. However, their empirical definition of vascular regions inside the kidney can leads to clamping strategy fails. Our aim was to develop and test new 3DVMs considering their different perfusion volumes instead of vascular regions empirically estimated, to evaluate their intraoperative accuracy in guiding selective clampings and to assess their impact on the renal function of the operated kidney.

METHODS: We implemented our 3DVMs together with the Voronoi diagram, a Euclidean distance-based mathematical tool used to calculate vascular dominant regions in other organs. A perfusion volume-based 3DVM was built for all the renal masses scheduled for robot-assisted partial nephrectomy (RAPN) from 12/2019 to 09/2022. On its basis a selective or superselective clamping, limited to the peritumoral area, was planned, and performed intraoperatively when feasible. To assess the functional impact of the clamping strategy on the operated kidney a sub-cohort of patients underwent baseline

and 3 months postoperative renal scintigraphy (RS), evaluating the split renal function (SRF) and estimated renal plasmatic flow (ERPF).

RESULTS: One hundred three patients were prospectively enrolled in the study. The median (IQR) number of kidney and tumor perfusion volumes were 8 (7-10) and 3 (2-3), respectively. In 79 patients (76.6%) a selective clamping was performed, for 16 (15.5%) patients the main artery was clamped, and 8 (7.8%) patients underwent clampless procedure. The median (IQR) ischemia time for global and selective clamping were 17 (15-25) and 16 (12-20) minutes, respectively. In the 51 patients underwent RS, mean change in SRF rate decreased from 11.3% to 7.7% and 1.7% for global, selective (I order artery) and super-selective (II order artery) clamping, respectively (P=0.004). Similarly, mean change in ERPF rate diminished from 18.9% to 9.9% and 6.0% for the same category groups (0.02).

CONCLUSIONS: The implementation of mathematical algorithms to 3DVMs allows a precise estimation of the kidney perfusion volumes, minimizing the extension of the ischemic region with the selective clamping and leading to reduce the postoperative renal function impairment.

SC224

The complementary role of laparoscopy in the era of robotic-assisted partial nephrectomy: a single center experience

I. Sanz, A. Uleri, A. Territo, A. Gallioli, F. Sanguedolce, A. Rosales, G. Basile, P. Verri, O. Rodriguez-Faba, J. Palou, A. Breda (Barcelona)

BACKGROUND: The benefits of robotic approach in PN (RAPN) are widely known, especially to treat complex masses. As technological innovations have continued to advance, there has been a collateral increase in surgical costs. With the specter of a new economic and commodity supply crisis we want to promote a mixed model of integrating robotic and laparoscopic surgery for partial nephrectomy to reduce healthcare costs without impacting on quality of care

METHODS: Clinical and pathological data of patients underwent laparoscopic or robotic partial nephrectomy at our institution from 2015 to 2022 were collected. CKD-EPI formula was used to estimate glomerular filtration rate (eGFR). The postoperative complications were classified according to Clavien-Dindo classification. Clinical and pathological data were compared between the laparoscopic and robotic group: for continuous variables with Mann-Whitney Test, for categorical with χ^2 test.

RESULTS: Two hundred eighty-one patients underwent partial nephrectomy of which 100 robotic (RAPN) and 181 laparoscopic (LPN). Age and eGFR at baseline were comparable between the two groups (P=0.53; P=0.87). Masses treated with robotic approach were larger (3.7 *vs.* 2.7 cm; P<0.01), with higher rate of intermediate and high complex masses according to PADUA and RENAL nephrometry scores (P<0.01; P=0.03) compared to LPN. The median percentage of eGFR decreasing at last follow-up was comparable between the two groups (4.8% *vs.* 7.6%; P=0.15) as the rate of de novo CKD stage ≥3 (10% *vs.* 13%; P=0.48). Median warm ischemia time (15 *vs.* 18 min; P=0.8) and the rate of postoperative complications were comparable (overall 24% *vs.* 29%; P=0.35 and CD ≥3a 4% *vs.* 5%; P=0.6) between the two groups. The complication rate was higher in LPN group than in RAPN for masses with PADUA Score ≥8 (25% *vs.* 42%; P=0.03), exophytic rate <50% (24% *vs.* 42%; P=0.03) and mesorenal location (12% *vs.* 38%; P=0.001). These masses should be treated robotically to reduce the rate of complication. The complication rate in masses with a PADUA Score <8 (24% *vs.* 18%; P=0.44), exophytic rate ≥50% (23% *vs.* 20%; P=0.72) and polar location (30% *vs.* 23%; P=0.29) did not show a significant difference between laparoscopy and robotic and these patients can be treated with LPN or RAPN. In this population no differences in terms of operative time (155 LPN *vs.* 170 RAPN; P=0.19) and length of hospital stay (4 days LPN *vs.* 5 days RAPN; P=0.12) were found between LPN and RAPN.

CONCLUSIONS: Our integration model between RAPN and LPN proposes to treat lesions with PADUA less than 8, with exophytic rate ≥50% and polar location with a laparoscopic approach. According to this model, 30% of PN in our population could be performed laparoscopically without impacting on the complication rate.

SC225

A new model to predict novel trifecta achievement and validation of its prognostic significance in a large single center series of minimally invasive partial nephrectomy

F. Sanguedolce, A. Uleri, A. Gallioli, A. Territo, G. Basile, P. Verri, J.M. Gaya, S. Fontanet, A. Tedde, J. Palou, A. Breda (Barcelona)

BACKGROUND: Novel trifecta has been proposed to define surgical success in patients undergoing partial nephrectomy (PN). The aim of this study is to validate the role of this surgical success score to predict survival outcomes and to provide a new machine-learning based model to identify the predictors of novel trifecta achievement.

METHODS: Clinical and pathological data of patients underwent minimally invasive PN at our Institution from 2003 to 2022 were collected. CKD-EPI formula was used to estimate glomerular filtration rate (eGFR). Surgical success was defined through the achievement of Novel Trifecta (No Clavien-Dindo ≥3 postoperative complications, negative surgical margins and change in postoperative eGFR<30%). Change in eGFR discriminating patients according to Trifecta achievement was analyzed with the ANOVA test. Kaplan Meyers curves were set to analyze the impact of Trifecta achievement on survival outcomes. We relied on automated χ^2 interaction detection (CHAID); a recursive machine learning partitioning algorithm developed to predict Novel Trifecta achievement. A logistic regression was fit to assess the predictive power of individual clusters.

RESULTS: Four hundred sixty-five patients were included in the analysis with a median age was 63 (55-70) years and Age-Adjusted Comorbidity Index (ACCI) 4 (3-5). Median tumor size was 3 (2.2-4.1) cm with a median warm ischemia time of 15 (0-22). Median follow-up was 72 (38-108) months. No difference was found at 10-year follow-up in local recurrence free survival (P=0.4) metastasis free survival (P=0.2) and cancer specific survival (P=0.16) based on the Trifecta achievement. Patients in which Trifecta was not achieved had a worse overall survival (70% *vs.* 85%; P=0.04) than those where it was reached. The changes in eGFR were significan-

tly lower in the cohort where trifecta was not achieved at 6, 24 and 60 months (P<0.01). Patients with single kidney, age ≥65, and surgical experience >80 cases were selected as the most informative risk factors to classify patients according to their probability to achieve trifecta, leading to the creation of three clusters. The trifecta achievement rates for cluster N. 1 (patients with single kidney), cluster N. 2 (Surgical experience ≤80 cases or surgical experience >80 cases and age ≥65) and cluster N. 3 (experience >80 cases and age <65) were 43.6%, 71.2% and 88.5%, respectively. At logistic regression the OR of trifecta achievement was 3.11(95% CI 1.6-6.1; P<0.01) in cluster N. 2 *vs.* N. 1 and 9.54(95% CI 3.9-23.4; P<0.01) in cluster N. 3 *vs.* N. 1.

CONCLUSIONS: Novel trifecta achievement after PN is related to the overall survival but not to oncological outcomes, underlining the link between kidney function decline and mortality. We identified a predictive model for Trifecta achievement after PN where the only modifiable factor is the surgical experience.

SC226
Robotic partial nephrectomy using Padua Score assessed via 3D virtual models: preliminary results of functional outcomes prediction of a collaborative ERUS study

D. Amparore, F. Piramide, S. De Cillis, A. Piana, E. Checcucci, G. Basile, A. Larcher, A. Gallioli, A. Territo, J.M. Gaya, P. Piazza, S. Puliatti, A. Grosso, A. Mari, R. Campi, L. Zuluaga, K. Bedani, S. Serni, U. Capitanio, F. Montorsi, A. Mottrie, C. Fiori, A. Minervini, A. Breda, F. Porpiglia (Orbassano, Turin)

BACKGROUND: 3D virtual models (3DVMs) already demonstrated their role in planning the strategy of robot-assisted partial nephrectomy (RAPN) based on the evaluation the anatomical features of the tumor. The aim of this prospective observational study was to test their accuracy in assessing the tumor complexity in relationship with the functional outcomes.

METHODS: Six high-volume robotic centers took part in the study, enrolling prospectively patients scheduled for RAPN from 06/2019 to 09/2022. The PADUA Score of each renal mass undergoing surgery was assessed with 2D-imaging and 3DVMs. For the purpose of the study, baseline, postoperative (at discharge) and 3-month serum creatinine (SCr), estimated Glomerular Filtration Rate (eGFR) and chronic kidney disease (CKD) category, were recorded and analyzed. Paired sample *t*-test was used to compare functional data. Finally, multivariable logistic analyses were built, looking for the predictors of worsening CKD category, including the Charlson's Age Adjusted Index, the PADUA Score assessed with the two imaging tools and the intraoperative variables potentially impacting the functional outcome (renal pedicle management, type of tumor's resection, violation of calyces and type of parenchymal suture).

RESULTS: Three hundred eighteen patients were included in the study. Median age, BMI and lesion size were 65 (55:72) years, 26 (23.5:29.1) and 36 (25:48) mm, respectively. Median PADUA scores, as calculated *via* 2D imaging and 3DVMs, resulted significantly different (P<0.001), being 8 (7:10) and 8 (7:9), respectively. Mean preoperative, postoperative and 3-month SCr were 0.99 (+0.34), 1.14 (+0.47) and 1.01 (+0.38), respectively. Mean preoperative, postoperative and 3rd month eGFR were 81.36 (+23.24), 72.46 (+24.95) and 79.78 (+26.99), respectively. The *t*-test showed significant differences between the preoperative and discharge values of SCr and eGFR (both P<0.001) while no differences in the same variables were found comparing the preoperative and 3-month values (P=0.056 and P=0.076). In 71/318 patients (22.3%) a worsening of CKD category was recorded. Multivariable analyses concerned the 3DVM based-PADUA Score as the only independent predictor of worsening CKD category (OR: 1.38; 95% CI: 1.01-1.90; P=0.044).

CONCLUSIONS: In this multi-institutional study, 3DVMs resulted to be accurate in assessing the tumor complexity in relationship with the functional outcomes. In fact, their use to evaluate the PADUA Score was the only factor related to the postoperative worsening of CKD category.

SC227
Partial *versus* radical nephrectomy for complex renal mass: multicenter comparative analysis of functional outcomes (ROSULA Collaborative Group)

C. Cerrato, M.F. Meagher, R. Autorino, G. Simone, B. Yang, R.G. Uzzo, A. Kutikov, F. Porpiglia, U. Capitanio, F. Montorsi, J. Porter, A.T. Beksac, D. Puri, M. Nguyen, S.D. Pandolfo, K. Hakimi, A. Minervini, C. Lau, M. Aron, D. Eun, A. Mottrie, C. Mir, C. Sundaram, A. Antonelli, J. Kaouk, I.H. Derweesh (Verona)

BACKGROUND: Utility of partial nephrectomy (PN) for complex renal mass (CRM) is controversial. We determined the impact of surgical modality on postoperative renal functional outcomes for CRM.

METHODS: We retrospectively analyzed a multicenter registry (ROSULA). CRM was defined as RENAL Score 10-12. Patients were divided into PN and radical nephrectomy (RN) for analyses. Primary outcome was development of *de-novo* eGFR<45 mL/min/1.73m^2. Secondary outcomes were *de-novo* eGFR<60 and DeGFR between diagnosis and last follow-up. Cox proportional hazards (MVA) was used to elucidate predictors for *de-novo* eGFR<60 and <45. Linear regression (MVA) was utilized to analyze DeGFR. Kaplan-Meier Analysis (KMA) was performed to analyze 5-year freedom from *de-novo* eGFR<60 and <45.

RESULTS: We analyzed 969 patients (RN=429, PN=540; median follow-up = 24.0 months). RN patients had lower BMI (P<0.001) and larger tumor size (P<0.001). Overall post operative complication rate was higher for PN (P<0.001), but there was no difference in major complications (Clavien III-IV; P=0.702). MVA demonstrated age (HR=1.05, P<0.001), tumor size (HR=1.05, P=0.046), RN (HR=2.57, P<0.001), and BMI (HR=1.04, P=0.001) to be associated with risk for *de-novo* eGFR<60 mL/min/1.73m^2. Age (HR=1.03, P<0.001), BMI (HR=1.06, P<0.001), baseline eGFR (HR0.99, P=0.002), tumor size (HR1.07, P=0.007) and RN (HR=2.39, P<0.001) were risk factors for de novo eGFR<45 mL/min/1.73m^2. RN (B= -10.89, P<0.001) was associated with greater DeGFR. KMA revealed worse 5-year freedom from *de-novo* eGFR<60 (71% *vs.* 33%, P<0.001) and *de-novo* eGFR<45 (79% *vs.* 65%, P<0.001) for RN.

CONCLUSIONS: PN provides functional benefit in selected patients with CRM without significant increase in major complications compared to RN and should be considered when technically feasible.

SC228
Redo partial nephrectomy for local recurrence after previous nephron sparing surgery: surgical insights and oncologic results from a high-volume robotic center

F. Di Maida, A.A. Grosso, A. Cadenar, L. Lambertini, S. Giudici, V. Salamone, S. Coco, D. Paganelli, A. Mari, A. Minervini (Florence)

BACKGROUND: The role of redo partial nephrectomy (PN) for recurrent renal cell carcinoma (RCC) is still overlooked. Only few studies explored the effects of PN and radical nephrectomy (RN) on survival outcomes after previous nephron sparing surgery (NSS). As such, it is still controversial whether PN may represent a safe option in redo renal surgery setting. In the current study we sought to evaluate feasibility, safety, and oncologic outcomes of redo PN for local recurrence (LR) after NSS.

METHODS: We prospectively gathered data from patients treated with robotic redo PN for locally recurrent RCC after previous NSS from January 2017 to January 2023. LR was defined as any recurrence in the ipsilateral retroperitoneum, defining the exact location of recurrence (distant or not from the tumor enucleation bed). Type of resection technique was assigned in the operating theatre on the pathologic specimen according to the Surface-Intermediate-Base (SIB) Score.

RESULTS: Twenty-six patients were included. 18 (69.2%) were male, median age was 62 (IQR 59-72). Median clinical diameter was 3.5 (IQR 2.2-4.9) cm, median PADUA Score was 8 (IQR 7-9). 2 (7.7%) patients presented with bilateral renal tumor. 1 functional (3.8%) and 6 (23.1%) surgical single kidney patients were recorded. Median time from previous NSS to recurrence was 38 (IQR 13.8-97) months. 14 (53.8%) recurrences were found at the level of previous resection bed. Median operative time was 177 (IQR 148-200) min and hilar clamping was performed in 14 (46.2%) cases with a median warm ischemia time of 16 (14.5-22) min. Two (7.7%) intraoperative complications were recorded. No conversions to RN or open surgery occurred. Median SIB Score was 2 (IQR 1-2). Pure enucleation (SIB Score 0-1), hybrid enucleation (SIB Score 2) and pure enucleoresection (SIB Score 3) were recorded in 13 (50%), 8 (30.8%) and 5 (19.2%) cases, respectively. All LR far from previous resection bed received a SIB Score of 0-1, while in nearly 93% of LR on previous resection bed a hybrid enucleation or pure enucleoresection was preferred. pT1a, pT1b, pT2 and pT3a disease was recorded in 18 (69.2%), 5 (19.2%), 1 (3.8%) and 2 (7.7%) cases. Positive surgical margins were registered in 3 (11.5%) cases. At a median follow up of 37 (IQR 16-45) months, 5 (19%) patients experienced disease recurrence, being local and systemic in 3 (11.5%) and 2 (7.7%) cases. All LR were far from tumor resection bed. 1 (3.8%) cancer related death was recorded. Median serum creatinine level and eGFR at 6 months were 1.40 (IQR 0.96-1.64) mg/dL and 48.8 (IQR 38.6-71.6) mL/min/1.73m^2, with no differences between resection techniques.

CONCLUSIONS: Our study highlights the feasibility and safety of redo PN for treatment of locally recurrent RCC after NSS, either on previous resection bed or elsewhere in the kidney. Assignment of SIB Score after PN represents a major strength of the study, allowing a deep insight into surgical nuances, resection strategy and resection technique case by case for redo PN in a high-volume center.

SC229
Level III and IV Inferior vena cava thrombectomy in renal cell carcinoma: beating heart surgery with normothermic cardiopulmonary bypass

L.F. Carmignani, S. Guzzo, E. Bonacina, C. Silvani, A. Li Puma, R. Di Benedetto, A. Sala, A. Baudo, D. Vizziello, E. Finkelberg, P. Acquati, C. De Vincentiis (San Donato Milanese, Milan)

BACKGROUND: Radical nephrectomy with inferior vena cava thrombectomy for renal cell carcinomas (RCCs) with Mayo levels III and IV thrombus is considered one of the most challenging urological procedures. Serious intraoperative complications, such as bleeding and embolism may occur. In this setting, extracorporeal circulation and deep hypothermic circulatory arrest has become the gold standard treatment for Mayo levels III and IV RCC. The latter involves full heparinization, coagulopathy secondary to hypothermia and long operative time. The aim of this study was to assess perioperative and oncologic outcomes of renal cell carcinoma patients treated with a less invasive operative strategy aimed at minimizing the complication rate associated with treatment of tumor thrombus at Mayo level III and IV.

METHODS: Between 2016 and 2020, 12 patients diagnosed with Renal Cell Cancer and a vena cava tumor thrombus were treated with radical nephrectomy and thrombectomy at our Institution. Among them, 5 had supradiaphragmatic extension (Mayo level IV) seeking a complex and multidisciplinary surgical approach. Therefore, a coordinated thoracic and abdominal procedure was performed between urological and cardiosurgical teams. For level IV thrombi, a beating heart surgery using a simplified cardiopulmonary bypass (CPB) technique was used for thrombus retrieval from the right atrium. On the other hand, Mayo level III thrombi were approached exclusively through an abdominal access. Intraoperative blood salvage was performed when feasible. Perioperative complication and mortality rates within 30 and 90 days of surgery were recorded.

RESULTS: Of 12 patients 5 were male (41.7%) and 7 were female (58.3%). Median age was 70.5 years (interquartile range [IQR]: 6.1). Median BMI was 26.6 (IQR:20.8-28). ASA Score was 2 in 4 (33.3%) and 3 in 8 (66.6%). According to tumor characteristics, cT stage was cT3b in 3 (25%), cT3c in 5 (41.7%) and cT4 in 4 (33.3%). cN stage was cN0 in 9 (75%) and cN+ in 3 (25%). Finally, 4 patients (33.3%) had metastatic disease. Median surgical time was 240 minutes (IQR:210-281). Median CPB time was 40 minutes (IQR:40-48). Median blood loss was 1500 mL (IQR: 1200-2500). Median intensive care stay was 2 days (IQR:1-3) and median duration of hospitalization was 10.5 (IQR: 8-15.3). No patients died during the procedure. Overall, 50% of patients had postoperative complications. Specifically, 4 (33.3%) patients had Grade II surgical complications, according to the Clavien-Dindo classification, 1 (8.3%) had Grade IIIb and 1 (8.3%) Grade IV. All patients were discharged home or for rehabilitation. At final pathology pT stage was pT3b in 5 (41.7%), pT3c in 6 (50%) and pT4 in 1 (8.3%).

CONCLUSIONS: The use of beating heart on simplified CPB is a less invasive method for radical resection of renal cell carcinomas with intracardiac tumor extension, while extended intracaval tumor thrombus, such as Mayo level III, can be treated safely and effectively with an abdominal approach.

SC230
Redo robotic partial nephrectomy for RCC local recurrence: video-description of the technique

A.A. Grosso, F. Di Maida, S. Giudici, A. Cadenar, L. Lambertini, V. Salamone, D. Paganelli, F. Valastro, M. Bacchiani, S. Coco, A. Tuccio, M. Salvi, A. Mari, A. Minervini (Florence)

BACKGROUND: Local recurrence is a relatively rare adverse outcome following partial nephrectomy (PN). In this context the role of redo PN for recurrent renal cell carcinoma (RCC) is still overlooked. Only few studies explored the effects of either PN and radical nephrectomy (RN) on survival outcomes after previous local therapy for RCC. As such, it is still controversial whether PN may represent a safe and effective treatment option as compared to RN also in the redo renal surgery setting. In the present study, we aimed to video-report the surgical feasibility of salvage PN for local recurrence after previous nephron sparing surgery (NSS) focusing on technical nuances.

METHODS: We prospectively gathered data from patients treated with robotic redo PN for locally recurrent RCC after previous NSS from January 2017 to January 2023. Local recurrence (LR) was defined as any recurrence in the ipsilateral retroperitoneum, defining the exact anatomical location of recurrence (whether distant or not from the tumor enucleation bed). As general PN surgical concept cannot be automatically translated to redo surgery scenario, we decided to additionally focus on the surgical trick commonly employed at our Institution during robot assisted PN in this specific subgroup of patients.

RESULTS: Overall, 26 patients were considered eligible for the present study. Median clinical diameter was 3.5 cm and median PADUA Score was 8. Median time from previous NSS to recurrence was 38 months. In 14 cases the recurrence was found at the level of previous tumor resection bed. Median operative time was 177 minutes. Hilar clamping was performed in 14 (46.2%) cases. Median warm ischemia time of 16 minutes. No conversion to RN occurred. At a median follow-up of 37 months, 6 (23%) patients experienced disease recurrence, being local and systemic in 3 (11.5%) and 2 (7.7%) patients.

CONCLUSIONS: In experienced hands, robotic redo PN for RCC local recurrence after primary NSS is technically feasible with favorable results. Specific surgical nuances are necessary to maximize the outcomes.

SMART (SC231-SC247)

Prostate cancer: active surveillance, focal therapy, hormonal and radiotherapy

SC231
Rate of therapy failure and free-survival failure with different histological failure definitions: a retrospective analysis of patients treated with focal primary cryotherapy for localized prostate cancer
SC232
Long-term oncological outcomes of patients with MCRPC: a longitudinal real-life multicenter cohort
SC233
Does prostate cancer family history have an impact on active surveillance adherence in men with low- or favorable intermediate risk disease?
SC234
Survival in adjuvant *vs.* salvage radiation therapy in pathological node positive prostate cancer patients: a multicentric study
SC235
The prognostic role of 68GA-PSMA PET/CT and the impact of metastasis-directed therapy on cancer progression in men with biochemical recurrence from prostate cancer. results from a large, single institution series
SC236
Exploring the effect of metastasis directed therapy on progression patterns of patients with positive 68GA-PSMA PET/CT and biochemical recurrence from prostate cancer
SC237
Approach (NCT05649943): multimodal approach in patients with MHSPC. A pragmatic randomized phase 3 trial of androgen-deprivation therapy (ADT) plus apalutamide (APA) *versus* ADT plus apalutamide (APA) and local treatment
SC238
Managing non-metastatic castration resistant prostate cancer: real life snapshot from a longitudinal multicenter cohort
SC239
Oncological outcomes of patients with high volume MCRPC: results from a longitudinal real-life multicenter cohort
SC240
Upgrading and upstaging after radical prostatectomy in patients potentially eligible for high-intensity focused ultrasound (HIFU) according to the Chronos study criteria: a single-center experience
SC241
Intermittent *versus* continuous androgen deprivation therapy for biochemical progression after primary therapy in hormone-sensitive non-metastatic prostate cancer: comparative analysis in terms of CRPC-M0 progression
SC242
Clinical characterization and development of a predictive model of 1-year overall survival amongst patients with metastatic hormone sensitive prostate cancer (MHSPC) treated with one of the approved treatment plans using real-world data (RWD): preliminary results from the European Network of Excellence for big data in prostate cancer (PIONEER)
SC243
Adverse events related to darolutamide treatment: analysis of "real-life" data from Eudra-Vigilance (EV) and the Food and Drug Administration (FDA) database entries
SC244
Identifying the optimal candidates for concomitant androgen-deprivation therapy among patients receiving metastasis-directed therapy for positive 68GA-PSMA PET/CT for biochemical recurrent prostate cancer after radical prostatectomy
SC245
Tailoring the optimal use of androgen-deprivation therapy concomitant to postoperative radiotherapy among men with PN1 prostate cancer: long-term results of a large, single institution series
SC246
Early patient-reported outcome measures on functional outcomes after high-intensity focused ultrasound based focal therapy for prostate cancer
SC247
Is there an impact of the center performing baseline multiparametric MRI on active surveillance outcomes in prostate cancer patients?

SC231

Rate of therapy failure and free-survival failure with different histological failure definitions: a retrospective analysis of patients treated with focal primary cryotherapy for localized prostate cancer

G. Maiolino, E. Fernández Pascual, C. Martín Vivas, E. Lledó-García, C. Martínez Ballesteros, J.I. Martínez-Salamanca (Perugia)

BACKGROUND: In focal therapy (FT) for localized prostate cancer (PCa), a "therapy failure" is difficult to define. Among the several consensus projects on various aspects of FT that have been undertaken in the past years, various definitions of FT failure have been described. Moreover, new evidence on active surveillance (AS) for low-risk patients have introduced the possibility to use AS for eventually postfocal therapy in-field or out-filed low-grade PC. In an attempt to evaluate the impact of different FT failure definitions we will show the change in rates and the failure free survival (FFS) values, using the three histological definitions of FT failure found in literature, in a population of patients with localized PCa treated with focal primary cryotherapy.

METHODS: We reviewed medical records of all patients treated with cryotherapy in one center between October 2018 and January 2022 with at least 12 months of follow-up. For patients with re-biopsy after FT we used the following histological definition of FT failure: 1) "very wide definition" (A) defined as "any PCa found in biopsy core from out-field or in-field areas;" 2) "wide definition" (B) defined as "PCa with GS≥3+4 in biopsy core from out-field or in-field areas;" and 3) "strict definition (C) defined as "PCa with GS≥3+4 in biopsy core from in-field area, with or without negative or cancer positivity with any GS in out-field." We maintained fixed the presence of no-histological criteria for FT failure: 1) if patients did not have a follow-up biopsy, after 12 months, we defined "therapy failure" as a PSA>2 ng/mL and/or any type of suspicious area on mpMRI; 2) "therapy failure" was defined also as an "evidence of metastasis, node-involvement or locally advanced progression at any imaging performed;" and 3) if patients underwent rescue whole gland treatment (prostatectomy, radiotherapy or androgen-deprivation therapy) were defined as "therapy failure."

RESULTS: Ninety patients were enrolled with a mean follow-up of 43.4±22.4 months. Mean age was 66.7±8.09 years. Mean pretreatment PSA was 7.2±3.6 ng/mL. According to NCCN group risk we found the following patients' groups: 35 (38.9%) very low-, 10 (11.1%) low-, 28 (31.1%) favorable intermediate, 10 (11.1%) unfavorable intermediate, 5 (5.6%) high- and 2 (2.2%) very-high risk PCa. Using the three different histological definitions of FT failure in combination with the other no- histological criteria, rate of failure results 50 (55.6%), 37 (41.1%) and 27 (30%) with A, B, and C definition, respectively. Median failure-free survival (FFS) resulted in 41.0 (95% CI: 33-48), 55.0 (46.1-63.8) and 76.0 (44.7; 107.2) months with A, B, and C definition, respectively.

CONCLUSIONS: We need to define a modern and evidence-based concept of histological FT failure. The first aim should be to assess oncological outcomes of in-field and out-field histological recurrences, in multicenter and prospectively setting, defining their unsignificant or significant clinical prognosis.

SC232

Long-term oncological outcomes of patients with MCRPC: a longitudinal real-life multicenter cohort

M. Izzo, M. Ferriero, E. Franzese, A. Pappalardo, G. Facchini, C. De Nunzio, G. Tema, A. Tubaro, B. Turchi, R. Naspro, S. Chiellino, G. Tuderti, U. Anceschi, R. Mastroianni, L. Misuraca, A.M. Bove, A. Brassetti, F. Calabrò, S. Astore, G. Simone (Pozzuoli, Naples)

BACKGROUND: Natural history of prostate cancer (PC) changed in the last years thanks to the introduction of multiple novel treatment strategies. We reported long-term oncologic outcomes of patients with metastatic castration resistant prostate cancer (mCRPC) population from a longitudinal real_ x0002_life multicenter cohort.

METHODS: We retrospectively collected data on CRPC patients treated at five centers. The Kaplan-Meier method was used to compare differences in terms of radiologic progression-free survival (PFS) after treatment in a chemo-naïve or postchemo setting, high-volume (defined as more than 6 bone lesions or bulky node ≥5 cm) *vs.* low-volume disease and more treatment lines. Survival probabilities were computed at 12, 24, 60 and 120 months. Age, non-metastases at initial diagnosis, high-volume disease, first-line drug and therapy lines were included in a univariable and multivariable Cox regression analyses to identify predictors of PFS.

RESULTS: Out of 216 patients, 108 received abiraterone (AA), and 89 enzalutamide (EZ) as first treatment line. Five-year PFS, CSS and OS were 63.4%, 67.2% and 67.7%, respectively. At Kaplan-Meier analysis PFS probabilities were comparable for chemo-naïve *vs.* non-chemo-naïve patients (log-rank P=0.16), as well as for cases who received one *versus* more than 1-treatment line (log-rank P=0.49). Conversely, patients with high-volume disease displayed lower PFS probabilities (log-rank P=0.006). Overall, 57 patients (23.4%) after a first line shifted to a second-line therapy: EZ was prescribed in 36 cases, AA in 11 cases and radiometabolic therapy in 7 patients. Forty-six cases (21.3%) developed significant progression and were treated with chemotherapy. Age, short-time interval to CRPC and high-volume disease were predictors of lower PFS probabilities at multivariable analysis (P=0.002, P=0.006 and P=0.005, respectively).

CONCLUSIONS: Survival outcomes of mCRPC patients were mostly driven by volume of disease and longer hormone-sensitive status. The natural history of disease seems to be marginally affected by previous chemotherapy, being PFS probabilities comparable between chemo-naïve and after-chemo cohorts. Relying on targeted agents and delaying the shift to chemotherapy seems a viable option with negligible impact on patients' survival.

SC233

Does prostate cancer family history have an impact on active surveillance adherence in men with low- or favorable intermediate risk disease?

R. Leni, A. Stabile, G. Gandaglia, E. Mazzone, V. Cucchiara, M. Bandini, A. Pellegrino, M. De Angelis, L. Quarta, P. Zaurito, D. Robesti, N. Fossati, G. Brembilla, E. Zaffuto, F. Dehò, F. De Cobelli, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Men with family history (FH) of prostate cancer (PCa) on active surveillance (AS) for low grade PCa

are at higher risk of reclassification. In these patients, however, adherence to AS may be influenced by factors other than reclassification. We assessed the relationship between FH and AS dropout without evidence of reclassification compared to patients without FH.

METHODS: We identified 779 men on AS for grade group 1 or 2 PCa at our Institution (2005-2021). Reclassification was defined as an increase in Gleason Score from diagnosis. The cumulative incidence function estimated the 5-year discontinuation rate without reclassification according to FH (any-degree, *vs.* no FH), with discontinuation for reclassification as a competing event. The Fine and Gray model was used to derive the adjusted sub-distribution hazard ratios (aSHR). A sensitivity analysis was conducted incorporating a definition of volume reclassification (>33% of cores involved or >50% of a single core involved), and the NCCN definition of strong FH (≥1 first-degree or ≥2 second-degree relatives). To assess clinical utility, we evaluated rates of adverse pathology ([AP], grade group ≥2, extracapsular extension, or positive lymph nodes) in 246 men who underwent delayed radical prostatectomy (RP) according to the reason for discontinuation.

RESULTS: Median age was 65 years (59-70 years), 135 men (18%) had FH, and 112 (14%) had strong FH. Median follow-up was 50 months, the overall 5-year reclassification rate was 42%. The overall 5-year rate of discontinuation without reclassification was 23% (N.=118). The cumulative incidence of 5-year discontinuation without reclassification in patients with, *vs.* without FH was 27% *vs.* 15% (aSHR 1.61, P=0.029). The effect of FH on discontinuation without reclassification remained significant in all sensitivity analyses. No difference was observed in terms of AP at delayed RP according to FH in those reclassified *vs.* those treated without reclassification (all P>0.05).

CONCLUSIONS: Although FH is associated with higher risk of reclassification, almost a third of men with positive FH discontinue AS without evidence of progression. The absence of a difference in AP rates at delayed RP should guide patient counseling about safety of AS also in men with FH.

SC234
Survival in adjuvant *vs.* salvage radiation therapy in pathological node positive prostate cancer patients: a multicentric study

D. Giovanni, G. Felici, A. Porcaro, N. Pavan, D. Amparore, R. Bertolo, C.A. Bravia, G. Bozzini, C. Trombetta, E. Mearini, E. Montanari, P. Ditonno, A. Simonato, P. Bove, C. De Nunzio, A. Tubaro, R. Schiavina, E. Brunocilla, A. Antonelli, A. Galosi, A. Mottrie, F. Porpiglia, C. Terrone, M. Borghesi, G. Drocchi, S. Tappero, G. Guano (Genoa)

BACKGROUND: The aim of this study was to compare metastasis-free survival (MFS), CRPC-progression free survival (CRPC-PSF) and overall survival (OS) rates between adjuvant (adj) *vs.* salvage (Salv.) radiotherapy (RT) in pathological node positive (pN1) prostate cancer (PCa) patients.

METHODS: We relied on a multicentric database of 92 consecutive pN1 patients from 16 Academic institutions, of whom 72 (77%) *vs.* 22 (23%) were treated with primary AdjRT *vs.* SalvRT, respectively. Kaplan-Meier plots and Cox regression models tested the effect of AdjRT *vs.* SalvRT on CRPC-PFS, MFS, and OS. All analyses were adjusted for D'Amico risk group, percentage of positive lymph nodes at final pathology, and administration of androgen deprivation therapy (ADT).

RESULTS: Overall, no statistically or clinically relevant difference was recorded between AdjRT *vs.* SalvRT in age (medians 66 *vs.* 66 years), PSA at diagnosis (medians 25 *vs.* 25.5 ng/mL), biopsy grade group, D'Amico classification, extension of lymph node dissection and features at final pathology, including percentage of positive lymph nodes (all P>0.2). 5-year MFS, CRPC- PFS, and OM were respectively 77 *vs.* 49% (P=0.15), 91% *vs.* 89% (P=0.13), and 91 *vs.* 100% (P=0.25) in AdjRT *vs.* SalvRT. After Cox regression analysis, when compared to AdjRT, SalvRT yielded HR of 6.65 (95% CI 0.64-68.98, P=0.1) for CRPC- PFS, 3.80 (95% CI 1.11-12.99, P=0.03) for MFS, and 0.26 (95% CI 0.02-3.77, P=0.3) for OS, after adjustment for D'Amico risk, percentage of positive lymph nodes and administration of ADT.

CONCLUSIONS: Our study suggests that despite AdjRT might offer better MFS, it provides equal OS outcomes compared to SalvRT, even after adjustment for adverse clinical and pathologic features and ADT. Therefore, both AdjRT and SalvRT can be considered as viable options for the treatment of pN1 PCa patients.

SC235
The prognostic role of 68GA-PSMA PET/CT and the impact of metastasis-directed therapy on cancer progression in men with biochemical recurrence from prostate cancer. results from a large, single institution series

D. Robesti, E. Mazzone, G. Gandaglia, A. Stabile, A. Necchi, D. Raggi, L. Marandino, G.O. Cirulli, S. Scuderi, F. Barletta, M. De Angelis, E. Balestrazzi, S. Fanti, V. Cucchiara, A. Farolfi, L. Bianchi, R. Schiavina, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Use of 68Ga-PSMA PET is recommended for prostate cancer (PCa) re-staging in patients with either PSA persistence or biochemical recurrence (BCR) after radical prostatectomy (RP). Since evidence on the role of metastasis directed therapy (MDT) on progression-free survival (PFS) is still poor, we aimed at assessing, in patients with positive PSMA PET, whether MDT may impact on PFS.

METHODS: We retrospectively identified 361 patients evaluated with 68Ga-PSMA PET/CT for BCR after RP between 2016 and 2022. Patients were stratified according to PSMA PET results in negative (N.=135) and positive (N.=226) group. In the latter group, MDT consisted of stereotactic ablative radiation therapy (SABR) on positive spots. Clinical recurrence (CR) was defined as any new metastases detected at imaging after a first PSMA PET. Adverse pathological features (*i.e.*, grade group 4-5 with ≥pT3a stage and/or lymph node invasion) and salvage treatments were also compared between two groups. Cox regression analyses assessed the impact of a positive PSMA PET and its interaction with MDT on CR after adjusting for PSA level at PSMA PET, number of positive spots and concomitant use of hormonal therapy. Lastly, multivariable Cox-derived Kaplan-Meier (KM) analyses depicted the time from the first PSMA PET to CR.

RESULTS: Among patients with a positive scan, 113 (31%) received MDT. Median follow-up (FU) was 30 months after PSMA PET. The 3-year CR-free survival rates were 72 *vs.* 42% for negative *vs.* positive PSMA PET scan since BCR. At Cox analyses, a positive PSMA PET scan was associated with 2-fold higher risk of PFS during FU as compared to a negative PSMA PET (HR: 2.09; P=0.003) after adjusting for

confounders. When testing interaction with use of MDT in patients with positive PSMA PET, men with positive PSMA PET not receiving MDT had higher risk of CR (HR: 2.66; P<0.001), while such risk was higher but with lesser magnitude in men with positive PSMA PET (HR: 1.74; P=0.04) receiving MDT as compared to patients with negative PSMA PET. Lastly, at the Cox derived KM, the 3-year CR-free survival rates were 73 *vs.* 51 *vs.* 29% in patients with negative PSMA PET *vs.* positive PSMA PET with MDT *vs.* positive PSMA PET without MDT, respectively.

CONCLUSIONS: A negative PSMA PET scan represents a protective factor for further metastases during follow-up. Notably, in patients with positive spots, MDT significantly improved PFS, but it is still not able to compensate the protective effect of a negative PET PSMA.

SC236
Exploring the effect of metastasis directed therapy on progression patterns of patients with positive 68GA-PSMA PET/CT and biochemical recurrence from prostate cancer

A. Pellegrino, G. Gandaglia, A. Stabile, V. Cucchiara, E. Mazzone, A. Necchi, D. Raggi, L. Marandino, G. Rosiello, G. Sorce, F. Pellegrino, S. Scuderi, F. Barletta, D. Robesti, M. De Angelis, M. Longoni, P. Scilipoti, F. Montorsi, A. Briganti (Milan)

BACKGROUND: In men with positive PSMA PET for biochemical recurrence (BCR) after radical prostatectomy (RP), metastasis directed therapy (MDT) may represent a treatment option. However, there is little evidence regarding the role of MDT in terms of prognostic implications as well as on the patterns of subsequent clinical recurrence (CR).

METHODS: We retrospectively identified 226 patients with positive 68Ga-PSMA PET at BCR after RP between 2016 and 2022 at a single institution. MDT consisted of stereotactic ablative radiation therapy on positive spots, either nodal, bony, or visceral. CR was defined as any new metastases detected at imaging after a first PSMA PET. Patients were stratified according to the use of MDT (N.=109) *vs.* no MDT (N.=117). Kaplan-Meier analyses assessed time to CR. Per-lesion analysis using Pearson χ^2 assessed the impact of MDT on the location of CR after a positive PSMA PET. The variation of the site of recurrence compared to the location of positive spots at first PSMA PET (pelvic *vs.* non-pelvic distant spots) was tested and represented using alluvial plots.

RESULTS: At median follow-up of 24 months after the first PSMA PET, 73 patients had CR. The 3-year CR-free survival rates were 51 *vs.* 28% for MDT *vs.* no MDT. The distribution of positive spots location at first PSMA PET did not differ between men receiving or not MDT (pelvic 19% *vs.* 22%, retroperitoneal 19% *vs.* 15%, bone 38% *vs.* 34%, visceral 13% *vs.* 12%, P=0.6). Similarly, in men with CR after a positive PSMA PET (N.=73), no statistically significant differences in terms of site of CR were observed based on MDT use (pelvic 29% *vs.* 14%, retroperitoneal 8% *vs.* 14%, bone 35% *vs.* 55%, visceral 24% *vs.* 17%, P=0.4). However, while a significant increase in rate of distant metastases at CR was reported in men not receiving MDT compared to the pre-MDT PSMA PET (from 77 to 86%), a reduction in proportion of distant metastases at CR was observed in patients receiving MDT (from 76 to 67%).

CONCLUSIONS: The use of MDT represents a protective factor for metastases during follow-up. Interestingly, the pattern of recurrence was influenced using MDT with lower rate of CR to non-pelvic distant sites. Salvage therapies might alter patterns of PCa dissemination.

SC237
Approach (NCT05649943): multimodal approach in patients with MHSPC. A pragmatic randomized phase 3 trial of androgen-deprivation therapy (ADT) plus apalutamide (APA) *versus* ADT plus apalutamide (APA) and local treatment

V. Guadalupi, M.C. Sighinolfi, T. Calcagnile, S. Assumma, A. Rametta, E. Verzoni, M. Claps, P. Sepe, M. Stellato, A. Bottiglieri, M.A. Catanzaro, B. Avuzzi, B. Jereczek, G. Procopio, B. Rocco (Milan)

BACKGROUND: It is reasonable to offer radiotherapy (RT) to improve outcomes for patients with newly diagnosed M1 prostate cancer with <5 bone metastases (HORRAD) or low volume disease (STAMPEDE) (Burdett *et al*., Eur Urol 2019). Data from clinical randomized trials evaluating feasibility and overall benefit of cytoreductive radical prostatectomy (cRP) in oligometastatic hormone sensitive patients are not available. The rationale for performing cytoreductive radical prostatectomy is to eliminate lethal clones of castration-resistant intraprostatic PCa, which can favor the process of metastasis (Heidenreich *et al*., Curr Opin Urol 2020), to improve OS and PFS and to prevent local progression and correlated events. We report a study proposal that is already ongoing in Italy with different centers activated yet.

METHODS: APPROACH is an Italian multicenter study, which is enrolling ~566 patients with oligometastatic hormone sensitive prostate cancer who are candidates to receive treatment with apalutamide. After 6 months from the start of treatment, patients will be randomized 1:1 to receive local treatment or not in addition to apalutamide (investigator's choice between primary radiotherapy and cytoreductive prostatectomy).

RESULTS: The protocol aims to evaluate some issues. The primary endpoint was to determine whether treatment with apalutamide plus ADT for 6-month followed by locoregional treatment with radiotherapy or radical prostatectomy has better efficacy than treatment with apalutamide plus ADT alone in terms of radiographic progression-free survival (rPFS). Secondary endpoint was to evaluate tumor shrinkage after locoregional approach and to evaluate short and long-term side effects after locoregional surgery or RT, time to PSA progression, time to castration resistance, cancer specific survival, overall survival, and quality of life according to EPIC-26 and EQ-5D-5L questionnaires. Local event-free survival is another secondary endpoint that encompasses absence of urethral stricture and ureteral stenosis, urinary retention, of hydronephrosis, of acute renal failure. Local treatment free survival will be considered as well (no need for catheterization, ureteral stenting, nephrostomic tube positioning).

CONCLUSIONS: The APPROACH trial aims to cover the unmet needs of patients with oligometastatic PCa patients, currently eligible to medical treatment alone. The trial will highlight possible advantages of a local treatment combined with apalutamide in the setting of oligometastatic hormone sensitive patients.

SC238
Managing non-metastatic castration resistant prostate cancer: real life snapshot from a longitudinal multicenter cohort

S. Astore, M. Ferriero, E. Franzese, M. Izzo, A. Pappalardo, G. Facchini, C. De Nunzio, G. Tema, B. Turchi, A. Tubaro, R. Naspro, S. Chiellino, G. Tuderti, U. Anceschi, R. Mastroianni, L. Misuraca, A.M. Bove, A. Brassetti, F. Calabrò, G. Simone (Rome)

BACKGROUND: Management of nonmetastatic castration resistant prostate cancer (nmCRPC) received a paradigm shift with new generation anti androgen receptor inhibitors. In this study, we evaluated the safety and the role on oncological outcomes of patients with nmCRPC treated with antiandrogen receptor targeted agents (ARTA) from a longitudinal real life multicenter cohort.

METHODS: A multicenter chemo-naïve nmCRPC patients' dataset was queried for patients receiving either Abiraterone Acetate (AA) or Enzalutamide (EZ) as first treatment line. Toxicity and survival outcomes were endpoints of the study. The therapeutic effectiveness of ARTA as well as the role of established prognosticators were assessed with the Kaplan-Meier method and the log-rank test was applied to assess statistical significance between groups.

RESULTS: Overall, 49 patients were identified as nmCRPC patients using conventional imaging or PSMA-PET/CT scan, according to physician discretion and treated with ARTA. Twenty-four patients received AA (49%), 21 (42.9%) received EZ. Two-year and 5-year PFS probability after first line of therapy were 52.6% and 22.3%. Comparable PFS probabilities were found regardless the first line ARTA (AA *vs.* EZ, log rank P=0.74). Toxicity rate was 24.5%. Two grade 3 adverse events occurred (4.1%), one bone fracture and one severe bradycardia. Twelve (24.5%) patients shifted to a second line therapy. Six patients (12.2%) underwent salvage chemotherapy for disease progression after a second line of therapy. Two-year progression free survival (PFS) and cancer specific (CSS) survival probabilities were 84% and 87.7% respectively.

CONCLUSIONS: We report clinical data from a real-life setting about toxicity and oncologic outcomes of patients treated with ARTA for nmCRPC. We acknowledge the small number of cases as the main limitation. Our data support evidence from clinical trials about safety and oncologic effectiveness of novel antiandrogens.

SC239
Oncological outcomes of patients with high volume MCRPC: results from a longitudinal real-life multicenter cohort

E. Franzese, M. Izzo, A. Pappalardo, G. Facchini, C. De Nunzio, G. Tema, A. Tubaro, B. Turchi, R. Naspro, S. Chiellino, G. Tuderti, U. Anceschi, R. Mastroianni, L. Misuraca, A. Bove, A. Brassetti, G. Simone, F. Calabrò, S. Astore, M. Ferriero (Pozzuoli, Naples)

BACKGROUND: Registrative trials recommended the use of upfront chemotherapy in high volume metastatic prostate cancer. We reported survival outcomes of patients with metastatic castration resistant prostate cancer (mCRPC) population from a longitudinal real-life multicenter series.

METHODS: We retrospectively collected data on mCRPC patients treated at five centers. The dataset was queried for high volume disease (defined as more than 6 bone lesions or bulky node ≥5 cm). We compared the main clinical features of chemo-naïve versus postchemo patients. Mann-Whitney Test and $\chi 2$ test were used to compare continuous and categorial variables, respectively. The Kaplan-Meier method was used to compare differences in terms of progression-free survival (PFS), cancer specific survival (CSS) and overall survival (OS) in a chemo- naïve or postchemo setting. Survival probabilities were computed at 12, 24, 48, and 60 months.

RESULTS: Out of 216 patients, 88 cases with high volume disease were selected. Sixty-nine patients (78.4%) were chemo- naïve, while 19 patients received chemotherapy as first treatment option. Forty-eight patients received Abiraterone (AA), 21 patients received Enzalutamide (EZ) as first treatment line. The chemo-naïve population was older (P=0.007) and less likely to receive further lines of treatment (P=0.001) than the after-chemo cohort. Five-year PFS, CSS and OS were 60%, 73.3% and 72.9%, respectively. Overall, 28 patients (31.8%) after a first line shifted to a second-line therapy: EZ was prescribed in 17 cases, AA in 7 cases and radiometabolic therapy in 4 patients. Sixteen cases (18.2%) developed significant progression and were treated with chemotherapy. At Kaplan Meyer analysis PFS, CSS and OS were comparable for chemo-naïve vs. postchemo setting (log-rank P=0.10, P=0.64 and P=0.36, respectively).

CONCLUSIONS: We reported comparable survival probabilities in a real-life series of high volume mCRPC patients who were chemo-naïve or not. These data support the use of novel antiandrogens as first line treatment regardless tumor burden, delaying the beginning of a more toxic chemotherapy in case of significant disease progression.

SC240
Upgrading and upstaging after radical prostatectomy in patients potentially eligible for high-intensity focused ultrasound (HIFU) according to the Chronos study criteria: a single-center experience

E. Dibilio, R. Nicoletti, A. Alberti, G.R. Resta, F. Davide, E. Ciaralli, C. Caneschi, A. Sebastianelli, P. Spatafora, F. Sessa, A. Rivetti, A. Pecoraro, I. Mattei, S. Serni, R. Campi, M. Gacci (Florence)

BACKGROUND: According to the latest EAU Guidelines, whole-gland ablative therapies (such as high-intensity focused ultrasound [HIFU] and cryotherapy) are considered as alternative therapeutic options for intermediate-risk prostate cancer within a clinical trial setting or well-designed prospective cohort studies. In this scenario, HIFU is increasingly being employed for the treatment of well selected patients at referral Institutions, aiming to reduce the morbidity of surgery while ensuring equivalent oncological outcomes. Yet, the proportion of patients who may be candidate for focal therapy but who ultimately harbor an aggressive disease is still unclear. The aim of our study was to evaluate the prevalence and predictors of upstaging and upgrading at final histopathology in a contemporary cohort of patients potentially eligible for HIFU, treated with radical prostatectomy (RP) at a referral academic center.

METHODS: After ethical committee approval, we queri-

ed our prospective RP database to select patients potentially eligible for HIFU, according to the randomized controlled trial CHRONOS (NCT04049747) study criteria (PSA<20 ng/mL, prostatic adenocarcinoma, ISUP grade group <3 after MRI-fusion biopsy, radiological cT2b/cT3a stage), between March 2017 and December 2021. Upgrading was defined as ISUP≥4 while upstaging was defined as clinical stage ≥cT3b at final histopathology.

RESULTS: Overall, 605 patients were included; of those 185 (30.6%) were non eligible for HIFU, while 420 (69.4%) were potentially eligible. At final histopathology, 10 (2.4%) patients of the HIFU-eligible group harbored different histological features, with a Ductal or Intraductal component not previously reported at biopsy. Four of the eligible patients (1%) had pN+ disease. In the cohort of patients eligible for HIFU, the prevalence of upstaging was 6% (N.=25), while upgrading was reported in 6% of cases (N.=25, 19 [4.5%] ISUP 4 and 6 [1.5%] ISUP 5). Overall, at final histopathology, 52/420 patients (12.4%) were found to be no more eligible for HIFU according to the CHRONOS criteria.

CONCLUSIONS: In our series, the rates of upgrading and upstaging after RP in patients who could be potentially candidates for focal therapy according to the CHRONOS study criteria was modest. This information can be valuable during shared decision-making in patients who may be candidate for focal therapy. Larger studies are needed to inform on long-term outcomes of HIFU and to identify those patients who harbor aggressive disease and who are currently captured by preoperative risk models.

SC241

Intermittent *versus* continuous androgen deprivation therapy for biochemical progression after primary therapy in hormone-sensitive non-metastatic prostate cancer: comparative analysis in terms of CRPC-M0 progression

S. Salciccia, F. Del Giudice, G.B. Di Pierro, G. Bevilacqua, A. Gentilucci, M. Frisenda, A. Tufano, P. Viscuso, M. Moriconi, D. Rosati, L. Gobbi, G. Basile, A. Tubaro, C. De Nunzio, A. Carbone, A.L. Pastore, G. Franco, A. Sciarra (Rome)

BACKGROUND: The aim of this study was to analyze whether the use of an intermittent (IAD) *versus* continuous (CAD) androgen deprivation therapy for the treatment of biochemical progression after primary treatments (radical prostatectomy and radiation therapy) for hormone sensitive non-metastatic prostate cancer can determine a different incidence of non-metastatic castration resistant prostate cancer (CRPC-M0).

METHODS: One hundred seventy male patients aged 64-73 years with a histologically confirmed diagnosis of PC, presenting a biochemical progression after primary treatments (82 after radical prostatectomy and 88 after radiation therapy), non-metastatic at imaging (PET TC or bone scan + CT scan) were considered for continuous (85 cases) or intermittent (85 cases) administration of androgen deprivation therapy (LHRH agonist or GnRH antagonist). we collected all data regarding histological diagnosis, primary treatment, imaging for staging M0 at biochemical progression, PSA at progression, time to biochemical progression from primary therapy, ADT used, IAD cycles, to compare in the two groups (IAD *versus* CAD) time to progression from the beginning of ADT treatment and type of progression in terms of CRPC M0 *versus* CRPC M1 cases.

RESULTS: No significant (P=0.4955) difference in all CRPC development was found between IAD (25.8%) and CAD (30.5%) treatment at a mean of 33.4±15.7 months. Mean time (±S.D.) to CRPC development was 32.7±7.02 and 35.6±13.1 months respectively in the IAD and CAD group (P=0.0738). Mean PSA at CRPC development was significantly higher in the IAD group (5.16±0.68 ng/mL) than in the CAD group (3.1±0.7 ng/mL) (P<0.001).Imaging to detect M status at CRPC development was mainly PET TC scan in both groups (IAD 100% and CAD 92.0%).Considering all 48 cases who developed a CRPC progression, no metastatic (CRPC M0) progression was found in 4.5% of cases in the IAD group and in 30.5% in the continuous ADT group (P=0.0203). At univariate analysis CAD administration significantly increase the RR for CRPCM0 development (RR: 3.48; 95% CI: 1.66-7.29; P=0.01) when compared to the IAD administration, and this effect at multivariate analysis remained significant and independent from the variables (RR: 2.34; 95% CI: 1.52-5.33; P=0.03).

CONCLUSIONS: In our population with biochemical progression after primary treatment for PC, the intermittent administration of ADT significantly reduces the development of CRPC M0 disease when compared to a continuous administration of ADT, whereas no difference between the two strategies in terms of CRPC M1 progression exists.

SC242

Clinical characterization and development of a predictive model of 1-year overall survival amongst patients with metastatic hormone sensitive prostate cancer (MHSPC) treated with one of the approved treatment plans using real-world data (RWD): preliminary results from the European Network of Excellence for big data in prostate cancer (PIONEER)

R. Nicoletti, J. Moreno-Sierra, J. Gomez Rivas, N. Mottet, L. Ibáñez, A. Merseburger, C. Steinbeißer, J. Ndow, B. de Meulder, A. Golozar, S. Evans Axelsson, R. Snijder, P. Willemse, T. Murtola, R. Campi, M. Gacci, A. Bjartell, P. Cornford, M. Van Hemelrijck, K. Beyer, J. Moreno-Sierra, N. Mottet, A. Merseburger, J. Ndow (Florence)

BACKGROUND: Androgen deprivation therapy (ADT) was the standard of care (SOC) for patients with metastatic hormone sensitive prostate cancer (mHSPC) for decades; recently, emerging therapies (the so-called ARTA, Taxane-based chemotherapy and their combinations) associated with ADT have proven to be more effective than ADT alone, however metastatic disease is still a clinical state that remains poorly understood and there is an unmet need of standardization of randomized control trials (RCTs). Recently, real-world data were be claimed to have potential for generating real-world evidence for designing and conducting confirmatory trials and answering questions that may not be addressed otherwise; also, they may be used to identify relevant outcomes and clinical cohorts with unmet clinical needs with a greater likelihood of benefiting from new therapies. The aim of this study was to develop and present preliminary results of a predictive model for 1-year overall survival (OS) amongst patients with mHSPC treated with one of the approved tre-

atment plans using RWD and to describe demographics, clinical characteristics, treatment patterns and clinical outcomes under the PIONEER project.

METHODS: Data of patients with mHSPC across a distributed network of observational databases were collected. Male patients without prior orchiectomy with mHSPC were enrolled in cohort 1, while cohort 2 was defined as the start of ADT as a surrogate definition of mHSPC disease, both in metachronous and synchronous disease settings.

RESULTS: Overall, 94,261 mHSPC patients were included among which 77,123 patients received treatment. 28% of mHSPC diagnosed were not on ADT monotherapy. More than half of the patients were over 70 years old (54%); In cohort 2, 2819 patients were metachronous, and 55,502 patients were synchronous. Most of the patients are treated with ADT only; after a median follow-up (ranged from 398-699 days) in the metachronous setting 22% of patients discontinued the treatment. Regarding the clinical outcomes, time to admission to hospital or emergency department, adverse events, and death increase with time, but noticeably events are more common in synchronous disease. The 60% of deaths occur in the first two years after date of diagnosis. The accuracy of the model in prediction of 1-year OS was 75%: the variables increasing death odds were age >90, non-ADC variants, M1c disease and liver metastasis; The variables decreasing death odds were age <80, adenocarcinoma of the prostate, M1a-M1b disease, grade group 3 or lower and cT1 disease. The major limitation of our findings are loss of follow-up and missing data.

CONCLUSIONS: This is the largest study in Europe with RWD in the mHSPC setting. In RWD that patients are older, with more co-mobilities and 1/3 of them do not undergo a SOC treatment when compared to RCT. Our prediction models show promising results; however, a large validation cohort is needed to confirm the reliability of our findings.

SC243
Adverse events related to darolutamide treatment: analysis of "real-life" data from Eudra-Vigilance (EV) and the Food and Drug Administration (FDA) database entries

A. Tubaro, L. Sarcinelli, R. Lombardo, A. Franco, L.M. Rovesti, C. Gravina, B. Turchi, A. Guercio, J. Stira, G. Gallo, O.A. Voglino, V. Baldassarri, A. Cicione, A. Nacchia, A. Tartarone, G. Di Sabato, F. Di Giacomo, C. De Nunzio (Rome)

BACKGROUND: Darolutamide, an oral androgen receptor inhibitor, has been approved for treating nonmetastatic castrationresistant prostate cancer (nmCRPC), based on significant improvements in metastasis-free survival (MFS) in the ARAMIS clinical trial. Aim of our study was to analyse adverse events (AEs) associated with darolutamide using real life data from Eudra-Vigilance (EV) and the Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) databases.

METHODS: EV database in European Economic Area and the FDA Adverse Event Reporting System (FAERS) database were queried to identify darolutamide AEs occurred from July 30, 2019, to October 1, 2021. AEs were recorded in according to category and severity. Real-life data were compared to Aramis registry study. Furthermore, AEs reported in EV database were categorized by patient's age into more or less than 85 years. Pooled relative risk (PRR) was used to compare groups.

RESULTS: On EV database 139 AEs related to darolutamide were identified, of which 54 (39%) were serious and 2 (0,01%) were deaths. On FDA FAERS database 257 adverse events related to darolutamide were reported with 137 (53%) serious events and 8 (3%) death cases. On registry study, 794 AEs were reported, with serious AEs occurring in 24.8% of patients in the darolutamide group and with 1 death related to trial regimen. Fatigue was the most common AE reported in all three datasets, respectively 115 events (12,1%) in the registry study, 33 events (12,8%) in FDA-FAERS and 13 events (9.3%) in EV. However, no significative differences were found in all three datasets for fatigue, diarrhea, and nausea (PRR 0.80-1.50; P>0.05). Higher rates of back pain, arthralgia, hypertension, constipation, pain in an extremity, anemia, hot flush, UTIs and urinary retention were found in the registry study when compared to EV and FDA-FAERS databases (PRR 1.50-7.00; P<0.05). Unfortunately, no information on the number of patients under treatment was reported in the EV database.

CONCLUSIONS: According to our results darolutamide is safe in a real-life scenario and the most frequent side effect is fatigue. Although up to now there are few reports in both real-life databases, these data are encouraging for clinicians using darolutamide in every day clinical practice.

SC244
Identifying the optimal candidates for concomitant androgen-deprivation therapy among patients receiving metastasis-directed therapy for positive 68GA-PSMA PET/CT for biochemical recurrent prostate cancer after radical prostatectomy

E. Mazzone, G. Gandaglia, A. Stabile, D. Robesti, A. Necchi, D. Raggi, L. Marandino, G.O. Cirulli, S. Scuderi, F. Barletta, A. Pellegrino, M. De Angelis, V. Cucchiara, G. Rosiello, G. Sorce, L. Nocera, F. Pellegrino, M. Longoni, P. Scilipoti, L. Quarta, A. Gallina, N. Fossati, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Metastasis directed therapy (MDT) represents a treatment option for recurrent prostate cancer (PCa) patients with clinical relapse at PET PSMA scan. However, evidence on the protective effect of concomitant androgen deprivation therapy (ADT) at the time of MDT is scarce. Based on this unmet need, we aimed at identifying the optimal candidates for concomitant ADT among positive PSMA PET patients after biochemical recurrence (BCR) and who are candidate for MDT.

METHODS: We identified 361 patients evaluated with 68Ga-PSMA PET/CT for BCR after RP between 2016 and 2022 at a single center. Among positive PSMA PET patients (N.=226), only MDT-treated men (N.=109) were included. MDT consisted of stereotactic ablative radiation therapy (SABR) on positive spots (nodal, bony, or visceral). The main outcome was clinical recurrence (CR), defined as any new metastases detected at PSMA PET during follow-up. To identify the optimal candidates for ADT, a regression tree analysis predicting 3-year CR was used to stratify patients into risk groups based on location (pelvic *vs.* non- pelvic nodes or distant metastases) and number of PSMA spots. Lastly, Kaplan-Meier (KM) and Cox regression analyses tested the impact of ADT on CR in each risk group.

RESULTS: Among 109 included patients, 71 (65%)

patients received concomitant ADT. Overall, 37 patients experienced CR. At KM analysis, 3-year CR-free survival was 56%. At Cox analysis, ADT was associated with more favorable CR rate (HR=0.47; P=0.039). The regression-tree analyses identified three risk groups with good discrimination accuracy (C-Index 78%). After stratification, only 2 groups of patients benefited from ADT: patients with >1 nodal spot (HR=0.06; P=0.002) and patients with distant spots, either non-regional lymph nodes, bone, or lung (HR=0.24; P=0.03), regardless of other disease characteristics.

CONCLUSIONS: The beneficial impact of concomitant ADT in patients receiving MDT for positive PSMA PET and BCR is highly influenced by the results of PSMA PET. Men with single pelvic nodal spot are those who may undergo MDT alone, while patients with ≥1 nodal or distant spots represent the ideal candidates for ADT at the time of MDT.

SC245
Tailoring the optimal use of androgen-deprivation therapy concomitant to postoperative radiotherapy among men with PN1 prostate cancer: long-term results of a large, single institution series

E. Mazzone, G. Gandaglia, A. Stabile, D. Robesti, A. Necchi, G.O. Cirulli, A. Pellegrino, S. Scuderi, D. Raggi, L. Marandino, F. Barletta, M. De Angelis, V. Cucchiara, G. Rosiello, G. Sorce, F. Pellegrino, M. Longoni, P. Scilipoti, N. Fossati, F. Montorsi, A. Briganti (Milan)

BACKGROUND: The role of androgen-deprivation therapy (ADT) during adjuvant (aRT) or salvage radiotherapy (sRT) in men with node- positive prostate cancer is still debated. In particular, it is unclear whether adding ADT may provide further benefit based on the metastatic nodal burden. The aim of this study was to explore the correlation between ADT and the number of positive nodes at pathology and its impact on survival.

METHODS: Eight thousand three hundred sixty-two patients treated with RP at a single center between 1987 and 2020 were identified. Only patients with lymph node invasion (LNI) treated with aRT or sRT for BCR were included, resulting in 710 eligible men. The endpoint was overall mortality (OM). The probability of receiving ADT was weighted through an inverse-probability of treatment and the resulting weight was used as propensity adjustment in Cox regression models testing the impact of ADT on OM after further adjustment for age, RT type, adverse pathology, and number of positive nodes. An interaction term tested the correlation between ADT and number of positive nodes on OM and the result was represented using Lowess.

RESULTS: Of 710 patients, 578 (81%) *vs.* 132 (19%) men received aRT *vs.* sRT, respectively, and 559 (78%) received ADT. Median follow-up was 116 months. A total of 112 patients died during follow-up. The 10-year overall survival rate was 82%. At Cox analyses, ADT use was associated with reduced risk of OM (HR 0.61, P=0.042). Similarly, higher metastatic nodal burden was associated with increased risk of OM (HR 1.02, P=0.001). The interaction terms confirmed a significant interaction between ADT use and number of positive nodes (P=0.02). At Lowess, ADT did not provide a survival benefit in patients with a single positive node (10 *vs.* 12% 10-year OM in no ADT *vs.* ADT group). Conversely, not administering ADT with increasing metastatic nodal burden was associated with higher risk of OM (from 14 to 28% 10-year OM in patients with 2 to 6 positive nodes), while OM rates remained stable at 12% when ADT was administered.

CONCLUSIONS: Among patients with LNI undergoing salvage or adjuvant RT, the use of concomitant ADT can be omitted in case of a single metastatic node. Conversely, ADT use provides a significant survival benefit in patients with higher metastatic nodal burden.

SC246
Early patient-reported outcome measures on functional outcomes after high-intensity focused ultrasound based focal therapy for prostate cancer

D. Maffei, V. Fasulo, E.N.Y.D. Adjaye, S. Moretto, P.P. Avolio, P. Arena, N. Frego, G. Chiarelli, F. De Carne, F. Dagnino, M. Aljoulani, R. Hurle, A.R. Saita, M. Lazzeri, G.F. Guazzoni, P. Casale, N.M. Buffi, G. Lughezzani (Pieve Emanuele, Milan)

BACKGROUND: Focal therapy (FT) for localized prostate cancer (PCa) offers minimally invasive localized ablative treatment while providing reduced treatment-related toxicity and improved genitourinary function compared to standard radical options. We presented early functional outcomes of a novel PCa FT program with high-intensity focused ultrasound (HIFU) using patient-reported outcome measures (PROMs).

METHODS: This is a preliminary analysis from an ongoing prospective single-center cohort study of patients undergoing HIFU FT for localized PCa since February 2021. Inclusion criteria were: PSA<20 ng/mL, ISUP grade group (GG) 1-3, stage ≤T2b, and staging with ≥2 imaging modalities *i.e.* mpMRI, microUS, PSMA-PET/CT. Patients with anterior and extreme apical lesions were excluded as not amenable by HIFU-based FT. Treatment extent was tailored as focal, quadrantectomy or hemiablation to cover index lesion and a margin. Functional PROM questionnaires (IPSS, IIEF-5, EQ-5D and QoL) were collected pretreatment, at 3- and 12-months postoperative. Outpatient evaluation was done at 3, 6 and 12 months. Changes in PROMs were evaluated between pre- and postoperative using the matched-pair Wilcoxon Signed-Rank Test. Only patients with 3-month follow-up were analyzed.

RESULTS: Out of 66 patients undergoing FTx, 38 have completed 3-month follow-up and PROM reporting. Median age was 67 years (IQR 62-73), initial PSA (iPSA) was 7.2ng/mL (4.9-8.6) and prostate volume was 43mL (36-60). Out of 14 (36.8%) patients on medical therapy for lower urinary tract symptoms (LUTS), 9 were on alpha-blockers, 2 on 5-ARI and 3 on combination therapy. Four patients had received surgical treatment for voiding LUTS. Presurgery median IPSS, IIEF-5, EQ-5D and QoL scores were 8 (6-14), 17 (9-23), 75 (60-85) and 2 (1-3), respectively. ISUP Score was GG1 in 21 patients (55.3%), GG2 in 11(28.9%), GG3 in 3 (7.9%). Twelve (31.6%) patients received strict focal ablation, with 18 (47.4%) undergoing quadrantectomy and 8 (21.1%) hemiablation. Median treated volume was 7.3mL (3.9-10.3) and 14.1% (7.2%-23.2%) of overall volume. Median IPSS, IIEF-5, EQ-5D and QoL scores at 3 months were 7 (4.3-11.8) (P=0.31), 17.5 (8-24) (P=0.43), 80 (65-83) (P=0.69) and 1 (1-2) (P=0.87). PROMs at 12 months were available for 16 patients, with median IPSS, IIEF-5, EQ-5D and QoL scores of 7 (5.8- 10.8) (P=0.37), 11 (IQR 6.5-19) (P=0.83), 80 (73-90) (P=0.72) and 2 (1-2)

(P=0.86). No patient reported urinary incontinence at 3 or 12 months. No statistically significant differences were found in PROMs at 3- and 12-month follow-up from baseline.

CONCLUSIONS: FT may be used for primary PCa treatment with low genitourinary toxicity in terms of incontinence and erectile dysfunction. Some patients may experience improvement in obstructive lower urinary tract symptoms.

SC247

Is there an impact of the center performing baseline multiparametric MRI on active surveillance outcomes in prostate cancer patients?

R. Leni, A. Stabile, G. Gandaglia, E. Mazzone, V. Cucchiara, G. Rosiello, G. Sorce, D. Robesti, M. De Angelis, S. Scuderi, D. Cannoletta, G. Brembilla, A. Esposito, F. De Cobelli, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Magnetic resonance imaging (MRI) of the prostate has been incorporated as a tool to confirm eligibility for active surveillance (AS). The impact of radiologist expertise on MRI diagnostic performance has been widely demonstrated. However, the increased number of centers performing MRI has increased the variability of both quality and performance. In this study, we assessed the diagnostic accuracy of MRI performed at a single-, high-volume center *vs.* external center for patients under AS.

METHODS: We identified 535 men on AS at our Institution with a baseline MRI followed by at least one surveillance biopsy (sBx). MRIs were stratified according to centers performing the scan (high volume single center performing more than 500 MRIs per year *vs.* external centers) and to the detection of visible lesions (negative: PI-RADS 1-2, positive: PI-RADS 3-5). Reclassification was defined as an increase in Gleason Score at sBx, or higher disease volume (>33% of involved cores, or >50% of a single core involved). Reclassification-free survival (RFS) was estimated with the Kaplan-Meier method. A Cox model tested the prognostic impact of the center performing MRI, according to lesion visibility, after adjusting for covariates.

RESULTS: Median age was 65 years (IQR 59-70), 52% (N.=280) and 48% (N.=255) of patients underwent baseline MRI at our Institution (internal) *vs.* external Institutions. A lower proportion of negative scans was observed among the external MRI scans (18% *vs.* 35%; P<0.001). After a median follow-up of 43 months, 47% (N.=253) of men were reclassified. The 5-year RFS was 76% *vs.* 40% for internal *vs.* external negative MRI scans (P<0.001). A negative external MRI was associated with a 1.98-fold increased risk of reclassification compared to a negative internal MRI (95% CI: 1.07-3.65; P=0.03). In contrast, the 5-year RFS was 37% *vs.* 35% for internal *vs.* external positive MRI scans, respectively (P=0.2).

CONCLUSIONS: We demonstrated that the negative predictive value of MRI scans performed at a high-volume center is significantly higher compared to MRIs performed externally. Our findings indirectly support the need for centralization of MRIs in men on AS, as well as the invariable need of follow-up biopsies for those with negative MRIs performed externally.

Functional diseases 2

SC248
Trends and incidence of reported events associated with male slings: an analysis of the Food and Drug Administration's manufacturer and user facility device experience database

SC249
Real-life practice of pelvic floor muscle therapy after radical prostatectomy in Italy: results of a national survey

SC250
Multicenter study on modified surgical technique of bilateral pubococcygeus plication to repair native tissue cystocele: long-term follow-up

SC251
Robot-assisted sacropexy: comparison between the novel Hugo™ robot-assisted surgical system and the established da Vinci surgical system at a tertiary referral robotic center

SC252
Robot-assisted sacrocolpopexy *versus* transvaginal prolapse repair: impact on lower bowel tract function

SC253
Does detrusor overactivity cause detrusor underactivity through muscle exhaustion? Results from a single-center urodynamic database

SC254
LUTS and OSAS: a misunderstood bond

SC255
Is older age a contraindication to Virtue® suburethral sling placement for stress urinary incontinence treatment after radical prostatectomy?

SC256
Transobturatory urethral sling for the treatment of male stress incontinence: a comparison study between AdVance XP and ArgusT in efficacy

SC257
ATOMS™ implant for the treatment of male stress urinary incontinence: long-term results and device survival

SC258
One-step pelvic organ prolapse repair associated to OnabotulinumtoxinA injection: preliminary results

SC259
Comparison between two surgical techniques of bilateral pubococcygeous repair of symptomatic cystocele

SC260
Long-term functional outcomes of Virtue® suburethral sling for stress urinary incontinence after radical prostatectomy: a single-center experience

SC261
Artificial urinary sphincter implantation: a refined technique to prevent urethral complications

SC262
Stress urinary incontinence treated with Altis® single-incision sling: a double-center four-year follow-up study

SC263
Comparison study between functional outcomes of artificial urinary sphincter and the adjustable male device ATOMS™: a propensity score-matched analysis

SC264
Comparison study between artificial urinary sphincter and the adjustable male device ATOMS™: safety and survival of the prostheses

SC265
Vaginal mesh exposures after colposacropexy: a good learning curve is the only tip and trick to avoid it

SC248
Trends and incidence of reported events associated with male slings: an analysis of the Food and Drug Administration's manufacturer and user facility device experience database

C. Gravina, A. Nacchia, G. Gallo, D. Fiasconaro, L. Sarcinelli, F. Zammitti, N. Ghezza, A. Guidotti, R. Lombardo, A. Franco, G. Tema, A. Cicione, A. Pastore, A. Sciarra, G.B. Di Pierro, S. Salciccia, C. Leonardo, M. Al Salhy, G. Franco, A. Tubaro, C. De Nunzio (Rome)

BACKGROUND: To summarize medical device reports (MDRs) between 2013 and 2022 relating to male slings within the Manufacturer and User Facility Device Experience (MAUDE) database maintained by The Food and Drug Administration (FDA).

METHODS: The MAUDE database was analyzed for all MDRs relating to each FDA-approved male slings for the last ten years. Event descriptions were reviewed and characterized into specific event types. Outcome measures include specific ureteroscopes and reported events as detailed by the MDRs. All data were deidentified and in compliance with the Health Insurance Portability and Accountability Act (HIPAA). No further data were available in the database. Pooled relative risk was used to compare data.

RESULTS: Overall, 1356 reports were retrieved in 10 years; between 2019 and 2021 a higher number of events was reported. Overall, 1308/1356 (96%) were reported as injury, while 41/1356 (3%) as malfunction of the device. The most frequently reported adverse events (AEs) were unsolved incontinence in 495/1356 (37%), pain in 40/1356 (3%), erosion in 34/1356 (3%) and infection in 23/1356 (1.7%) of the cases. Overall, 144/1356 (115) events were from Coloplast, 1161/1356 (85%) from Boston and 51/1356 (45) from AMS. Incontinence (PRR: 1.4-2.2; $P<0.05$) and erosions (PRR: 2-12; $P<0.05$) were more frequently reported in Coloplast slings while infection (PRR: 2-6; $P<0.05$) and pain (PRR: 5-8; $P<0.05$) in AMS slings.

CONCLUSIONS: Standing to MAUDE database the most frequent complication related to male slings is unsolved incontinence. Profiles differ between brands.

SC249
Real-life practice of pelvic floor muscle therapy after radical prostatectomy in Italy: results of a national survey

G. Sampogna, L. Pelizzari, V. Li Marzi, D. Giraudo, E. Bassini, S. Pelizzari, M. Spinelli, G. Del Popolo, G. Lamberti, S. Musco (Milan)

BACKGROUND: Pelvic floor muscle therapy (PFMT) may represent a valid treatment for urinary incontinence (UI), erectile dysfunction (ED) and pelvic pain after radical prostatectomy (RP). Related outcomes are controversial, limiting the ability to draw definitive conclusions about the efficacy of this approach. This issue is mostly due to the heterogeneity of methods applied for PFMT and to the lack of standardized protocols. The aim of this study was to investigate real-life practice of PFMT after RP in Italy to highlight the adopted approaches and employed techniques.

METHODS: An original questionnaire was designed by PFMT experts aimed to evaluate the real-life practice of PFMT after RP. The online anonymous questionnaire was administered to members of the Italian Association of Physiotherapy and Italian Society of Urodynamics.

RESULTS: The survey was completed by 97 experienced professionals with a median age of 40 years and a median PFMT-specific experience of 8 years. Most of them were physiotherapists (93.8%), working in a private setting (60.8%). PFMT is applied preoperatively by 30.2% cases, whereas 69.8% responders start PFMT 1-3 months after RP, requiring histology before electrical treatment. The approaches used for UI are patient education (96.9%), behavioral treatment (95.8%), manipulation (88.5%), biofeedback (64.6%), electrostimulation (55.2%), percutaneous tibial nerve stimulation ([PTNS] 16.7%), and external magnetic stimulation (6.3%). The approaches used for DE are behavioral treatment (69.9%), vacuum erection device ([VED] 63.4%), patient education (61.3%), manipulation (50.5%), biofeedback (31.2%), electrostimulation (22.6%), external magnetic stimulation (7.5%), and PTNS (6.5%). Electrostimulation is performed with transrectal probes (72.0% for UI *vs.* 30.4% for DE) and perineal electrodes placed anteriorly (20.7% for UI *vs.* 48.2% for DE) and less frequently laterally. The majority of patients (76.7%) take phosphodiesterase type 5 inhibitors (PDE5i) during PFMT. Most rehabilitators (57.0%) perform one session per week. Up to 96.8% responders use validated tools to assess treatment outcomes.

CONCLUSIONS: PFMT, mainly considered as behavioral modifications, education, manipulation, and biofeedback, is the first-line treatment for post-RP UI. However, the type of electrostimulation (endocavitary or transcutaneous) and the placement of electrodes (on tibial nerve, perineal body or anteriorly on the bulbo/ischiocavernosus muscles) highly vary by experts and may be influenced by the coexistent pelvic dysfunctions. Moreover, despite the poor evidence and the weak European Association of Urology (EAU) guidelines recommendation, a high percentage of professional rehabilitators advise VED as first-line treatment in association with PDE5i. To overcome this heterogeneity, the authors advocate the development of an international consensus to deliver PFMT after RP.

SC250
Multicenter study on modified surgical technique of bilateral pubococcygeus plication to repair native tissue cystocele: long-term follow-up

F.A.M. Saccà, E. Rubilotta, V. Mancini, F. Montanaro, S. Costantino, F. Ditonno, L. Martino, G. Carrieri, A. Antonelli, M. Balzarro (Verona)

BACKGROUND: Aim of the study was to report long term follow-up of women underwent anterior vaginal-wall repair by modified surgical technique of bilateral pubococcygeus plication (BPC) for symptomatic cystocele.

METHODS: This was a multicenter prospective study on women undergoing BPC for symptomatic anterior vaginal wall defect (AVWD) with data retrospectively collected (2010-2022). Inclusion criteria were symptomatic AVWD>2 associated or not to urinary incontinence. Exclusion criteria

were apical or posterior associated compartment defect. All women had native tissues repair with the same standardized technique (BPC). Preoperative evaluation included medical history, physical evaluation, urinalysis. Urodynamic was always performed in the cases with associated UI. Surgical data and intra-/peri-/postoperative complications were collected. Catheter was removed 48 hours after surgery and postoperative urinary retention (POUR) was investigated by catheterization (POUR: PVR>100 mL). Likert Scale (pre- and postoperative) assessed subjective evaluation. Objective success was asymptomatic AVWD<2° POP-Q stage.

RESULTS: Data were completed on 215 women; mean follow-up was 72.4 months (range: 4-216). Mean operating time was 53 (28-122) minutes. Transient POUR (<10 days) was found in 1 patient (0.5%). Complications (5.6%) were: intraoperative bladder injury (3), hematoma (4), pain requiring therapy (2), vaginal sinsynechiae (2), wound dehiscence (1). Objective success rate was 92.0%, subjective success rate was 94.2%. Reoperation rate was 3/215 (1.4%).

CONCLUSIONS: Our data showed that native tissue repair by BPC was a safe and effective surgical technique for AWVD repair with a mean follow-up of 6 years. The rate of complications was low, and only a few cases were major. Objective and subjective success was obtained in more than 90% of the women, with results higher than those reported in literature with other AWVD surgical repair techniques. POUR and voiding dysfunction were almost lacking due to the urethral sparing technique. This multicentric study on BPC technique showed the long-term efficacy of this native tissue surgical repair for AVWD and its reproducibility on other centers.

SC251

Robot-assisted sacropexy: comparison between the novel Hugo™ robot-assisted surgical system and the established da Vinci surgical system at a tertiary referral robotic center

C. Collà Ruvolo, M. Afonina, S. Rebuffo, N. Frego, M. Ticonosco, M. Belmonte, G. Sorce, M. Paciotti, C.A. Bravi, A. Piro, E. Balestrazzi, F. Piramide, R. De Groote, A. Mottrie, G. De Naeyer (Naples)

BACKGROUND: Robotic sacropexy (RSC) emerged as a valid alternative to the laparoscopic technique in the last years. However, the robotic approach is still limited by platform availability. Recently, new robotic platforms joined the market, offering the possibility to expand the robotic approach. The aim of our study was to demonstrate the technical feasibility and the comparability of the procedure with the novel Hugo™ Robot-Assisted Surgery (RAS) System (Medtronic, Minneapolis, MN, USA), operative at Onze Lieve Vrouw (OLV) Hospital (Aalst, Belgium) from January 2022, relative to the established da Vinci surgical system (Intuitive Surgical, Inc., Sunnyvale, CA, USA).

METHODS: We reported data on the RSC performed with the da Vinci surgical system (Intuitive Surgical, Inc.) or with the Hugo™ RAS system (Medtronic), from January 2021 to January 2023, at OLV Hospital (Aalst, Belgium), by three expert robotic surgeons. The novel Hugo™ RAS platform (Medtronic) consists of four fully independent carts, an open 3D console, and a system tower equipped for both laparoscopic and robotic surgery. We collected patients' characteristics, intraoperative data, perioperative complications, and clashes of instruments.

RESULTS: Data from 38 women affected by a ≥2-grade pelvic organ prolapse (POP) according to the POP quantification system, released by the International Continence Society, who underwent RSC at our center, were recorded. Of all, 15 (39.5%) and 23 (60.5%) procedures were performed with da Vinci surgical system (Intuitive Surgical, Inc.) and with Hugo™ RAS system (Medtronic), respectively. The overall median age was 67 years (da Vinci [70-76.5] *vs.* Hugo RAS: 66 [IQR:57.5-74], P=0.4). No statistically significant differences were recorded regarding previous abdominal surgery, ASA Score and comorbidities, between patients treated with either system. Of 20 RSC performed in 2022, 14 (70%) were executed with the Hugo™ RAS system. The median total operative time was 121.5 minutes (da Vinci: 123 [IQR:106.5-140.5] *vs.* Hugo™ RAS 120 [IQR:120-146], P=0.5). All patients removed the catheter between postoperative days 1 and 2 (median da Vinci: 1 [IQR: 1-1] *vs.* Hugo™ RAS: 1 [IQR: 1-1], P=0.5). The median length of stay was 2 days (da Vinci: 2 [IQR: 2-2] *vs.* Hugo™ RAS: 2 [IQR: 2-2.5], P=0.4). No need for conversion to open/laparoscopic surgery was required. No intraoperative complications, instrument clashes, or system failures that compromised the surgery's completion were recorded. No postoperative complications occurred. One patient who underwent RSC with Hugo™ RAS system (Medtronic) was readmitted 7 days after surgery for abdominal pain. Due to negative imaging response, a conservative approach was used, and the patient was discharged the next day.

CONCLUSIONS: This study represents the first worldwide RSC comparison executed with the Hugo™ RAS (Medtronic) *vs.* da Vinci system (Intuitive Surgical, Inc.). The RSC may be safely performed with both robotic platforms achieving optimal perioperative outcomes. Future investigations are needed to compare functional long-term outcomes between the novel Hugo™ RAS (Medtronic) and the established da Vinci system (Intuitive Surgical, Inc.).

SC252

Robot-assisted sacrocolpopexy *versus* transvaginal prolapse repair: impact on lower bowel tract function

A. Martoccia, Y. Al Salhi, A. Fuschi, A. Carbone, A. Antonioni, O.A. Rera, F.M. Valenzi, P.P. Suraci, S. Scalzo, M.B. Sequi, C. De Nunzio, R. Longobardo, A. Pastore (Latina)

BACKGROUND: Pelvic organs prolapse (POP) causes heterogeneous symptoms, only few studies analyzed the effect of surgical repair on lower bowel tract function (LBTF). The aim of this study was to evaluate effects, safety, and any changes in LBTF after multicompartment prolapse surgery in patients using two different surgical approaches, transvaginal mesh surgery with levatorplasty (TVMLP) and robot-assisted sacrocolpopexy (RSC) with anterior and posterior mesh.

METHODS: This was a randomized prospective study. The exclusion criteria were age over 75, BMI≥35, neurogenic voiding and bowel symptoms, previous pelvic sur-

gery and any medical condition. Inclusion criterium was patients with symptomatic multicompartment prolapse stage III-IV. All patients were studied preoperatively at time 0 and postoperatively at 6 and 12 months. All patients underwent a pelvic and rectal examination to assess the severity of POP using POP-Q staging system and to evaluate anal sphincter tone. The preoperative evaluation included a urodynamic study and pelvic magnetic resonance defecography. All the patients completed Wexner's questionnaire at time 0, 6 and at 12 months.

RESULTS: From March 2018 to November 2021, 73 patients were enrolled and classified into two group: RSC group (36 cases) and TVMLP (37 cases). No significant baseline differences were observed between demographic data. After surgery, the main POP-Q stage in each group was stage I (RCS=80.5% *vs.* TVMLP=82%). There was a significant difference (P<0.05) according to postoperative anal sphincter tone: 35% of TVMLP patients experienced hypertonic anal sphincter. The operation time in the TVMLP group was significantly shorter than the RSC group (mean: 76.62 *vs.* 109.35), while the bleeding amount was significantly higher in the TVMLP group (mean: 20.89 *vs.* 4.94). There were no significant differences regarding hospital stay, complications rate, recurrence of POP and mesh exposure between two groups (P>0.005). According to BLTF, at the baseline were not significant differences between two groups. At 12 months of follow-up after surgery, both groups exhibited a significant improvement. The main postoperative differences between the two groups were observed in favor of RSC, especially regarding the domain of pain (RSC mean: 0.50 *vs.* TVMLP mean: 2.00) and the total Wexner Score (RSC mean: 6.88 *vs.* TVMLP mean: 8.56).

CONCLUSIONS: RSC and TVMLP successfully correct multicompartment POP. RSC seems to be less invasive in terms of decreasing blood loss. RSC causes an improvement in total Wexner Score: the mesh and relative peritoneum fibrosis obliterate the deep Pouch of Douglas and eliminate the potential space of enterocele, rectocele and sigmoidocele. TVMLP is associated with increased pain during defecation, maybe because stiches suture could alter the physiological distensibility of the rectum during stool passage and determines a painfully hypertonic status of external anal sphincter, as confirmed to follow-up digital rectal examination.

SC253
Does detrusor overactivity cause detrusor underactivity through muscle exhaustion? Results from a single-center urodynamic database

E. Rosato, E. Finazzi Agrò, V. Laurendi, P. Bachetti, F. Fanara, L. Mollo (Rome)

BACKGROUND: The International Consultation on Incontinence Research Society recently proposed the definition of coexisting overactive-underactive bladder (COUB) as a possible new syndrome. This is characterized by coexisting storage and emptying symptoms in the same patient without implying any specific urodynamic/functional findings. In COUB, detrusor is abnormally activated during the filling phase without a complete rest, thus wasting energy required for the next voiding phase, which is then impaired due to muscle asthenia and exhaustion. Aim of this retrospective study was to verify this hypothesis.

METHODS: We included male patients undergoing urodynamic study at our center between 2011-2022. All patients were affected by lower urinary tract symptoms (LUTS). Neurologic disease and patients with previous urinary tract surgery were excluded. Patients were divided in 2 groups: normal detrusor function (NDF, group A) and with detrusor overactivity (DO, group B) during the filling phase. Number of patients with bladder outlet obstruction ([BOO], defined for a Bladder Outlet Obstruction Index [BOOI]>40), number of patients with detrusor underactivity ([DU], defined for a Bladder Contractility Index [BCI]<100), BCI, post-voiding residual (PVR) and voiding efficiency (bladder capacity-PVR/bladder capacity) were compared in the two groups. DO patients were divided according to the phasic or prevoiding DU and mean BCI was calculated.

RESULTS: We analyzed 499 male patients with LUTS (mean age 62.6 years). Fifty-nine (11.8%) patients had long-term urinary catheters and 4 (0.8%) performed clean intermittent catheterization (CIC). Two hundred twenty-five patients (45.1%, group A) showed NDF, and 274 patients (54.9%, group B) DO, 194 of them (70.8%) have phasic detrusor contractions and 80 (29.2%) have prevoiding detrusor overactivity. In group A and B respectively, bladder capacity was 420.3 mL and 298.4 mL(P<0.05), PVR was 90.0 mL and 57.0 mL (P<0.05), and voiding efficiency was 78.6% and 81.6%, respectively. During the voiding phase, 177 patients (40.7%) were obstructed (BOOI>40), 100 (23.0%) were equivocal (20<BOOI>40) and 154 (35.4%) were not obstructed (BOOI<20). Fifty-nine (26.2%) and 119 (43.3%) patients showed BOO in group A and B, respectively (P<0.05). Ninety-three (41.3%) and 94 (34.3%) patients showed DU in group A and B, respectively. During the filling phase, 179 (65.3%) patients of the group B showed a phasic DO, while 95 (34.7%) patients showed a prefilling DO; their mean BCI was 116.8 and 117.0, respectively. To our knowledge, this is the first study trying to assess possible differences in terms of detrusor contractility in patients with DO or NDF in the filling phase. Further data against this hypothesis come from the observation that BCI is similar in patients with early and late appearance of DO. Limitations of this study are the retrospective design and the absence of a control group.

CONCLUSIONS: Our study seems to contradict the hypothesis that in the COUB, DU could be caused by the wasting of energy used during bladder filling, determining impaired voiding due to muscle asthenia and exhaustion.

SC254
LUTS and OSAS: a misunderstood bond

F. Di Bello, G. Pezone, S. Cilio, G. Califano, C. Collà Ruvolo, A. Fraia, E. Di Mauro, S. Morra, L. Napolitano, R. La Rocca, M. Creta, V. Mirone, N. Longo (Naples)

BACKGROUND: The aim of this study was to describe the prevalence of lower urinary tract symptoms (LUTS) evaluated according to International Prostatic Symptoms Score (IPSS) and obstructive sleep apnea syndrome (OSAS) in male patients.

METHODS: A cross-sectional web-based Italian survey was administered *via* Google Forms (Google LLC, Menlo

Park, CA, USA) between July 17 and October 31, 2022. A total of 1998 participants took part in the survey: 238 males and 1760 females. The overall sample of 238 people was stratified according to the presence of OSAS. The urinary functioning was measured through the IPSS questionnaire. Specifically, each item of IPSS scored ≥3 (meaning that occurred "more than half the time") was considered pathological.

RESULTS: Overall, 180 (75.5%) patients without OSA were compared to 58 (24.4%) with a confirmed diagnosis of the disease. The median age was 28 (IQR: 25-36) *vs.* 44 (IQR: 36.2-55.8) in non-OSAS patients *vs.* OSAS patients, respectively (P<0.001). The median Body Mass Index (BMI) was 23.7 (IQR: 21.9-26.1) *vs.* 29.6 (IQR: 24.9-36.7) in non-OSAS patients *vs.* OSAS patients, respectively (P=0.005). The median IPSS value was 5 (IQR: 3-8) *vs.* 6 (IQR: 4-13.8) in non-OSAS patients *vs.* OSAS patients, respectively (P=0.005). Moreover, the median QoL score was 0 (IQR: 0-1.2) *vs.* 2 (IQR: 0-3) in non-OSAS patients *vs.* OSAS patients, respectively (P<0.001). According to IPSS category, 159 (66.8%), 73 (30.6%) and 6 (2.6%) patients had mild, moderate and severe symptoms, respectively. Specifically, nocturia (scored at IPSS≥3) was present in 40 (22.2%) non-OSAS patients *vs.* 23(39.6%) OSAS patients, respectively (P=0.004). Moreover, incomplete bladder emptying (scored at IPSS≥3) was present in 16 (10%) non-OSAS patients *vs.* 8 (13.7%) OSAS patients, respectively (P=0.004). Low urinary flow (scored at IPSS≥3) was present in 8 (3.9%) non-OSAS patients *vs.* 5 (8.5%) OSAS patients, respectively (P=0.001). Finally, urgency (scored at IPSS≥3) was present in 8 (3.9%) non-OSAS patients *vs.* 5 (8.6%) OSAS patients, respectively (P=0.03).

CONCLUSIONS: The survey took a snapshot of the prevalence of LUTS within OSAS male patients. Indeed, OSAS patients exhibited high prevalence of bothering LUTS according to IPSS questionnaire. Specifically, nocturia and incomplete bladder emptying were most common LUTS experienced by OSAS patients.

SC255
Is older age a contraindication to Virtue® suburethral sling placement for stress urinary incontinence treatment after radical prostatectomy?

S. Scarcella, E. Beatrici, C. Del Prete, G. Giglioni, S. Cappuccelli, L. Pitoni, L. Perpepaj, V. Lacetera, G. Gabrielloni, V. Beatrici (Pesaro, Pesaro-Urbino)

BACKGROUND: We aimed to compare subjective and objective outcomes of male suburethral Virtue® sling (Coloplast, Humlebaek, Denmark) for stress urinary incontinence (SUI) after radical prostatectomy (RP) in older patients.

METHODS: We prospectively enrolled men with SUI after RP treated with the implantation of suburethral Virtue® sling at our institution between July 2017 and February 2023. Pre- and postoperative (1, 3, 6, and 12 months) SUI was evaluated according to the International Consultation on Incontinence Short-Form Questionnaire (ICIQ-SF), and the amount of pads/day. Clavien-Dindo was used to report complications, and Visual Analogue Scale (VAS) to report patients' pain during follow-up. Wilcoxon Signed-Rank Test was used to test the median difference between pre- and postoperative SUI. Patients were divided into two groups according to age: senior patients (S-Pt) were considered older than 75 years old and compared to younger patients (Y-Pt). Chi-square (χ^2) test and Student *t*-test were used to compare categorical and continuous variables, respectively.

RESULTS: A total of 74 men with SUI after RP (26.9% open, 3.0% laparoscopic, and 70.2% robotic) were prospectively enrolled and 47% (35) of these patients resulted S-Pt. The overall median preoperative ICIQ-SF was 13 (12-15), with no difference within the two groups 14 (12-16) S-Pt *vs.* 13 (11-15) Y-Pt, P=0.116. No difference regarding the median preoperative number of pads\day was recorded between the groups 4 (2-6) S-Pt *vs.* 3 (1-5) Y-Pt, P=0.983. Overall, 13% of patients developed a Clavien-Dindo Grade I/II complication after surgery with comparable frequencies between the groups 14% S-Pt *vs.* 12% Y-Pt, P=0.792. No major complications were reported. The median VAS Score resulted comparable between the two groups at all follow-up controls: 3 (1-5) S-Pt *vs.* 4 (2-6), P=0.203 on the first postoperative day, 2 (0-4) S-Pt *vs.* 3 (1-5) Y-Pt, P=0.141 upon discharge, and 1 (0-3) S-Pt *vs.* 2 (1-4) Y-Pt, P=0.334 after 1 month from the surgery. Compared to preoperative, Wilcoxon Signed-Rank Test showed a significant median reduction of ICIQ-SF Score and number of pads/day at each follow-up control (all P<0.001), with no differences within the two groups (ICIQ-SF [1-M:P=0.959], [3-M:P=0.549], [6-M:P=0.690], [12-M:P=0.755])(pads/day [1-M:P=0.198], [3-M:P=0.211], [6-M:P=0.336], [12-M:P=0.488]). Overall, 79.7% of men reached the 12-month follow-up. Among these, 30.5% of patients reached complete continence (0 pads\day) [29% S-Pt *vs.* 33% Y-Pt, P=0.410], and 45% referred only 1 pad\day [42% S-Pt *vs.* 51% Y-Pt, P=0.404].

CONCLUSIONS: According to our experience, the male suburethral Virtue® sling is safe and effective in improving both quality of life and recovery from SUI after RP even in senior patients older than 75 years old, with comparable results to younger patients.

SC256
Transobturatory urethral sling for the treatment of male stress incontinence: a comparison study between AdVance XP and ArgusT in efficacy

S. Ciarlariello, V. Silingardi, M. Benedetti, D. Martens, S. Di Bari, S. Gallo, S. Puliatti, S. Ferretti, A. Prati, R. Grisanti, S. Micali (Forlì, Forlì-Cesena)

BACKGROUND: The objective of the study was to compare two transobturator urethral slings: ArgusT® slings (Promedon, Cordoba, Argentina), adjustable, and AdVance® slings (American Medical Systems, Minnetonka, MN, USA), not adjustable, evaluating the effectiveness of patients subjected to the implantation of these devices.

METHODS: Patients between 50 and 85 years of age, with stress urinary incontinence for at least 9 months, not responding to pelvic floor rehabilitation therapy, regardless of severity, following prostate surgery for both benign pathology and oncological pathology (laparotomy, laparoscopic and robotics) were included. Fifty-five patients were compared with post-surgical urinary incontinence treated from

July 2015 and September 2020 at Fidenza Hospital (Fidenza, Parma, Italy; mono-operator), and 43 patients were treated at the Operating Unit of the Sassuolo Hospital (Sassuolo, Italy; mono-operator). ICIQ-SF and PAD tests were compared.

RESULTS: Comparing the results, 80% of patients subjected to AdVance® (American Medical Systems) and 83% of patients subjected to ArgusT® (Promedon) had total continence one year after the procedure (pads <1, P=0.884). As for ICIQ-SF, patients undergoing AdVance® (American Medical Systems) have a degree of satisfaction in 70%, for ArgusT® (Promedon) it was 73% (P=0.082). As for postoperative complications, 20% of AdVance® patients had complications that did not affect surgical outcome, while ArgusT patients had 13.4%. In addition, 20% of patients undergoing ArgusT had to adjust the device at 6 months in local anesthesia and in outpatient setting.

CONCLUSIONS: The results of our study show that these slings represent valid devices of treatment for the moderate and severe post-surgical male SUI. In particular, we can say that there is a significant improvement in the quality of life associated with a good satisfaction rate by patients, with rates of complications acceptable and not serious for both procedures. Unfortunately, patients need to be informed that there is a lack of long-term studies and that not everyone will get the expected benefit. Further studies are needed to understand which sling is better and above all how to better select the best sling for patients.

SC257
ATOMS™ implant for the treatment of male stress urinary incontinence: long-term results and device survival

E. Ammirati, P. Geretto, M. Falcone, A. Manassero, M. Agnello, A. Giammò (Turin)

BACKGROUND: Stress urinary incontinence (SUI) still represent a major drawback of prostate surgery. The aim of this study was to evaluate long-term efficacy, safety and survival of ATOMS™ system (A.M.I., Feldkirch, Austria) implant in a single center.

METHODS: We retrospectively included all consecutive patients treated with ATOMS™ implant (A.M.I.) for SUI from October 2014 to July 2019. Patients received anamnesis, urodynamic evaluation, pre- and postoperative 24-hour pad test and count. Patients were considered "continent" when dry or wearing a security pad (social continence).

RESULTS: We treated 99 patients with median age 77.98 years. Most patients had undergone radical prostatectomy. Median preoperative 24-hour pad test was 350 g, with a daily pad count of 4. Fifty patients had undergone previous incontinence surgery (44 ProACT, 2 AUS, 1 sling, 3 ProACT and then AUS, 1 ProACT and then urethral bulking). Median follow-up was 62.9 months (IQR: 47.5-75.9). At last follow-up we had a significant reduction in median 24-hour pad test to 60g (IQR: 0-100g, P<0.00001) and pad count to 1 (IQR: 0-1, P<0.00001); 29 patients were dry, 45 reached social continence. RT (P=0.44 and P=0.55) or previous urethral surgery (P=0.68 and P=0.88) did not interfere with continence results; we found worse continence result in patients who had previous continence (24-hour pad test variation +50 g, P=0.035; pad count variation +0.54, P=0.005). We had late postoperative complications in 28 patients (7 port dislocations requiring surgical repositioning [CD 3a], 11 device removals [CD 3a] due to port erosion [2], inefficacy [2], cushion leakage [1], mesh detachment [1], perineal pain [5], 2 cases of port extrusion solved with port removal leaving the device in place [CD 3a], 2 superficial wound dehiscence [CD 1], 2 UTI [CD 1], 1 scrotal edema [CD 1], 1 cushion deflate [CD 1], 1 dysuria [CD 1], 1 perineal pain [CD 1]). Median time from ATOMS™ implant and reintervention was 16.5 months (IQR: 7.1-29.4). The probability to have a working device was 97% at 12 months, 93% at 24 months, 91% at 36 months, 90% at 48 months and 87.9% at 60 months.

CONCLUSIONS: With a median follow-up of 62.9 months, we had positive continence results in 74.7% of patients. We had late complications in 28.3% of patients. We estimate that at 60 months of follow-up, 87.9% of the devices are still in place. ATOMS™ system demonstrated to be a safe and effective treatment for SUI in the long term.

SC258
One-step pelvic organ prolapse repair associated to OnabotulinumtoxinA injection: preliminary results

S. Costantino, E. Rubilotta, F. Montanaro, F.A.M. Saccà, F. Ditonno, A. Princiotta, M.A. Cerruto, A. Antonelli, M. Balzarro (Verona)

BACKGROUND: The aim of this study was to assess outcomes of concomitant OnabotulinumtoxinA detrusor injections (OBA-DI) for refractory overactive bladder syndrome (OAB) and pelvic organ prolapse (POP) and/or stress urinary incontinence (SUI) surgery.

METHODS: This was a pilot prospective study on women with refractory OAB undergoing OBA-DI associated to others female urology surgeries (2018-2022): urethral sling (US) for SUI, colpoisterectomy or sacrocolpopexy for apical POP, native tissue anterior or posterior vaginal wall repair. After counseling, candidates could choose to undergo OBA-DI concurrently with other procedures or subsequently. All women had urodynamics. Pre-/postoperative evaluation included medical history, physical evaluation, urinalysis, 3-days bladder diary (controls each 4 months). Catheter was removed 24-48 hours after surgery and postoperative urinary retention (POUR) was investigated by catheterization (POUR: PVR>100 mL resolved within 30 days from surgery).

RESULTS: Data were completed on 22 women: 16 POP surgery, 6 US placement. Mean overall follow-up was 36 months. In POP, 43.7% women do not need further OBA-DI, in US 16.7%. One patient undergone US and OBA-DI, developed transient POUR treated by CIC for 2 months and, after urodynamics showing obstruction, with tape incision. No major complications related to OBA-DI occurred.

CONCLUSIONS: Concomitant OBA-DI and procedures for POP/urinary incontinence was safe and effective. No major complications related to OBA-DI treatment were recorded. A great reduction in micturition episodes was found. OBA-DI efficacy was higher in women treated for SUI than in POP, as demonstrated by the greater delta difference in micturition episode reduction in US. Interestingly, approxi-

mately half of the women in POP group were cured for OAB not needing further treatments. In US group, the rate of OAB cure was relevantly lower. This finding may be explained by the correction of the obstructive condition due to POP. In these women the true effect of OBA-DI is questionable. However, the potential positive effect on OAB by POP correction needs some months to be achieved, and during this time a treatment should have been administered. This pilot study showed that after adequate counseling and patient-shared decision, OBA-DI associated to POP/US treatments was safe and effective.

SC259
Comparison between two surgical techniques of bilateral pubococcygeous repair of symptomatic cystocele

F. Montanaro, E. Rubilotta, S. Costantito, F. Ditonno, F.A.M. Saccà, M. Gubbiotti, V. Mancini, S. Rosadi, V. Giommoni, A. Antonelli, M. Balzarro (Verona)

BACKGROUND: The aim of this study was to compare surgical outcomes of two bilateral pubococcygeus plication (BPC) techniques to repair symptomatic cystocele.

METHODS: This was a multicenter prospective study on women undergoing native tissue repair for symptomatic cystocele. A first technique had BPC with urethra sparing (BPC-US), while the second technique had BPC with bladder neck/proximal urethra suspension (BPC-NUS). Data were retrospectively collected (2012-2021), all cases had at least 12 months follow-up. Inclusion criteria were symptomatic anterior vaginal wall defect (AVWD)>2 associated or not to urinary incontinence. Exclusion criteria were apical or posterior associated compartment defect. Preoperative evaluation included medical history, physical evaluation, urinalysis. Urodynamics was performed in cases of associated UI. Surgical data and intra-/peri-/postoperative complications were collected. Catheter was removed 48 hours after surgery and postoperative urinary retention (POUR) was investigated by catheterization (POUR: PVR>100 mL resolved within 30 days from surgery). Objective success was asymptomatic AVWD<2° POP-Q stage.

RESULTS: We collected data from 156 women with mean follow-up of 74.6 months (range 12–118): 84 in BPC-US, 72 in BPC-NUS. Mean operating time was 53 minutes in BPC-US and 58 in BPC-NUS. In BPC-US 2 women had preoperative stress urinary incontinence (SUI) that persisted after surgery. In BPC-NUS 6 patients had preoperative SUI, and 2/6 still reported SUI after surgery. Transient POUR was 0.5% in BPC-US, while 27.8% in BPC-NUS. None of these POUR required surgery. Complications for BPC-US were 7.1%: intraoperative bladder injury (1), hematoma (2), vaginal sin synechiae (2), wound dehiscence (1). Complications for BPC-NUS were 4.2%: hematoma (1), bleeding (1), wound dehiscence (1). Transient POUR rate was 1% in BPC-US and 27.8% in BPC-NUS. Objective success rate was 92.9% in BPC-US and 88.9% in BPC- NUS. Reoperation rate for recurrence were 2.4% after BPC-US and 6.9% for BPC-NUS.

CONCLUSIONS: Our data showed that native tissue repair by BPC was a safe and effective surgical technique for cystocele repair. The main difference between the two procedures was the occurrence of voiding disorders which was relevantly higher after BPC-NUS. This finding can be explained by the stitch placement under bladder neck and proximal portion of the urethra. This surgical phase that characterizes BPC-NUS can improve continence care. Indeed, this latter technique resolved SUI in more women. BPC-US did not resolve SUI, because sutures were placed far to bladder neck/proximal urethra to avoid POUR. Cure rate of the two BPC techniques was high and comparable. However, females undergoing BPC-NUS should be counselled on the risk of transient POUR and the potential positive impact on SUI cure. Postoperative voiding disorders did not occur in BPC-US procedure, but this technique was not effective for SUI treatment.

SC260
Long-term functional outcomes of Virtue® suburethral sling for stress urinary incontinence after radical prostatectomy: a single-center experience

E. Beatrici, S. Scarcella, C. Del Prete, G. Giglioni, S. Cappuccelli, L. Perpepaj, L. Pitoni, G. Gabrielloni, V. Lacetera, V. Beatrici (Milan)

BACKGROUND: Stress urinary incontinence (SUI) still represents one of the most common complications after radical prostatectomy (RP). We aimed to report our single-center experience with the suburethral Virtue® male sling (Coloplast, Humlebaek, Denmark) for SUI after RP.

METHODS: We prospectively enrolled men with SUI after RP who underwent suburethral Virtue® sling placement at our institution between July 2017 and February 2023. Pre- and postoperative (1, 3, 6, and 12 months) SUI was evaluated according to the International Consultation on Incontinence Short-Form Questionnaire (ICIQ-SF), and the amount of pads/day. Clavien-Dindo was used to report complications, and Visual Analogue Scale (VAS) to report patients' pain during follow-up. Wilcoxon Signed-Rank Test was used to test the median difference between pre- and postoperative SUI. Multivariable logistic regression models adjusted for age, BMI, RP approach, previous radiotherapy, and preoperative SUI severity were fitted to test the association between outcomes and patients' baseline characteristics.

RESULTS: A total of 74 men with SUI after RP (26.9% open, 3.0% laparoscopic, and 70.2% robotic) were prospectively enrolled. The mdian (IQR) age at surgery was 73 (69-77) years. The median preoperative ICIQ-SF was 13 (12-15), with 29.9% and 70.2% of patients who reported moderate and severe SUI, respectively. The median preoperative number of pads\day was 3 (2-5). Overall, 13.4% of patients developed a Clavien-Dindo Grade I/II complication after surgery. No major complications were reported. The median VAS score was 3 (2-4) on the first postoperative day, 2 (1-3) upon discharge, and 0 (0-2) after 1 month from the intervention. Compared to preoperative, Wilcoxon Signed-Rank Test showed a significant median reduction of ICIQ-SF score and amount of pads/day at each follow-up control (all P<0.001). Overall, 79.7% of men reached the 12-month follow-up. Among these, 30.5% of patients reached complete continence (0 pads\day), and 37.3% referred only 1 pad\day. The median number of pads\day was 1 (0-2). The median ICIQ-SF score was 6 (4-9), with 43.9% of patients reporting only slight incontinence. After conducting adjusted multivariable logistic regression analysis, we found

no association between patient baseline characteristics and increased odds of worse outcomes.

CONCLUSIONS: To our knowledge, this is the largest single-center experience with suburethral Virtue® sling (Coloplast) after RP. Our findings suggest that this device can effectively and safely improve quality of life and aid recovery for patients with SUI after RP. Further investigation with a larger case series might help tailor which patients most likely benefit from this treatment.

SC261
Artificial urinary sphincter implantation: a refined technique to prevent urethral complications

F. Marino, C. Gandi, R. Bientinesi, F. Gavi, S. Moretto, A. Totaro, M. Campetella, P. Russo, R. Ruocco, M. Racioppi, E. Sacco (Rome)

BACKGROUND: The artificial urinary sphincter (AUS) implantation is the most effective treatment option for moderate to severe male non-neurogenic incontinence after prostatic surgery. AUS implantation is an invasive procedure that can result in some troublesome complications. Particularly, intraoperative urethral injury is a very severe complication; infection and erosion are the most common postoperative complications, reported in 3-28% of patients. Given that the tunica albuginea of the corpora cavernosa is a bilayered structure, we assessed an alternative transalbugineal surgical technique for the placement of AUS, with the aim to decrease the risk of intraoperative urethral injury and postoperative urethral erosions, while preserving the integrity of the corpora cavernosa.

METHODS: A retrospective evaluation with a prospectively-maintained database was conducted in a tertiary referral center for male urinary incontinence management. From September 2012 to October 2021, 48 consecutive patients who underwent AUS transalbugineal implantation (AMS 800) were included. The primary outcome was the rate of intraoperative urethral lesions and noniatrogenic erosions at 12-month and 5-year follow-up. The overall erosion-free rate was also assessed. Functional urinary outcomes were evaluated with 24-hour pad use, 24-hour pad weighing test, and the International Consultation on Incontinence Questionnaire (ICIQ-UI SF). Erectile function was assessed with the International Index of Erectile Function Questionnaire (IIEF-5), and the patient's quality of life with the EuroQol Group Questionnaire (EQ-5D-5L).

RESULTS: Of 48 included patients, the mean age was 75±4.7 years. Thirty-nine patients presented with SUI (81.25%) and 9 with MUI (18.75%) related to prostate surgery, including radical prostatectomy (45 patients) and TURP (3 patients). Twenty-three patients (47.9%) had previously undergone radiation therapy, and 18 patients (37.5%) had a history of bladder neck contracture. At a median interquartile range (IQR) follow-up of 60 (24-84) months, no intraoperative urethral injury and only one noniatrogenic erosion occurred. Overall, three urethral erosions occurred: one post-AUS second radiotherapy, and one due to catheterization in the emergency room. The actuarial overall and non-iatrogenic erosion-free rates were 95.8% (95% CI: 84.3-98.9) and 100% at 12 months, and 91.8% (95% CI: 75.4-97.5) and 97.3% (95% CI: 82.3-99.6) at 5 years, respectively. The actuarial rate of social continence (no pads use or use of 1 security pad) was 83.3% (95% CI: 69.4-91.3) at 12-month and 77.2% (95% CI: 61.1-87.3) at 5-year follow-up. At 12-month follow-up, a statistically significant improvement was observed in mean 24-hour pad use, in 24-hour pad weighing test, in ICIQ and EQ-5D-5L score. In preoperatively potent patients, IIEF-5 score remained unchanged.

CONCLUSIONS: Our technically refined approach to AUS implantation may help to avoid intraoperative urethral lesions and lower the risk of subsequent erosion without compromising sexual function in potent patients.

SC262
Stress urinary incontinence treated with Altis® single-incision sling: a double-center four-year follow-up study

L. Ola, J. Antolini, D. Cidda, C. Ganga, D. Marcolin, A. Vigna, M. Leone, F. Varvello, G. Fasolis (Turin)

BACKGROUND: Stress urinary incontinence (SUI) is a urinary leak after an increase of intra-abdominal pressure (incidence between 20-29 years old: 3.5%; over 80: 38%). Though single incision sling (SIS) represents a valid alternative for the treatment of this pathology, the real long-term incidence (>36 months) of mesh exposure, recurrence of SUI and the impact on sexual function is still controversial. We present our results after 4 years of follow-up in patients treated with SIS, evaluating the efficacy of the device, and assessing its safety and its impact in terms of adverse events rate, quality of life and sexual activity changes.

METHODS: We performed a retrospective, double-center, single-arm study. All surgeries were performed in the lithotomy position and under spinal anesthesia, so patients could cooperate by performing the Valsalva Test. Data were collected by medical records and by telephone interview 4 years after the implant of the mini-sling single-incision Altis® (Coloplast, Humlebaek, Denmark) (made of macroporous polypropylene monofilament, measure 7.75 cm). Complication rate, subjective efficacy and degree of satisfaction were investigated.

RESULTS: One hundred fifty-four patients were treated between 2015 and 2019. The average operating time was 23 minutes. Concerning minor postoperative complications, 9 acute urinary retention and 1 major bleeding were reported. During the follow-up, there were 13 (11.5%) cases of urgency urinary incontinence (UUI), among this type 2 diabetes mellitus (DM2) seems to be a risk factor for *de-novo* UUI (P=0.030). We observed 4 (3.5%) cases of mesh extrusion, but none of the characteristics of our population seems to be predictive of it. One hundred thirteen patients answered the survey. Eighty-eight of 113 procedures (78%) were considered effective considering as primary outcome stress test's results at one year of follow-up. Among our patients DM2 appears to be a risk factor for failure (P=0.046). Concerning the subjective parameters at 4 years, investigated by using the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI SF), 92 (81.4%) patients reported subjective improvement in urinary continence, 12 (10.3%) patients did not observe any change and 9 (8.2%) patients reported a worsening of SUI. Using Patient Global Impression of Improvement (PGI-I) questionnaires, 83 (73.5%) patients reported subjective sati-

sfaction, 12 (10.6%) reported no change in quality of life and 18 (15.9%) had a worsening of symptoms. Sexual activity changes were investigated by using Pelvic Organ Prolapse Incontinence Sexual Questionnaire (PISQ 12): 25 (22.1%) patients reported an improved, 11 (9.7%) a worse and 78 (69%) an unchanged sexual life.

CONCLUSIONS: SIS represents a safe and effective treatment for SUI and seems to improve patients' sexual-related quality of life. We recommend the execution of a urodynamic examination in order to adequately identify preoperative bladder hyperactivity and to adequately counsel patients and to use extra-attention in treating patients with DM2.

SC263
Comparison study between functional outcomes of artificial urinary sphincter and the adjustable male device ATOMS™: a propensity score-matched analysis

P. Geretto, E. Ammirati, A. Manassero, M. Falcone, M. Agnello, A. Giammò (Turin)

BACKGROUND: The aim of this study was to compare the functional outcomes of artificial urinary sphincter (AUS) and of the adjustable male sling ATOMS™ (A.M.I., Feldkirch, Austria).

METHODS: Data from consecutive patients subjected to implantation of either AUS or ATOMS™ (A.M.I.) device in the treatment of post-surgical stress or mixed urinary incontinence were retrospectively collected. Outcomes were evaluated at the last follow-up. The comparison between prostheses was performed through the pad test/24 h and, under the subjective point of view, using the Patient's Global Impression of Improvement questionnaire (PGI-I). Propensity score matching between groups was performed in order to minimize selection bias. Comparative analysis for paired samples was then performed, using χ^2 test for categorical variables and Wilcoxon Test for paired samples or paired *t*-test for continuous variables.

RESULTS: After propensity score matching, 49 patients from each intervention group were included in the analysis. Patients baseline characteristics were balanced after PSM. In particular, age at surgery was 69±7 in the ATOMS group and 69±5 in the AUS group; 15 patients had been subjected to pelvic radiotherapy in both groups (P=1) and preoperative pad test/24 h was 554±297 mL in the AUS group and 522±210 mL in the sling group (P=0.37). PSM paired analysis showed that postoperative pad test at last follow up was 100±158 mL in the AUS group and 125±156 mL in the sling group (P=0.47). Urinary losses decrease/24 h was 320±45 mL in the AUS group and 217±31 mL in the sling group (P=0.25). Dry patients were 22 (44.9%) in the AUS group and 11 (22.5%) in the sling group (P=0.03). Patients declared themselves well improved (PGI-I 1-2) in 40 cases in the sling group (81%) and in 35 cases (71%) in the AUS group (P=0.78).

CONCLUSIONS: According to our study, both AUS and ATOMS™ (A.M.I.) can give good outcomes in terms of urine loss decrease and postoperative pad test/24 h without significant differences between devices. Nevertheless, patients subjected to AUS are more likely to be "dry." Patient's counselling should be tailored according to patient's expectancy of dryness or improvement. ATOMS™ (A.M.I.) should be strongly considered in patients who require a less invasive approach without renouncing to a good chance of improvement. On the contrary, AUS is more suitable for patients who require the highest chance of dryness, regardless the risk of complication and reintervention.

SC264
Comparison study between artificial urinary sphincter and the adjustable male device ATOMS™: safety and survival of the prostheses

P. Geretto, E. Ammirati, M. Falcone, A. Manassero, M. Agnello, A. Giammò (Turin)

BACKGROUND: The aim of this study was to compare the safety and the survival of artificial urinary sphincter (AUS) and of the adjustable male sling ATOMS™ (A.M.I., Feldkirch, Austria).

METHODS: Data from consecutive patients subjected to implantation of either AUS or ATOMS™ device (A.M.I.) in the treatment of post-surgical stress or mixed urinary incontinence were retrospectively collected. Outcomes were evaluated at the last follow-up. The comparison between prostheses included intra- and postoperative complications, reintervention and survival of the prosthesis until explantation. Then, we analyzed the role of baseline characteristic as predictors of reintervention. Statistical analysis was performed using the Mann-Withney's *U* Test and the χ^2 test. Survival was expressed using Kaplan-Meier's curves and the Log-Rank Test.

RESULTS: Ninety-four AUS and 95 ATOMS™ prostheses (A.M.I.) implantation were included. Baseline characteristics significantly differed between groups in terms of age at surgery (ATOMS: 71.5±6.7 y; AUS: 69±10 y; P=0.001); previous pelvic RT (25.2%; 38.2%; P=0.02), androgen deprivation therapy (11.6%; 34.5%; P<0.001) and urine loss/24 h (421±196 g; 646±325 g; P<0.001) while they were homogeneous in the remaining characteristics (*e.g.*, comorbidities and previous surgery). Mean follow-up was 43±35 months (31±1.8; 56.2±5; P<0.001). In the AUS group, 3 intraoperative complications were recorded (urethral injury). Postoperatively, the two groups did not differ significantly in terms of total complications (34.7%; 47%; P>0.05). However, in the AUS group Clavien ≥3 complications were significantly higher (14.7%; 45%; P<0.001) and significantly more reinterventions (22.1%; 50%; P<0.001) and explantations (5.2%; 13%; P<0.001) were recorded. Time to reintervention did not significantly differ between the two groups (19.2 [7.2-29.4] months; 21 [6.5-52.5] months; P>0.05). AUS survival was significantly inferior to ATOMS (67±7%; 53±6% at 5 years; P=0.03), fig1. At univariable analysis the kind of intervention was the only significant predictor of reintervention (P<0.001).

CONCLUSIONS: AUS is associated with a higher risk of high-grade complications, reintervention and shorter life span than ATOMS™ (A.M.I.). The kind of intervention (AUS *vs.* ATOMS) is the only predictor of reintervention. AUS should be proposed to patients who accept the risk of more high-grade complications, reinterventions and the shorter prosthesis survival when compared to the adjustable sling ATOMS™ (A.M.I.).

SC265
Vaginal mesh exposures after colposacropexy: a good learning curve is the only tip and trick to avoid it

E. Illiano, G. Vacilotto, M. Gioè, J.A. Rossi de Vermandois, E. Costantini (Terni)

BACKGROUND: The primary aim of our study was to evaluate the senior surgeon's open, laparoscopic and robot-assisted colposacropexy (CSP) learning curve, and to assess the trend of the vaginal mesh exposure rate over the years. The secondary objective was to assess how many procedures are needed to reduce the vaginal exposure rate.

METHODS: This is a retrospective study conducted in a III level Urogynecological Center. Vaginal mesh exposure rates were analyzed in women with advanced pelvic organ prolapse who underwent colposacropexy with or without uterine preservation. The procedures included also total and subtotal hysterectomy by open, laparoscopic, and robot-assisted access from 1995 to 2022. All the procedures were performed by a single surgeon. Vaginal mesh exposure assessment was performed by a different urologist at each postoperative follow-up visit through clinical urogynecological examination. Follow-up was conducted at 1, 3, 6, 12 months postoperatively and then annually.

RESULTS: Five hundred fifty-seven procedures were included in the analysis: 267 open, 214 laparoscopic, 76 robotic CSPs. All the procedures were performed using polypropylene or PVDF meshes. The same surgeon began his experience passing from the open approach to the laparoscopic and then robotic one in sequence. The total mesh vaginal exposure rate after open CSP was 4.5%. In the first 8 years, 6 CSPs were performed in women who had already undergone hysteroannexectomy and in 19 cases the uterus was preserved (HSP). In this period the vaginal mesh exposure rate tends to increase in the time, and this is due to the increasing number of hysteroannexectomy (HY) associated with CSP (16% in the first 25 HY procedures). After about 20 colposacropexy procedures the rate decrease significantly and from 2006 to 2022 it was 1.9% (3/154). The total mesh vaginal exposure rate for laparoscopic CSP was 5.6%. Laparoscopic approach started in 2003. The introduction in 2014 of concomitant HY significantly increased the mesh exposure rate (15% in the first cases). Again, after 20 procedures the total exposure rate tend to decrease. In 2018 subtotal HY (hysterectomy with uterine cervix preservation) was introduced, and no exposure was reported. Robotic assisted CSP started in 2014 and total vaginal exposure rate is 2.6%. All the exposure was in patients who underwent HY. After 12 procedures the exposure rate went to 0. In the 47 sub-total HY (7 open, 25 laparoscopy and 15 robot-assisted) no mesh exposure was reported.

CONCLUSIONS: Our study confirmed the decrease of vaginal exposure rate after CSP in experienced surgical hands, independently to the approach. The robotic learning curve is faster especially if the surgeon is already experienced with the laparoscopic approach. The laparoscopic approach seems to be harder in particular when contemporary HY is performed. HY is the most important risk factor, but the robotic approach seems to decrease this complication after an adequate learning curve.

SMART (SC266-SC280)

Prostate cancer: surgical treatment 4

SC266
Use of octreotide after pelvic lymphadenectomy during radical prostatectomy to limit postoperative lymphorrhea and the onset of lymphoceles

SC267
Second-line PSMA-targeted salvage treatment in patients with miN1/M1a-b oligorecurrent PCa

SC268
Use of augmented reality in nerve sparing approach robot-assisted radical prostatectomy: our experience

SC269
Robot-assisted PSMA-radioguided surgery to assess surgical margins and nodal metastases in prostate cancer patients: first report using an intraoperative PET-CT specimen imager

SC270
Robot-assisted radical prostatectomy performed with different robotic platforms: first comparative evidence between da Vinci and Hugo™ RAS robots

SC271
Radio-guided surgery with drop-in beta probe for 68Ga-PSMA in high-risk prostate cancer patients eligible for robotic-assisted radical prostatectomy

SC272
Three-dimensional prostate model use and augmented reality guided frozen section analysis during robot-assisted radical prostatectomy: updated results of a prospective randomized phase III trial

SC273
Assessing the learning curve for operative time during the introduction of a novel robotic platform: results from the largest series of patients receiving robot-assisted radical prostatectomy with Hugo™ RAS

SC274
Impact of complex cases on perioperative and functional outcomes in patients who underwent Retzius-sparing robot-assisted radical prostatectomy

SC275
Impact of surgeon experience on perioperative and functional outcomes in patients who underwent Retzius-sparing robot-assisted radical prostatectomy

SC276
Perioperative outcomes of robot-assisted radical prostatectomy performed with the new surgical robotic platform Hugo™ RAS: our experience with first 73 cases

SC277
Independent predictors of 3-month urinary continence recovery in a modern series of patients who underwent open or robot-assisted radical prostatectomy

SC278
Evaluation of a novel proficiency score for assessing quality and evolution of learning curve on trifecta outcomes of robot-assisted radical prostatectomy: results of a multicentric series

SC279
Comparison of the vesicourethral anastomosis with unidirectional (Filbloc®) and bidirectional (Quill™) running suture during robotic radical prostatectomy in a matched pair population

SC280
First Retzius-sparing radical prostatectomy in the world performed with Hugo™ RAS platform

SC266
Use of octreotide after pelvic lymphadenectomy during radical prostatectomy to limit postoperative lymphorrhea and the onset of lymphoceles

P. Mannone, A. Abrate, D. Baiamonte, G. Tulone, R. Giaimo, N. Pavan, A. Simonato (Palermo)

BACKGROUND: Lymphorrhea and the formation of lymphoceles are common complications after radical prostatectomy (RP) with pelvic lymph node dissection (PLND). Several studies have shown the presence of binding sites of somatostatin in human lymphatic tissue which could regulate lymphatic secretion. The aim of this work was to study the possible effect of octreotide administration in patients undergoing PLND.

METHODS: A prospective, double-blind, randomized study was conducted on patients underwent retropubic radical prostatectomy associated with PLND. Patients were randomly distributed into two groups, group 1 (study group) and group 2 (control group). Patients allocated in the study group underwent treatment with octreotide administered at a dose of 0.1 mg subcutaneously three times a day starting from surgery day until drainage was removed. Data were collected about preoperative PSA, biopsy Gleason Score, number of lymph nodes removed, daily amount of postoperative lymphatic drainage, days of drainage, hospital stay and onset of lymphoceles at ultrasound controls.

RESULTS: One hundred patients were enrolled in the study. Fifty patients were allocated in group 1 and 50 patients in group 2. No statistical differences were found in age (63.7±7.3 yo *vs.* 64.5±6.5 yo; P=0.59), serum PSA levels (10.66±9.5 ng/mL *vs.* 10.8±10.8 ng/mL; P=0.95) and in biopsy Gleason Score (6.78±0.82 *vs.* 6.52±0.89; P=0.13). No significant differences were also observed in the number of lymph nodes removed (8.32±4.58 *vs.* 8.24±5.14; P=0.9) and in the days of hospital stay (11.02±4.82 days *vs.* 10.6±3.83 days; P=0.63). Less lymphorrhea was observed in group 1 (190±276 mL/day *vs.* 403±650 mL/day; P<0.03) and a shorter timing of removal of the drainage (3.94±1.99 days *vs.* 4.98±2.97 days; P<0.04). No differences were found between the two groups in the possible onset of lymphoceles investigated with ultrasound scans performed on postoperative day 7 (11 *vs.* 10, P=0.8), 14 (18 *vs.* 21, P=0.54) and 21 (18 *vs.* 24, P=0.22).

CONCLUSIONS: In the patients of the control group of our study, less lymph drainage was observed in the postoperative period and octreotide could also be a useful tool in reducing hospitalization days. The utility of octreotide in limiting the onset of lymphoceles remains uncertain.

SC267
Second-line PSMA-targeted salvage treatment in patients with miN1/M1a-b oligorecurrent PCa

L. Bianchi, E. Balestrazzi, F. Ceci, F. Costa, M. Droghetti, A. Pissavini, P. Piazza, S. Tamburini, A. Farolfi, R. Mei, P. Castellucci, S. Puliatti, G. Gandaglia, A. Larcher, A. Mottrie, A. Briganti, A.G. Morganti, S. Fanti, F. Montorsi, R. Schiavina, E. Brunocilla (Bologna)

BACKGROUND: PSMA-PET is considered the imaging of choice in patients with recurrent prostate cancer (PCa) after primary treatments. Recurrent PCa includes various clinical settings. Thus, we aimed to explore the oncologic benefit of second-line salvage PSMA-guided MDT (metastases directed treatment) in PCa patients with recurrence after previous salvage treatments and oligo-recurrent N1/M1a-b disease at PSMA-PET.

METHODS: We retrospectively analyzed patients underwent RP (radical prostatectomy) for PCa and PSMA-PET (from January 2016 to February 2021) performed for biochemical recurrence (BCR) after first-line salvage therapies for BCR after PR at 3 high volume European Centers. Oligorecurrent (≤3 lesions) patients with N1/M1a-b disease at PSMA-PET and eligible for MDT were identified. MDT consist of salvage lymph node dissection (sLND) and stereotactic body radiotherapy (SBRT) or combination of both. Conventional approach includes observation or androgen deprivation therapy. Men were stratified according to treatment after PSMA-PET (MDT *vs.* conventional approach). Kaplan Meier curves were used to assess progression free survival (PFS), metastases free survival (MFS) and CRPC free survival (CRPC-FS) at 3 years of follow-up after stratifying according to treatment after PSMA-PET. In patients underwent MDT, oncologic outcomes were stratified according to the anatomic site (pelvic *vs.* extrapelvic localization) and stage (miN1 *vs.* miM1a-b) at PSMA-PET. Multivariable Cox regression was performed to identify independent predictors of progression and metastases.

RESULTS: Overall, 113 patients were enrolled: 91 patients were treated with MDT approach and 22 with conventional approach. The median (IQR) follow-up after PSMA-PET was 31 (19-42) months. Overall, no significant differences were found concerning 3-year PFS according to type of treatment (P=0.3). MFS and CRPC-FS estimates at 3 years were 73.5% and 94.7% in patients underwent MDT *vs.* 30.5% and 79.5% in men treated with conventional approach, respectively (all P<0.001). In patients who underwent MDT, no significant differences were found concerning PFS and MFS rates after stratifying according to anatomic site and stage (all P>0.05). The CRPC-FS estimates at 3 years were 100% in patients with pelvic disease and 83.3% in men with extrapelvic disease (P=0.004). In patients with N1 localization CRPC-FS at 3 years was 100% and in men with M1a-b was 86.1% (P=0.02). At the multivariable Cox regression analysis, age (HR=0.96) and pT3b- pT4 (HR=2.02) were independent predictors of progression (all P≤0.03), while MDT (HR=0.37) was the only independent predictor of metastases (P=0.02).

CONCLUSIONS: In a selected population of oligo-recurrent N1/M1a-b PCa patients with limited therapeutic chances due to previous salvage treatments, the MDT targeted to PSMA-PET may represent a promising second-line salvage approach to delay further progression to CRPC status.

SC268
Use of augmented reality in nerve sparing approach robot-assisted radical prostatectomy: our experience

G. Quarto, F. Passaro, D. Franzese, A. Izzo, L. Castaldo, G. Grimaldi, R. Muscariello, G. Spena, A. Tufano, F. Calabrò, D.E. De Falco, S. Desicato, P. Del Prete, S. Perdonà (Naples)

BACKGROUND: Augmented-reality robot-assisted radical prostatectomy is a relatively new surgical technique

that combines the use of advanced imaging technology and robotics to treat prostate cancer. The surgeon uses a high-resolution camera and a computerized system to create a 3D image of the prostate and surrounding tissues. This image is then overlaid on the surgeon's field of view using augmented reality technology, providing real-time visual guidance during the surgery. The aim of the work was to evaluate the improvement of nerve sparing prostatectomy with the aid of augmented reality.

METHODS: From January 2019 to July 2022, 75 consecutive prostate cancer patients underwent NS-RARP with the help of augmented reality and AR-3D models (study group). Control group consists of 75 patients matched with 1:1 propensity score for age, clinical stage, Prostate Imaging Reporting and Data System score v2, International Society of Urological Pathology grade, prostate volume, NS approach, and prostate-specific antigen in which RARP was performed by cognitive assessment of mpMRI.

RESULTS: Patients in the AR-3D group had comparable preoperative characteristics and those undergoing the NS approach were referred to as the control group. Overall, positive surgical margin (PSM) rates were comparable between the two groups; PSMs in patients with pt3 were significantly lower in patients referred to AR-3D than those in the control group (6.67 *vs.* 10.67).

CONCLUSIONS: Augmented-reality robot-assisted radical prostatectomy offers several benefits over traditional prostate cancer surgery. The advanced imaging technology and robotics improve surgical precision, minimizing damage to surrounding tissue and nerves. This can reduce the risk of side effects such as positive surgical margin. In particular, the advantage appears to be greater especially in patients with pathologically more aggressive prostate disease.

SC269
Robot-assisted PSMA-radioguided surgery to assess surgical margins and nodal metastases in prostate cancer patients: first report using an intraoperative PET-CT specimen imager

M. Oderda, S. Grimaldi, G. Rovera, L. Delsedime, D. D'Agate, F. Lavagno, A. Marquis, G. Marra, L. Molinaro, D. Deandreis, P. Gontero (Turin)

BACKGROUND: Prostate-specific membrane antigen (PSMA) is the most accurate radiopharmaceutical for prostate cancer (PCa) PET/CT imaging. A mobile, high-resolution PET/CT-imaging device (AURA 10 specimen PET/CT imager; XEOS Medical NV, Gand, Belgium) recently became available, with near five-fold optimization in spatial resolution as opposed to standard clinical PET/CT devices and holds potential for the *ex-vivo* identification of PCa foci in surgically resected specimens. The aim of this feasibility study was to test the intraoperative use of this brand-new specimen PET/CT to guide robot-assisted radical prostatectomy (RARP) and pelvic lymph node dissection (PLND).

METHODS: To date, we performed three cases of RARP and PLND with intraoperative use of the specimen imager. Patients on the study underwent preoperative staging with MRI and 68Ga-PSMA PET/CT for high-risk prostate cancer. Surgeries were performed with da Vinci Xi robot (Intuitive Surgical, Inc., Sunnyvale, CA, USA). During trocar placement, an intravenous injection of 68Ga-PSMA-11 (2 MBq/kg) was performed in the OR. Lymph nodes were immediately removed through the 12-mm assistant trocar and analyzed with the specimen imager. After complete excision, the prostate was removed through a short Pfannestiel incision while maintaining CO_2 insufflation and PET/CT images were acquired to check for positive surgical margins (PSM) before doing the urethra-vesical anastomosis. SUV_{max} of the scanned lymph nodes, background SUV_{max} and LN/Background Ratio (TBR) were calculated with the AMIDE software (v. 1.0.6).

RESULTS: On average, the time required by the specimen imager to scan each specimen was 12 minutes (SD=3). The median time between injection and specimen PET/CT imaging was 98 minutes for lymph nodes, and 3.8 hours for prostate specimens. The average nodal uptake was 17.3 (SD=5.8) nodes per patient, and only one node was positive at histopathology. Specimen PET/CT images showed a focal uptake in a metastatic node (TBR=13.6), and no uptake or diffuse, faint uptake in negative nodes (TBR range: 1-5.3). The specimen imager provided intraoperative PET/CT images which allowed to identify negative surgical margins in two patients, while findings were inconclusive in one locally advanced case.

CONCLUSIONS: The intraoperative use of the specimen PET/CT imager is safe and feasible and could improve the evaluation of prostate surgical margins and lymph node status. The intraoperative knowledge of prostate cancer (PCa) location within prostate or lymph nodes may improve the oncological radicality of the procedure while safely pushing the boundaries of a hyper-conservative surgery.

SC270
Robot-assisted radical prostatectomy performed with different robotic platforms: first comparative evidence between da Vinci and Hugo™ RAS robots

C.A. Bravi, E. Balestrazzi, M. De Loof, S. Rebuffo, F. Piramide, A. Mottaran, M. Paciotti, G. Sorce, L. Nocera, L. Sarchi, M. Peraire, C. Collà-Ruvolo, N. Frego, A. Piro, M. Ticonosco, P. De Backer, R. Farinha, H. Van Den Bossche, R. De Groote, G. De Naeyer, F. D'Hondt, A. Mottrie (Ghent)

BACKGROUND: In the field of robotic surgery, there is no comparative evidence on surgical and functional outcomes of different robotic platforms. The aim of this study was to assess outcomes of patients receiving robot-assisted radical prostatectomy (RARP) at a high-volume robotic center with da Vinci (Intuitive Surgical, Inc., Sunnyvale, CA, USA) and Hugo™ RAS surgical systems (Medtronic, Minneapolis, MN, USA).

METHODS: We analyzed data of 542 patients undergoing RARP±extended pelvic lymph node dissection at OLV hospital (Aalst, Belgium) between 2021 and 2023. All procedures were performed by 6 surgeons using da Vinci (Intuitive Surgical, Inc.) or Hugo™ RAS robots (Medtronic); the use of one platform rather than the other did not follow any specific preference and/or indication. Multivariable analyses investigated the association between robotic system (da Vinci *vs.* Hugo™ RAS) and surgical outcomes after adjustment for patient- and tumor-related factors. Urinary continence recovery was defined as the use of no/one safety pad.

RESULTS: A total of 378 (70%) and 164 (30%) patients underwent RARP with da Vinci (Intuitive Surgical, Inc.) *vs.* Hugo™ RAS surgical systems (Medtronic), respectively. Despite higher rate of palpable disease in the Hugo RAS group (34% *vs.* 25%), baseline characteristics did not differ between the groups (all P>0.05). After adjusting for confounders, we did not find evidence of a difference between the groups with respect to operative time (estimate: 8.96; 95% confidence interval [CI]: -9.08, 27.01; P=0.3), estimated blood loss (estimate: 4.62; 95% CI: -46.14, 55.39; P=0.8) and postoperative Clavien-Dindo ≥2 complications (Odds Ratio [OR]: 1.11; 95% CI: 0.56, 2.19; P=0.8). On final pathology, 55 (15%) and 20 (12%) men in the da Vinci *vs.* Hugo RAS group had positive surgical margins (PSM, P=0.5). On multivariable analyses, we did not find evidence of an association between robotic system and PSM (OR=0.84; 95% CI: 0.54, 1.32; P=0.5). Similarly, the odds of recovering continence did not differ between da Vinci and Hugo RAS cases both after one (OR=1.03; 95% CI: 0.69, 1.55; P=0.9) and three months (OR=1.75; 95% CI: 0.85, 3.63; P=0.13).

CONCLUSIONS: Among patients receiving RARP with da Vinci (Intuitive Surgical, Inc.) or Hugo RAS (Medtronic) surgical platforms, we did not find differences in surgical and functional outcomes between the robots. This may be a result of standardized surgical technique that allowed surgeons to transfer their skills between robotic systems. Awaiting future investigations with longer follow-up, these results have important implications for patients, surgeons and healthcare policymakers.

SC271
Radio-guided surgery with drop-in beta probe for 68Ga-PSMA in high-risk prostate cancer patients eligible for robotic-assisted radical prostatectomy

F.A. Mistretta, G. Graps, O. Guglielmo, M. Tallini, G. Lucignani, M.L. Piccinelli, M. Fontana, S. Luzzago, A. Cioffi, M. Ferro, G. Cordima, D. Bottero, L. Muraglia, F. Ceci, G. Musi, O. De Cobelli (Milan)

BACKGROUND: The primary aim of this analysis was to evaluate the diagnostic accuracy of the combined approach with a DROP-IN positron detector (β-Probe) and 68Ga-PSMA-11 PET/CT (PSMA-PET) in the correct identification of lymph node metastases in high-risk prostate cancer (PCa) patients undergoing robotic radical prostatectomy (RARP) and extended pelvic lymph-node dissection (ePLND). The standard of reference was the histopathological analysis.

METHODS: This is a prospective, single-arm, single-center, non-interventional, phase II trial (NCT05596851), aimed at enrolling fifteen (N.=15) PCa patients. We present an interim analysis in the first consecutive five (N.=5) patients enrolled. Inclusion criteria were: 1) biopsy proven, high-risk PCa; 2) patients candidate to RARP+ePLND as primary therapy; 3) PSMA-PET performed within 6 weeks prior to RP; 4) PSMA-positive nodes in PET; and 5) age >18. The surgery procedure started with the intravenous injection of 1.1 MBq/kg of 68Ga-PSMA11 directly in the surgery theater. After injection the surgery procedure proceeded first with ePLND followed by RP. The *in-vivo* measurements of the surgery templates with β-Probe were performed with a DROP-IN system, inserting the probe into a trocar. All removed nodes were also measured *ex vivo*. The Tumor-to-Background-Ratio (TBR) was evaluated graphically in a display showing real-time counts per time (a dedicated, operator- independent, algorithm to reliably identify pathologic *vs.* non-pathologic nodes is under development). PSMA-staining was performed in all specimens. Data derived by the PSMA-PET, β-Probe and histopathological analysis were compared in a per-region analysis.

RESULTS: The live β-Probe-guided ePLND was a feasible procedure, without significant changes in the surgery practice. No side effects have been observed during ePLND. In total, 36 specimens were removed and analyzed. Pathology results were used to validate *in-vivo* and *ex-vivo* β-Probe counts interpreted based on current interpretation criteria. According to visual interpretation criteria applied during surgery, the β-Probe sensitivity was 59%, while specificity was 89%. Visual TBR interpretation (operator-dependent) revealed to be more challenging than expected.

CONCLUSIONS: These are the first ever published data derived from a live surgery experience using a β-Probe to identify PSMA-positive lymph nodes. This new approach proved to be feasible and safe. Using current β-Probe counts' interpretation criteria, diagnostic accuracy is promising, even if still suboptimal. The implementation of a dedicated, operator-independent, algorithm for the identification of a cut-off in TBR analysis might improve these results. The completion of this phase II trial will provide more data about the efficacy of this new generation image-guided approach.

SC272
Three-dimensional prostate model use and augmented reality guided frozen section analysis during robot-assisted radical prostatectomy: updated results of a prospective randomized phase III trial

S. Luzzago, G. Graps, O. Guglielmo, M. Tallini, G. Lucignani, M.L. Piccinelli, M. Fontana, F.A. Mistretta, A. Cioffi, A. Brescia, M. Ferro, G. Petralia, S. Alessi, A. Bellin, G. Musi, O. de Cobelli (Milan)

BACKGROUND: The role of augmented reality (AR) during robot-assisted radical prostatectomy (RARP) to reduce the rates of positive surgical margins (PSMs) and its use during intraoperative frozen section (IFS) analysis has been poorly addressed.

METHODS: We designed a monocentric, prospective, double-blinded randomized trial (2022-2025). All patients with an EAU low or intermediate-risk prostate cancer, a preoperative IIEF score ≥20 and with at least one visible lesion at magnetic resonance (mpMRI) will be randomized (1:1 ratio) to: 1) AR RARP (3D reconstruction according to mpMRI) – the model will be projected in the surgical field using the TileProTM technology (during IFS, mixed reality [HoloLens glasses, Microsoft Corp., Redmond, WA, USA] will be used; and 2) standard RARP – nerve-sparing approach and IFS according to mpMRI. The primary outcome is the rate of PSMs. Secondary outcomes are: 1) the rate of nerve-sparing approaches; and 2) IIEF score after surgery. Given a hypothetical expected difference of 10% between groups, to have adequate statistical power (80%), the required number is 157 patients per group.

RESULTS: Overall, 85 patients have been enrolled (January 2023). Of those, 42 (49%) *vs.* 43 (51%) underwent

AR RARP *vs.* standard RARP. Median surgical time was 153 *vs.* 137 mins in AR RARP *vs.* standard RARP (P=0.04). Overall, 9 (21.5%) *vs.* 13 (30.5%) patients had PSMs in AR RARP *vs.* standard RARP (P<0.001). The rate of bilateral full nerve-sparing was similar (P=0.7).

CONCLUSIONS: AR RARP and intraoperative frozen section analysis according to AR models appear to reduce the rates of PSMs, relative to standard RARP, in patient candidates to nerve-sparing approach.

SC273

Assessing the learning curve for operative time during the introduction of a novel robotic platform: results from the largest series of patients receiving robot-assisted radical prostatectomy with Hugo™ RAS

C.A. Bravi, A. Piro, M. Peraire Lores, E. Balestrazzi, M. Paciotti, L. Sarchi, A. Mottaran, F. Piramide, L. Nocera, R. Farinha, G. De Naeyer, F. D'Hondt, R. De Groote, A. Mottrie (Melle, Cuneo)

BACKGROUND: Hugo™ RAS robotic system (Medtronic, Minneapolis, MN, USA) is gaining popularity with an increasing number of centers that are adopting this new technology. In this context, evidence on the number of cases required (*i.e.*, the learning curve) to achieve adequate operative time (OT) is scarce. Therefore, we aimed at assessing the association between OT and surgical experience in the largest series of patients treated with robot-assisted radical prostatectomy (RARP) with this surgical platform.

METHODS: We analyzed data of 96 patients who received RARP±extended pelvic lymph node dissection (ePLND) with Hugo™ RAS (Medtronic) at OLV hospital (Aalst, Belgium) between February and October 2022. Patients were operated by one in six surgeons; among them, the one with the largest experience with Hugo™ RAS (Medtronic) performed 44 RARPs. Multivariable regression investigated the association between OT and surgical experience, coded continuously as the number of prior RARPs performed with Hugo™ RAS (Medtronic) at index patient's operation. The adjustment for casemix included age, Body Mass Index, preoperative PSA, biopsy International Society of Urological Pathology (ISUP) group, T stage on preoperative MRI (iT2 *vs.* iT3a-b), ePLND (no *vs.* yes), prostate volume and nerve sparing (no *vs.* uni- *vs.* bi-lateral).

RESULTS: Median (interquartile range [IQR]) preoperative PSA was 7.8 (5.8, 10.5) ng/mL, and 33 (34%) men had biopsy ISUP 3-5 disease. On preoperative MRI, 21 (22%) patients had T3a-b disease, and median (IQR) volume was 40 (32, 52) cc. Median operative time was 180 (150, 200) minutes. On multivariable analyses, surgical experience with Hugo™ RAS (Medtronic) was not associated with operative time (P=0.2). Although a clear plateau cannot be identified, operative time required to complete a procedure slowly decreased with increasing number of procedures performed.

CONCLUSIONS: Our study described the association between surgical experience and operative time for RARP with Hugo™ RAS (Medtronic) robotic system. Awaiting further data with more surgeons and more cases performed, we provided relevant data with respect to the introduction of a new robotic platform such Hugo™ RAS (Medtronic) that allowed for adequate operative time since its introduction at a high-volume robotic center.

SC274

Impact of complex cases on perioperative and functional outcomes in patients who underwent Retzius-sparing robot-assisted radical prostatectomy

S. Viganò, M. Foti, M. Rossanese, L. Macchione, A. Isgrò, V. Ficarra (Messina)

BACKGROUND: Obese patients, prostate larger than 70 cc, previous prostatic endoscopic or surgical treatment for BOO, presence of median lobe, previous pelvic surgery and previous radiation/HIFU/cryo therapies represent challenge cases potentially impacting outcomes of radical prostatectomy. In the present study, we evaluated the impact of previous challenge cases on perioperative and functional outcomes in a series of consecutive patients who underwent Retzius-sparing robot-assisted radical prostatectomy (RS-RARP).

METHODS: All clinical records of patients who underwent RS-RARP in our center were prospectively collected in a dedicated database, approved by our ethical committee. In the present study, we selected and analyzed retrospectively patients who underwent RS-RARP from January 2020 to August 2022. All patients were followed for a 6-month minimum follow-up. All the procedures were performed by an expert robotic surgeon using the da Vinci Xi platform (Intuitive Surgical, Inc., Sunnyvale, CA, USA). Patients were stratified in two groups according to the complexity of surgery. Challenge cases included patients with: 1) BMI>30; 2) prostate volume >70 cc; 3) presence of median lobe; 4) previously endoscopic or surgical treatments for BPH; and 5) previous pelvic surgery and patients who underwent salvage RP. Operative time (OR), estimated blood loss (EBL), catheter time, 3-month postoperative complications, 1-week, 1-month, 3-month and 6-month urinary continence recovery and 6-month potency recovery were evaluated and compared in the two groups.

RESULTS: Overall, 180 RS-RARP were included in the present analysis. Specifically, 66 (36.7%) were classified as challenge cases and 114 (63.3%) as no challenge cases. In details, 51 (28.3%) cases showed only one unfavorable condition, 13 (7.2%) two conditions and 2 (1.1%) 3 conditions. Overall, challenge cases were due to presence of median lobe in 27 (40.9%) cases, obesity in 26 (39.3%) cases, large prostate in 22 (33.3%), previous treatment for BPH in 5 (7.5%), previous pelvic surgery in 2 (3%) and previous HIFU treatment in 1 (1.5%) case. The two groups resulted comparable for age (P=0.28), total PSA (P=0.25), bioptical ISUP Grading Group (P=0.82), risk stratification (P=0.31) and preoperative potency (P=0.65). Looking to the perioperative outcomes, challenge cases were associated with a longer catheter time (5 *vs.* 6 days; P=0.003) and lower percentage of watertight anastomosis (86% *vs.* 80%; P=0.01). No difference was observed in terms of 3-month overall postoperative complications (10.5% *vs.* 12.1%; P=0.96) and positive surgical margins (15% *vs.* 17%; P=0.67). No differences between the two groups were detected in terms of 1-week (88.6% *vs.* 83.3%; P=0.50), 3-month (94% *vs.* 91%; P=0.53) and 6-month (98% *vs.* 95%; P=0.27) urinary continence recovery. Analyzing only patients receiving a nerve-sparing procedure, 6-month potency recovery was 64.6% in the group including no challenge cases and 65% in the second one (P=0.96).

CONCLUSIONS: In our experience challenge cases who underwent RS-RARP showed perioperative, functional and early oncologic outcomes similar to the other cases.

SC275
Impact of surgeon experience on perioperative and functional outcomes in patients who underwent Retzius-sparing robot-assisted radical prostatectomy

M. Foti, S. Viganò, D. Maravigna, M. Rossanese, L. Macchione, V. Ficarra (Messina)

BACKGROUND: Few data were available about the learning curve of Retzius-sparing RARP for surgeons with previous experience with traditional anterior robotic approach. The aim of the present study was to evaluate the impact of learning curve on the main perioperative and functional outcomes of a single surgeon starting his experience with RS-RARP after a large experience with traditional anterior approach.

METHODS: All clinical records of patients who underwent RS-RARP in our Center were prospectively collected in a dedicated database, approved by our ethical committee. In the present study, we selected and analyzed retrospectively patients who underwent RS-RARP from January 2020 to August 2022. Therefore, all patients were followed for a 6-month minimum follow-up. All the procedures were performed by a single robotic surgeon using the da Vinci Xi platform (Intuitive Surgical, Inc., Sunnyvale, CA, USA). The surgeon had a large experience with the anterior approach before starting his learning curve with RS-RARP. For every patient the main pre-, intra- and postoperative variables were extracted from the database. Operative time (OR), estimated blood loss (EBL), catheter time, 3-month postoperative complications, 1-week, 1-month, 3-month and 6-month urinary continence recovery and 6-month potency recovery were evaluated and compared in the two groups.

RESULTS: Overall, 180 RS-RARP were included in the present analysis. Patients were assigned to 4 different subgroups including 45 consecutive cases according to the study period. Patient's age increased significantly during the study period (P<0.001). Conversely, preoperative potency decreased significantly (P<0.01) during the study period as well the percentage of performed nerve-sparing period (P<0.01). No differences were observed in terms of BMI (P=0.73), tPSA (P=0.06), bioptical GS (P=0.10), D'Amico risk groups (P=0.65) and ASA classification (P=0.46). Moreover, challenge cases including large prostate, obese patient, previous TURP/adenomectomy and large median lobe were performed more frequently in the last two groups of patients (P=0.02). We observed a significant improvement of OR (P<0.001) and EBL (P=0.008) during the time. Conversely, the catheter time resulted overlapping (P=0.28). No differences were observed between the 4 groups in terms of postoperative complications (P=0.10), PSM rate (P=0.11), 1-week (P=0.16), 1-month (P=0.52), 3-month (P=0.43) and 6-month (P=0.13) urinary continence recovery. The 6-month potency recovery rates resulted overlapping in the 4 subgroups analyzed (P=0.51).

CONCLUSIONS: Baseline characteristics of our patients who underwent RS-RARP showed that indications for RS-RARP have become progressively larger including above all older patients and more challenge cases. However, no significant differences were observed during the study period in terms of perioperative, functional, and early oncologic outcomes. Learning curve for RS-RARP for surgeons experienced in anterior approach should be considered very short.

SC276
Perioperative outcomes of robot-assisted radical prostatectomy performed with the new surgical robotic platform Hugo™ RAS: our experience with first 73 cases

M. Campetella, A. Totaro, C. Gandi, M. Ragonese, R. Bientinesi, G. Palermo, E. Scarciglia, F. Gavi, F. Marino, A. Cretì, S. Moretto, M. Racioppi, E. Sacco (Rome)

BACKGROUND: Robotic radical prostatectomy is now the gold standard for the treatment of localized prostate cancer. The most widely available platform is the Da Vinci RAS surgical system by Intuitive Surgical, Inc. (Sunnyvale, CA, USA). However, in the last few years new robotic platforms have been developed. Hugo™ RAS system (Medtronic, Minneapolis, MN, USA) is one of the most promising new robotic platforms. The aim of this study was to provide the early perioperative results of our initial experience in performing RARP using Hugo™ RAS system (Medtronic).

METHODS: All consecutive patients undergoing RARP with the new robotic platform were included in this prospective clinical study from April 2022 to March 2023. Preoperative, intraoperative and postoperative data were recorded. A transperitoneal, four-arm configuration was used following the Montsouris technique.

RESULTS: Seventy-three patients were included. Eleven patients underwent pelvic lymphadenectomy. Nerve-sparing technique was performed monolaterally in 18 patients and bilaterally in 22 patients. All surgeries were completed without the need for conversion. Median total operative time was 239.4 minutes while median console time was 110.5 minutes. Median estimated blood loss was 137.7 mL, no patients required transfusions. Early postoperative complications were classified as Clavien-Dindo Grade I in 7 patients, Grade II in one patient, Grade IIIa in one patient, and Grade IIIb in another patient. Mean hospital stay was 4.6 days. Pathological stage was: pT2c in 54 patients (74.0%), pT3a in 9 patients (12.3%) and pT3b in 10 patients (13.7%). Rate of positive surgical margin was 35.6% (26/73). No major technical issues occurred except for three cases of broken instruments.

CONCLUSIONS: Our early experience demonstrated the safety and reproducibility of the RARP performed with the Hugo™ RAS system (Medtronic). Further prospectively collected data are needed to assess the non-inferiority in comparison with the older robotic system.

SC277
Independent predictors of 3-month urinary continence recovery in a modern series of patients who underwent open or robot-assisted radical prostatectomy

S. Viganò, D. Maravigna, A. De Stefano, M. Rossanese, G. Mucciardi, V. Ficarra (Messina)

BACKGROUND: In the last decades the early urinary continence recovery rate after radical prostatectomy improved significantly and only a low percentage of patients refer urinary incontinence 3-month after surgery. The objective of the present study was to identify the independent predictors of 3-month urinary continence recovery in a recent series of patients who underwent radical prostatectomy (RP) for clinically localized prostate cancer.

METHODS: Clinical records of all RPs performed by a single surgeon from 2018 to 2022 in an academic center were prospectively collected in a dedicated database. Urinary continence was evaluated 3-month after catheter removal using validated questionnaire. Patients reporting no leak or using a safety pad were considered continent. Patient's age, BMI, prostate volume, surgical approach (open, anterior or posterior robot-assisted), nerve-sparing technique, bladder-neck management (resection/preservation) and pathologic extension of primary tumor were considered as covariates in the multivariable models. Binomial logistic regression analysis was used to identify independent predictors of 3-month urinary incontinence.

RESULTS: An overall 451 patients were evaluable at the 3-month follow-up. One hundred sixty-six (36.8%) patients underwent open RP, 105 (23.3%) anterior RARP and 180 (39.9%) Retzius-sparing RARP. Three-month after surgery 75 (16.6%) patients resulted still incontinent. Forty-five (60%) incontinent patients underwent open RP, 17 (22.7%) anterior RARP and 13 (17.3%) RS-RARP (P<0.001). Sixty-two (82.7%) incontinent patients did not perform nerve-sparing technique, 3 (4%) received a monolateral preservation and 10 (13.3%) a bilateral preservation (P<0.001). Twenty-eight (37.3%) incontinent patients performed a bladder-neck preservation and 47 (62.7%) a bladder neck reconstruction (P<0.001). At multivariable analysis only bilateral nerve-sparing (OR=0.235; 95% CI: 0.102-0.542) turned out to be an independent predictor of 3-month urinary continence recovery. However, nerve-sparing technique was performed in only 13 (8%) of patients who underwent open RP, in 64 (61%) of anterior RARP and 142 (79%) of RS-RARP (P<0.001). Similarly, bladder neck preservation was performed in only 20 (12.2%) open RP; 81 (77.1%) of anterior RARP and 165 (91.7%) of RS-RARP.

CONCLUSIONS: In our analysis, nerve-sparing technique resulted the only predictor of 3-month urinary continence recovery in patients who underwent radical prostatectomy. However, RS-RARP was associated with a significant increasing number of nerve-sparing procedure in comparison with both open and anterior RARP. Similarly, RS-RARP resulted associated with an increasing probability of bladder neck preservation in comparison with both the other techniques.

SC278
Evaluation of a novel proficiency score for assessing quality and evolution of learning curve on trifecta outcomes of robot-assisted radical prostatectomy: results of a multicentric series

U. Anceschi, F. Prata, P. Dell'Oglio, M. Oderda, A. Ragusa, T. Al-Hammouri, L. Misuraca, E. Vecchio, A. Iannuzzi, A. Olivero, G. Tuderti, A. Brassetti, M. Allasia, M.C. Ferriero, A.M. Bove, G. Spadaro, S. Tappero, S. Secco, M. Martiriggiano, A. Galfano, A.M. Bocciardi, P. Gontero, G. Shaw, G. Simone (Rome)

BACKGROUND: We aimed to evaluate proficiency score (PS) metric in a large multicentric series of robot-assisted radical prostatectomies (RALPs) performed with two different surgical techniques by both trainees and their respective mentors.

METHODS: Between 2019-2021, four prospective prostate-cancer datasets were merged and queried for RALP performed by 14 surgeons during their learning curve (LC) and 5 respective experts using two different-surgical approaches (Retzius-sparing and antegrade). Surgeons were considered "expert" with a caseload of consecutive RALPs>150, while a median of d50 procedures was used for the definition of trainees. Patients with low-intermediate risk prostate cancer scheduled for surgery without pelvic lymphadenectomy were included in the analysis. Logistic binary regression models were built to identify predictors of 1-year trifecta achievement (continence, potency, and cancer control) for trainees and the whole cohort, respectively.

RESULTS: Patients in the trainees group showed significantly increased median operative time and a trend toward lower pT stages and experience on laparoscopic radical prostatectomy, respectively (all P≤0.043). Overall, PS was 48.4%. One-year continence status and potency were significantly higher in the mentor series (P<0.001 and P=0.03, respectively) while trifecta rates were comparable between cohorts (P=0.87). On multivariable logistic regression analysis, proficiency score was the only independent predictor of 1-year trifecta achievement either in the pooled series (OR=2.48, 95% CI: 1.04-5.91; P=0.04) or in the trainees cohort (OR=2.79; 95% CI: 1.13-6.80; P=0.025), while a yearly center caseload >150 procedures (OR=3.54; 95% CI: 1.08-11.5; P=0.036) was an independent predictor of trifecta achievement in the trainees series.

CONCLUSIONS: We performed the first multicentric assessment of a clinical score predicting 1-year RALP composite outcomes, specifically conceived to evaluate naïve surgeons during their LC. Institutional yearly caseload and PS were the only independent predictors of trifecta, confirming the role of both institutional and individual surgical exposure as main determinant of surgical quality.

SC279
Comparison of the vesicourethral anastomosis with unidirectional (Filbloc®) and bidirectional (Quill™) running suture during robotic radical prostatectomy in a matched pair population

A. Ninivaggi, S. Staffieri, N. d'Altilia, U.G. Falagario, F. Guzzi, L. Montrone, G. Ciavarella, P. Annese, G.M. Busett, C. Bettocchi, L. Cormio, G. Carrieri (Foggia)

BACKGROUND: Robotic radical prostatectomy (RARP) is the most common technique for the treatment of prostate cancer. Vesicourethral anastomosis (VUA) is one of the most important surgical steps. Several technical modifications based on different type of suture have been proposed. The aim of the present study was to compare operative time, early continence recovery and complications after RARP when VUA was performed using two different types of synthetic monofilament absorbable barbed suture, Quill™ (bidirectional; B Braun, Melsungen, Germany) and Filbloc® (helical; Assut Europe, Magliano dei Marsi, L'Aquila, Italy).

METHODS: We retrospectively reviewed our prospectively maintained radical prostatectomy database to retrieve patients who underwent VUA using Barbed suture. Group A included all patients in whom Quill™ (B Braun) was used whereas Filbloc® (Assut Europe) was used in Group B. Preoperative and postoperative care followed our internal policy. A catheter was placed after the procedure and removed on postoperative day 5 if no leakage was noted on cystogram. A urinary nurse blinded to clinical and surgical details recorded 24-hour pads weight and complication during the follow-up. Study endpoint were robotic console time, incontinence recovery defined as 24 hours pad weight >20 grams and complication according to Clavien-Dindo Classification.

RESULTS: Four hundred eight patients were included in the present study, 204 in the Quill group and 204 in the Filbloc group. No significant differences were found between the two groups in terms of age (66 *vs.* 65, P=0.5), PSA value (6.1 ng/mL *vs.* 6.8 ng/mL, P=0.2), Gleason grade group >1 (53% *vs.* 58%, P=0.8) and nerve sparing technique (40.6% *vs.* 50%, P=0.2). In Filbloc group, robotic median console time was shorter (150 *vs.* 170; P=0.04) and Clavien-Dindo postoperative complications Grade I-II (urinary infections and acute urine retention) were inferior (1.5% *vs.* 5.3%, P=0.03). No differences were found in Clavien-Dindo Grade III-IV (uroperitoneum, 0.9% *vs.* 0.5%, P=0.6). Incontinence recovery rate was similar in the two groups at 1 week, 2 weeks and 1 month (38.7% *vs.* 50.7%, P=0.2; 25% *vs.* 34%, P=0.2; and 17% *vs.* 20%, P=0.5 respectively).

CONCLUSIONS: In our experience Filbloc® (Assut Europe) resulted in reduced robotic median console time and Clavien-Dindo Grade I-II postoperative complications compared to Quill™ (B Braun). No difference was found in terms of incontinence recovery.

SC280
First Retzius-sparing radical prostatectomy in the world performed with Hugo™ RAS platform

A. Galfano, A. Olivero, S. Secco, G. Petralia, A.M. Bocciardi, P. Dell'Oglio (Milan)

BACKGROUND: Aim of this study was to report the case of the first patient who underwent Retzius-sparing radical prostatectomy with the Hugo™ RAS system (Medtronic, Minneapolis, MN, USA).

METHODS: All the surgeons and nurses had been officially trained with the Hugo™ RAS system (Medtronic) for 3 days with theoretical and practical sessions _x000B_ (dry and wet lab with cadaver and animal training) Surgery was performed in December 2022 with the Hugo™ RAS platform (Medtronic).

RESULTS: The patient was a 56-year-old man, with no comorbidities and a BMI of 28. PSA was 5.3 ng/mL; MRI showed a PIRADS 4 lesion of 13 mm on the right base. Prostate biopsy diagnosed a Gleason 3+3 adenocarcinoma of the prostate in 7/28 cores. It was the first surgical case performed at our center. Surgical time was 145 minutes; docking time was 12 minutes; consolle time 80 minutes. The patient was discharged in POD2, the suprapubic tube was removed in POD7. No complications occurred. Pathological report showed a Gleason 4+5 adenocarcinoma, pT2Nx, with a focal positive margin on the posterior right base. The patient was continent at catheter removal. At 3 months follow-up, PSA was 0.01 ng/mL, the patient had partial erections not sufficient for sexual intercourse.

CONCLUSIONS: Retzius-sparing prostatectomy with the Hugo™ RAS platform (Medtronic) is feasible without specific difficulties. Our center continued performing Retzius-sparing RARPs after the first case (more than 30 cases as of April 10, 2023). We are widening our indications for more difficult cases. Equipe training and selection of cases is the key.

SMART (SC281-SC294)

Muscle invasive bladder cancer 3

SC281
Modified Frailty Index in radical cystectomy peri- and postoperative complication risk assessment

SC282
ERAS protocol in cystectomy: increasing compliance to improve postoperative outcomes

SC283
A new-enhanced recovery after surgery (ERAS) protocol in patients treated with robot-assisted radical cystectomy with intracorporeal reconstruction: evaluation of perioperative outcomes and complications after 5 years of follow-up

SC284
Increasing adherence to ERAS protocol reduces length of stay after cystectomy

SC285
Combined spinal/epidural *versus* general anesthesia in patients who underwent open radical cystectomy for bladder cancer: an exploratory, controlled study

SC286
Chemotherapy *versus* immunotherapy as neoadjuvant therapies in cisplatin-eligible patients undergoing radical cystectomy for muscle invasive bladder cancer

SC287
Survival outcomes of solid organ transplant recipients treated with radical cystectomy for bladder cancer

SC288
Radical cystectomy and urinary diversion for bladder cancer in northern Italy: a ten-year population-based analyses

SC289
Negative pressure therapy for the prevention of surgical site complications in patients undergoing open radical cystectomy

SC290
Patient reported outcomes on radical cystectomy performed according to the ERAS Society perioperative protocol

SC291
The role of robotic cystectomy in the salvage and palliative setting as new standard of care

SC292
Long-term oncologic outcomes of robot-assisted radical cystectomy: update series from a high-volume robotic center beyond 10 years of follow-up

SC293
Perioperative and functional outcomes of robot-assisted radical cystectomy with totally intracorporeal orthotopic Y ileal neobladder: results from a high-volume institution

SC294
Urinary diversions in radical cystectomies: when and why does the surgeon's choice divert from the preoperative planning?

SC281
Modified Frailty Index in radical cystectomy peri- and postoperative complication risk assessment

F. Rossi, P. Russo, F. Marino, G. Maioriello, D. Nigro, E. Scarciglia, F. Pinto, E. Sacco, N. Foschi (Rome)

BACKGROUND: The aim of this study was to investigate the discriminative ability of standard risk score (ASA, CCI) and mFI and demographic factors including age, Body Mass Index, and gender for perioperative adverse outcomes following RC.

METHODS: In our prospectively collected database, we collected 227 consecutive BC patients who underwent RC between January 2018 and January 2023. Patients were categorized according to mFI, ASA, and CCI. Indices were divided into two groups, reporting them as categorical variables: mFI (<2 and ≥2), CCI (<5 and ≥5), and ASA (<3 and ≥3). To test differences between groups we used Pearson's χ^2 test and independent *t*-tests. Receiver operator curve (ROC) analysis was used to evaluate the performance of risk scores as continuous variables for predictive outcomes. Covariates were analyzed to determine the association with Clavien-Dindo Grade ≥3 complications at 1 month and 3 months, readmission, relapse, mortality rate, hospitalization length, stage of local invasion, and lymph node involvement.

RESULTS: A statistically significant association was found between mFI and readmission rate (P=0.049), mortality rate (P=0.003), locally invasive tumors (P=0.039), and lymph node involvement (P=0.047). ROC analysis demonstrated an association of all indices with 3-month complications after RC: the area under the curve was 0.61 for the ASA Score (95% CI: 0.55-0.67); 0.58 for mFI (95% CI: 0.51-0.65); and 0.42 (95% CI: 0.34-0.49) for CCI. Clavien-Dindo's Classification, relapse rate, and hospitalization length were not associated with any frailty assessment tool.

CONCLUSIONS: This study found an association between mFI and hospital readmission rate, mortality rate, locally advanced tumors, and lymph node involvement. No differences were shown between mFI, ASA, and CCI, indicating non-inferiority when compared with other indices and the potential usefulness of this tool. mFI can help urologists in the patient selection and postoperative complications prevention.

SC282
ERAS protocol in cystectomy: increasing compliance to improve postoperative outcomes

E. Dalmasso, A. Giordano, E. Alessandria, S. Palmisano, S. Dalmasso, M. Carrega, R. Parola, F. Garino, R. Aimar, G. Coletta, I. Morra (Cuneo)

BACKGROUND: Enhanced recovery after surgery (ERAS) protocols are multimodal perioperative care pathways designed to achieve early recovery after surgical procedures by maintaining preoperative organ function and reducing the profound stress response following surgery. Those protocols have been recently implemented also for radical cystectomy although few evidence on their results are available. The study was designed to evaluate perioperative outcomes after open cystectomy before and after adopting ERAS protocol in a single referral center.

METHODS: The study group comprises 100 consecutive patients who underwent open cystectomy with any diversion for oncological or functional reasons during and after the ERAS Society accreditation program. Fifty patients (50%) were enrolled after the implementation of ERAS protocol (ERAS group), 50 (50%, pre-ERAS group) where previously collected. Data were prospectively collected on the ENCARE database. Compliance to the 21 pre-, intra- and postoperative items of the ERAS Society protocol were automatically calculated by the ENCARE software. The primary outcomes were postoperative length of stay (LOS) and perioperative complications. Complications were collected using Clavien-Dindo Classification. Relation between length of stay and ERAS groups was analyzed with generalized linear model, the effect of ERAS groups on complications was evaluated with logistic modeling.

RESULTS: The overall compliance to the ERAS pathways was 82.4±7.6% *vs.* 39.4±6.3% in the two groups (P<0.001). The postoperative LOS in ERAS group was significantly lower compared to the pre-ERAS group (11.0±7.7 days *vs.* 21.2±12.2 days, P<0.001). At multivariable regression modeling, the adoption of ERAS protocol for patients who underwent cystectomy reduced by 10 days the postoperative LOS (ß of the model -10.3±2.2) and it was the only independent predictor of postoperative LOS. Complications after surgery were lower in the ERAS group compared to pre-ERAS (38% in the ERAS group *vs.* 72% in the pre-ERAS group, P<0.001) and logistic model confirmed the protective effect of ERAS protocol (OR=0.12, 95% CI: 0.04-0.39, P<0.001). A significant reduced rate of severe complications (Clavien-Dindo ≥3b) in the ERAS group was evident (4.0% *vs.* 20.0%, P=0.028), with an 8-time reduced risk (OR=0.12, 95% CI: 0.01-1, P=0.05).

CONCLUSIONS: Preliminary results from this prospective observational study confirmed that adherence to the ERAS protocol holds advantages in terms of outcomes. ERAS was related to a significant decrease of postoperative LOS, and it also leads to a reduction of complications after surgery. The adoption of ERAS protocols for urologic surgery showed to share the same advantages already pointed out in general surgery.

SC283
A new-enhanced recovery after surgery (ERAS) protocol in patients treated with robot-assisted radical cystectomy with intracorporeal reconstruction: evaluation of perioperative outcomes and complications after 5 years of follow-up

E. Palagonia, B. Bianchi, R. Xhaferi, F. Chiaramonti, S. Khorrami, A. Palumbo, F. Annino (Arezzo)

BACKGROUND: Enhanced recovery after surgery (ERAS) concepts are implemented in various surgical disciplines to improve morbidity, enhance recovery, and reduce hospital stays. To describe our new ERAS protocol used in patients (pts) who underwent robot-assisted radical cystectomy (RARC) with intracorporeal ileal conduit (IIC) or ileal intracorporeal neobladder (NB) reconstructions for bladder cancer. First evaluation after 5 years of RARC in a high-volume referred center.

METHODS: One hundred two RARC were performed

from 2016 to 2022, 60 were IIC and 42 were NB, all operated by the same surgeon. All pts were selected for our ERAS protocol. It consists of preoperative counselling and education of pts and caregivers with optimization of medical and nutrition conditions. No bowel preparation is performed. The day before surgery antithrombic prophylaxis is started, then continued following guidelines, also antibiotics prophylaxis (piperacillin + tazobactam) is started and followed for 48 hours. To create loading carbohydrates the pt takes maltodextrin 800 mL the evening before and 200 mL before the procedure. After surgery, the nasogastric tube (NGT) is removed and support therapy consists of 2000 mL of normal saline for 1 day, metoclopramide 3 per day and paracetamol 3 per day for 48 hours. Mobilization is encouraged on the first postoperative day and then progressively day by day. We suggest the use of chewing gum and oral nutrition starts with soft food on the 2nd day and increases progressively. Perioperative, functional outcomes and complications were recorded.

RESULTS: The median age was 74 years (range: 55-87). Mean BMI was 27 (range: 19-40). The mean follow-up was 6 months. The median operative time was 317 min (range: 190-530). The median length of hospital stay was 9.6 days (range 5-27). In 4 (4.1%) pts NGT was positioned 48 hours after surgery because of nausea and vomiting and in 11 pts (11.2%) was removed the day after surgery. Mean bowel canalization was 2 days (range: 1-7), and defecation was 4.8 days later (range: 1-14). Seventeen pts (17.3%) developed complications Clavien-Dindo (CD) <2 (8 anemia, 6 urinary infections, 1 TEP, 1 lymphocele, 1 urinoma) and in 4 cases (4.1%) CD>3, 2 reintervention for abdominal occlusion, 1 for laparocele, 1 nephrostomy positioning.

CONCLUSIONS: These initial results show that a careful nutritional evaluation and progressive rehabilitation are fundamental for a rapid recovery of bowel canalization in RARC with intracorporeal reconstructions. This first analysis shows promising results, a multidisciplinary approach with nutritionists and physiotherapists can improve the recovery of the canalization after surgery.

SC284
Increasing adherence to ERAS protocol reduces length of stay after cystectomy

S. Palmisano, E. Dalmasso, A. Giordano, S. Dalmasso, M. Carrega, R. Parola, F. Garino, G. Coletta, I. Morra (Cuneo)

BACKGROUND: The adherence to Enhanced Recovery After Surgery (ERAS) protocols is considered a key point for maximizing their positive effects on patients, although there are still few evidence describing the effect of compliance with ERAS on postoperative length of stay (LOS) after cystectomy. This study has been designed to explore potential relationship between postoperative length of stay after cystectomy and compliance with the ERAS protocols in a single referral center for ERAS protocol.

METHODS: One hundred consecutive patients who underwent open cystectomy with any diversion for oncological or functional reasons during and after the ERAS Society accreditation program were enrolled in this prospective observational cohort study: 50 patients (50%) after the implementation of ERAS protocol (ERAS group) and 50 (50%) before ERAS (pre-ERAS group). Data were prospectively collected on the ENCARE database. Compliance to the 21 pre-, intra- and postoperative items of the ERAS Society protocol were automatically calculated by the ENCARE software. The primary outcomes were postoperative length of stay and its relationship with pre-, intra-, postoperative compliance with ERAS protocol. This relationship was evaluated with generalized linear models.

RESULTS: Mean LOS after surgery was 15.9±11.3, significantly lower in the ERAS group compared to pre-ERAS group (11.0±7.7 *vs.* 21.2±12.2, P<0.001). Pre-, intra-, and postoperative compliance was 98.7±4.4%, 98.0±6.9%, 67.0±14.3% in the ERAS group and 78.6±10.4%, 65.0±16.8%, 15.8±5.9% in the pre-ERAS group (P<0.001). In the univariable analysis, increase in pre-, intra- and postoperative compliance resulted in a significant reduction of postoperative LOS (ß: -0.29±0.08, P=0.001; ß: -0.17±0.06, P=0.001; ß: 0.19±0.04, P<0.001, respectively). Nonetheless, in the multivariable models including also baseline characteristics and comorbidities, the relationship between LOS and preoperative and intra-operative compliance was not confirmed and only postoperative compliance with ERAS has been found to independently reduce postoperative LOS (ß: 0.19±0.04, P<0.001), with a 2-day reduction for a 10% increase of compliance. Subanalysis in the ERAS subgroup confirmed that postoperative compliance to ERAS was the only factor affecting LOS.

CONCLUSIONS: High compliance to ERAS protocols is a critical point to guarantee the expected improvement in terms of outcomes. In this early experience, we demonstrated that the weakness of the compliance with ERAS is in the postoperative, while the pre- and intraoperative compliance have been already maximized and do not furthermore influence postoperative LOS. The reduction of length of stay is independently related to the postoperative compliance with ERAS and its increase can lead to significant reduction of postoperative LOS.

SC285
Combined spinal/epidural *versus* general anesthesia in patients who underwent open radical cystectomy for bladder cancer: an exploratory, controlled study

M. Galletta, M. De Pasquale, S. Vigano, D. Maravigna, G. Mucciardi, G. Giannarini, V. Ficarra (Messina)

BACKGROUND: Only very few studies have explored the feasibility of spinal and/or epidural anesthesia in the setting of patients who undergo open radical cystectomy (ORC), and none has included a control group undergoing surgery with standard GA. The objectives of this exploratory, controlled study were: 1) to further evaluate the feasibility of combined spinal and epidural anesthesia (SpEA); and 2) to compare perioperative outcomes between SpEA and standard GA in patients undergoing ORC.

METHODS: For the present comparative, non-randomized study, 60 consecutive patients with bladder cancer scheduled for ORC from May 1, 2020, to December 2021 were selected, and one every three patients was assigned to the study group. The study group, thus, included 15 patients undergoing surgery with SpEA, and the control group was composed by 45 patients being operated on under GA. Exclusion criteria were contraindications for SpEA. Patients agreed to participate in the study by signing an informed consent where they accepted the possibility to receive SpEA instead of GA. Intraoperative outcomes were hemodynamic stability, estimated blood loss,

intraoperative red blood cell transfusion rate, and anesthesia time. Postoperative outcomes were pain assessment 24 hours after surgery, time to mobilization, return to oral diet, time to bowel function recovery, length of stay and rate of 90-day complications.

RESULTS: The two groups were comparable for all demographic, clinical and pathological characteristics. No patients required conversion from SpEA to GA for surgical or anesthesiology issues. Both abdominal wall and bowel were adequately relaxed during the entire procedure. No patients in the study group showed hypotension. No intraoperative complications were recorded, and no significant differences were observed between the two groups with regard to other intraoperative parameters, except for a shorter anesthesia time in the study group. Postoperative SpO_2 was comparable in the two groups (P=0.12). Pain VAS Score 24 hours after surgery was significantly lower in the study *vs.* control group (P<0.001). Compliance to ERAS protocol was observed in 15/15 (100%) patients in the study, and in 39/45 (86.7%) patients in the control group (P=0.13). No significant differences between the two groups were detected with regard to mobilization, return to oral diet and bowel function recovery. Median LOS was 12 days (IQR: 10-16) in the study, and 14 days (IQR: 11-17) in the control group (P=0.46). Rate of 90-day postoperative complications was comparable in the two groups (P=0.76). No SpEA-related complications (epidural hematoma or other bleeding complication) were recorded.

CONCLUSIONS: Our study confirmed the feasibility, safety and effectiveness of a pure loco-regional anesthesia in patients with bladder cancer undergoing ORC. No significant differences were observed in intra- and postoperative outcomes, except for a significantly shorter anesthesia time and greater pain reduction in the early postoperative period for the loco-regional anesthesia.

SC286
Chemotherapy *versus* immunotherapy as neoadjuvant therapies in cisplatin-eligible patients undergoing radical cystectomy for muscle invasive bladder cancer

L. Nocera, R. Li, S. Naidu, M. Bandini, M. Moschini, K. Rose, F. Montorsi, P. Spiess, A. Necchi (Milan)

BACKGROUND: Chemotherapy has represented one of the cornerstones of the treatment landscape of muscle invasive bladder cancer (MIBC) due to its improvement in survival outcomes. Recently, also immunotherapy also showed to improve both pathological responses, as well as survival outcomes. However, no comparison has ever been performed between the two neoadjuvant treatments. We aimed to compare cisplatinum-based chemotherapy and pembrolizumab in MIBC patients undergoing radical cystectomy (RC).

METHODS: We retrospectively identified patients with MIBC and treated with RC after neoadjuvant treatment with either cisplatin or pembrolizumab in two tertiary referral centers. Cisplatinum-eligibility represented an inclusion criterion. Conversely, clinical node positive disease and adjuvant chemotherapy administration were exclusion criteria. The endpoint of the analyses was recurrence-free survival (RFS). Statistical analyses consisted of Kaplan-Meier (KM) curves before and after inverse-probability treatment weighting (IPTW), adjusting for age, gender, pathological stage, concomitant CIS and variant histology (VH).

RESULTS: Of all 346 patients, median age was 67 years (IQR: 60-73), and the majority of patients were male (80.3%). The majority of patients harbored a pT0N0 disease (30.3%) at RC pathology followed by pT2-4N0 (29.5%), pTanyN1-3 (20.5%) and pT1-a-isN0 (19.6%). Moreover, 113 patients (32.6%) exhibited concomitants CIS, while 255 patients (73.7%), 27 patients (7.8%) and 64 patients (18.5%) showed respectively presence of pure/mixed urothelial carcinoma, pure VH and other histology. Overall, 70 patients (20.2%) experienced recurrence (33.9% pelvic *vs.* 66.1% distant) after a median follow-up of 24 months (12-39). KM showed a 24-months RFS of 76.9 *vs.* 86.6% for cisplatinum-based chemotherapy *versus* pembrolizumab (P<0.01). After IPTW for age, gender, pathological stage, concomitant CIS and VH, KM showed 76.8 *vs.* 93.2% for cisplatinum-based chemotherapy *versus* pembrolizumab (P=0.01).

CONCLUSIONS: We compared RFS after cisplatinum chemotherapy *vs.* pembrolizumab as neoadjuvant treatment in MIBC undergoing RC. Our findings suggest a potentially higher benefit of pembrolizumab, that was confirmed after adjustment for confounders.

SC287
Survival outcomes of solid organ transplant recipients treated with radical cystectomy for bladder cancer

E. Tonin, L. Bianchi, S. Brönimann, F. Berndl, F. Chessa, B. Pradere, E. Comperat, R. Schiavina, E. Brunocilla, S.F. Shariat, D. D'Andrea (Bologna)

BACKGROUND: The aim of this study was to assess the survival outcomes of solid organ transplant recipients (SOTRs) treated with radical cystectomy (RC) and pelvic lymph node dissection (PLND) for urinary bladder cancer (UBC) compared to non-transplanted patients (non-SOTRs).

METHODS: We performed a retrospective analysis of 645 patients treated with RC and PLND for UBC, originating from our multicenter cooperation program (treated period: 2002 to 2022). Patients were stratified according to the presence of a previous solid organ transplant. Cancer-specific survival (CSS) and overall survival (OS) were calculated using mixed-effects Cox analysis.

RESULTS: Analysis was conducted on 361 patients treated with RC and PLND for UBC, 23 of which had a previous solid organ transplant. Twelve-month and 24-month OS estimates of SOTRs was 70% and 36% compared to 80% and 68% of the non- SOTR group (P=0.011), while 12-month and 24-month CSS estimates of SOTRs was 81% and 55% compared to 85% and 76% of the non-SOTR group (P=0.016). At multivariable Cox regression analyses the presence of a previous solid organ transplant (OR=5.2; 95% CI: 1.88-16.5; P=0.002), higher pathologic stage (OR=3.8; 95% CI: 1.22-14.3; P=0.03 for pT2, OR=3.6; 95% CI: 1.13-13.4; P=0.04 for pT3, OR=4.5; 95% CI: 1.25-18.3; P=0.03 for pT4, respectively), and the administration of "any systemic treatment" (OR=0.3; 95% CI: 0.21-0.69; P=0.001), were independent predictor of OS; while the presence of a previous solid organ transplant (OR=3.0; 95% CI: 1.10-8.71; P=0.03), higher pathologic stage (OR=9.8; 95% CI: 1.66-190; P=0.04 for pT3, OR=13; 95% CI: 2.02-

258; P=0.02 for pT4, respectively) and the administration of "any systemic treatment" (OR=0.4; 95% CI: 0.25-0.94; P=0.03) were independent predictors of CSS.

CONCLUSIONS: Our study generates the hypothesis that patients with previous solid organ transplant and bladder cancer treated with RC and PLND have worse survival outcomes compared to non-transplanted patients. The evidence provided by our study could be used for individualized patient counselling regarding systemic therapies, follow-up, and planning future clinical trials. Further studies with a larger cohort of patients and longer follow-up are needed for more solid conclusions.

SC288
Radical cystectomy and urinary diversion for bladder cancer in northern Italy: a ten-year population-based analyses

C. Silvani, E. Bonacina, A. Li Puma, R. Di Benedetto, S. Guzzo, D. Vizziello, E. Finkelberg, P. Acquati, L.F. Carmignani (San Donato Milanese, Milan)

BACKGROUND: Radical cystectomy (RC) represents the standard of care of muscle-invasive bladder cancer (MIBC). All patients undergoing RC should be counseled regarding all possible alternatives for urinary diversion. Continent diversion (CD) should be offered to patients lacking any contraindication, although postoperative complications rate appears to be higher. In the last few years, with the introduction of robotic radical cystectomy (RARC) and general population aging, trends in urinary diversion after RC could be changed. We aimed to assess trends in urinary diversion choice in Lombardia region (northern Italy).

METHODS: Discharge records of patients undergoing radical cystectomy for bladder cancer in 2012-2021 were extracted from the regional archives of hospital discharges. Data on RC, type of urinary diversion and surgical technique (open *vs.* laparoscopic *vs.* robotic) were obtained from intervention codes. For every procedure we also recorded age, sex, year of intervention, in-hospital mortality, and length of stay (LOS).

RESULTS: Overall, 8487 cystectomies were performed in Lombardia from 2012 to 2021 and the number of procedures remains stable over years. Among patients 81.38% were males; median age and median LOS were 72 (65-78) years and 16 (12-22) days, respectively. Three hundred fifty-nine procedures (4.23%) were RARCs while 304 (3.58%) were reported as laparoscopic cystectomy. Continent urinary diversion, ileal conduit and ureterocutaneostomy were performed in 16.32%, 37.26% and 46.42%, respectively. Patients who received a CD decreased among years from 21.28% in 2012-13 to 12.38% in 2020-21 (P<0.001). In CD group men were 92.43% and, compared to general population, median age at surgery was lower (64 *vs.* 72, P<0.001) and in- hospital mortality was lower (0.36% *vs.* 1.90%, P<0.001); while LOS was longer (20 *vs.* 16, P<0.001). The CD rate differed across age groups. The CD rate was highest in those aged under 55 at 47.11%, followed by 39% in the 55-59 age group, 31.79% in the 60-64 age group, 23.95% in the 65-69 age group, 14.61% in the 70-74 age group, 3.21% in the 75-79 age group, and 0.43% in those over 80. CD rate was higher in patients that underwent RARC compared to radical laparotomic cystectomy (27.02% *vs.* 15.4%, P<0.001). At the univariate analyses, male gender, RARC, and receiving surgery in 2012-13 *vs.* 2020-21 were associated with recourse to CD with an OR of 3.04 (P<0.001); 2.034 (P<0.001) and 1.913 (P<0.001), respectively. Increasing age was correlated with decreasing in CD recourse with an OR of 0.895/year (P<0.001). All of these remain associated also at the multivariate analyses.

CONCLUSIONS: Although the number of radical cystectomies performed in Lombardia remained stable from 2012 to 2021, there was a decrease in the use of urinary CD over the years. As already reported in literature, CD is more commonly chosen in younger and male patients, despite being associated with a longer hospital stay LOS. The advent of RARC appears to be associated with a resurgence in the use of CD.

SC289
Negative pressure therapy for the prevention of surgical site complications in patients undergoing open radical cystectomy

F. Traunero, E. D'Andrea, C. Bignù, C. Costi, G. Rossin, A. Piasentin, G. Liguori, C. Trombetta (Trieste)

BACKGROUND: The aim of this study was to evaluate the role of an iNPWT medication in reducing the number of postoperative wound complications at 90-day in surgical site complications in patients undergoing laparotomic radical cystectomy.

METHODS: From February 1, 2015, until August 31, 2022, a total of 146 patients were included in the study. Of these, 80 patients (55%) received conventional postoperative dressing (group 1), while 66 (45%) underwent prophylactic iNPWT using the PICO system (group 2). Seventy-seven percent of the surgical procedures performed were CR operations with ileal conduit packing according to Bricker. For each patient, information on general and clinical characteristics, surgery and underlying pathology were collected and compared between the two groups in order to identify the main factors associated to early wound complications and the role of the PICO dressing in preventing it.

RESULTS: The mean age of the patients included in the study was 72.9±8.4 years and the population was predominantly male (70.5%), with no particular differences between the two groups. The mean BMI was 25.96±3.9 kg/m^2 and 36% of the patients were active smokers. The general clinical conditions were essentially comparable between patients in the two groups. In both groups, the average CCI Score was ≥5. In general, SSCs are associated with high mean BMI values (28.9 kg/m^2 *vs.* 25.2 kg/m^2, P=0.001), especially with BMI values >30 kg/m^2 (P=0.001), and high anesthesia risk (P=0.03). In addition, previous abdominal and open surgery (P=0.01) and uncontrolled diabetes mellitus (P=0.043) were also risk factors for SSCs. Prolonged mean operative time (336.9±20 min *vs.* 310±9 min, P=0.02) and operative time >300 min (P=0.04) were statistically significantly associated with the occurrence of SSCs at 90 days after CR surgery. In contrast, no statistically significant relationship was found between SSCs and type of urinary diversion or estimated blood loss. Patients who developed SSCs were hospitalized for significantly longer than those who did not develop them (25.6 gg *vs.* 18.5 gg, P=0.03). SSCs occurred less frequently among patients managed by prophylactic iNPWT than in the conventional medication group (7.6% for group 2 *vs.* 22,5%

for group 1) with a statistically significant value (P=0.03). The OR calculation (95% CI) is highly in favor of the PICO group, with a value of 0.282 and a relative risk of 0.438 compared to the standard dressing group.

CONCLUSIONS: The use of prophylactic iNPWT on closed, clean-contaminated laparotomy wounds in patients undergoing RC with urinary diversion could play a role in reducing the incidence of SSCs at 90 days postoperatively. Among patients in our study cohort, its application is indeed associated with a percentage reduction in the incidence of SSCs and hospital length of stay. The patients who could benefit most from iNPWT are those at highest risk of developing such complications, *i.e.*, obese, frail (according to ASA Classification) and/or diabetic patients.

SC290
Patient reported outcomes on radical cystectomy performed according to the ERAS Society perioperative protocol

R. Parola, E. Dalmasso, A. Giordano, S. Palmisano, S. Dalmasso, M. Carrega, G. Coletta, I. Morra (Cuneo)

BACKGROUND: Radical cystectomy is a highly invasive procedure with a significative impact on mental and physical status. Enhanced Recovery After Surgery (ERAS) is a multimodal perioperative care pathway designed to achieve early recovery by reducing stress and invasiveness of surgeries. Aim of this study was to evaluate the in-hospital health status of patients undergoing radical cystectomy according to the protocol by the ERAS Society.

METHODS: This study includes consecutive patients who underwent open radical cystectomy with any urinary diversion for oncological reasons during and after the ERAS Society accreditation program of our division. All the patients were asked to fill out a questionnaire about their health state during the hospital stay. All patients were managed according to the perioperative ERAS Society protocol. Data were prospectively collected on the ENCARE database. Questionnaire was validated by the ERAS Society. Rating scale of the questionnaire ranged from 1 (best answer) to 10 (worst answer). Median value of the scores were reported and t student test was used to compare the first 10 patients to the last 26.

RESULTS: Thirty-six consecutive patients were enrolled (31 males and 5 females). Mean age was 73.7±7.7. Mean adherence to ERAS protocol was 82.4±7.6%. Median hospital stay was 11±7 days. Sixty-two of patients experienced some complications (severe in 6%). Median scores of the questionnaire were the following: pain 2 (1-8), anxiety 2 (1-8), tiredness 4 (1-8), nausea 2 (1-8), depression 1 (1-7), drowsiness 2 (1-10), appetite 5 (1-10), feeling of concern 1 (1-6), comfort 3 (1-9), quality of life 3 (1-9). All the scores were lower (better) after the first 10 patients: differences on mean scores were statistically significant for anxiety (3.2 *vs.* 2.04, P=0.032), tiredness (4.4 *vs.* 3.2, P=0.028), nausea (4.1 *vs.* 2.4, P=0.016) and drowsiness (4.3 *vs.* 2.3, P=0.018).

CONCLUSIONS: ERAS Society protocol for radical cystectomy allows patients to keep a good health status. Most concerning problems were tiredness and lack of appetite. Scores improved after the first cases as result of a normal learning curve. Data about patients reported outcomes are key point of the audit system aiming to implement the ERAS protocol.

SC291
The role of robotic cystectomy in the salvage and palliative setting as new standard of care

A. Brassetti, F. Proietti, A.M. Bove, S. D'Annunzio, M. Ferriero, S. Flammia, C. Leonardo, U. Anceschi, R. Mastroianni, L. Misuraca, G. Tuderti, G. Simone (Rome)

BACKGROUND: The aim of this study was to compare surgical and survival outcomes of robot assisted (RARC) *vs.* open (ORC) radical cystectomy with cutaneous ureterostomy (CU) for the treatment of frail patients with limited life expectancy diagnosed with bladder cancer (BC).

METHODS: Our prospectively maintained database was searched for cystectomy cases with CU, from June 2016 onwards. The study population was split into two groups, according to surgical approach. Baseline characteristics and surgical outcomes were compared: Mann-Whitney and Kruskal-Wallis's tests were used for categorical variables, the χ^2-test for continuous ones. Logistic regression analyses (LRA) identified predictors of major bleeding events (MBE) (which either caused a hemoglobin loss □3.5 g/dL or required blood transfusion) and re-operation within 30 days from surgery. Kaplan-Meier (KM) method estimated the impact of the robotic approach on overall survival (OS) and Cox regression analysis (CRA) assessed its predictors.

RESULTS: Overall, 145 patients were included: 30% (N.=43) underwent RARC. Baseline characteristics and tumor stages distribution were comparable in the two groups but those receiving a robot-assisted approach showed significantly reduced times to flatus, bowel and hospital discharge (all P<0.001). Although operation time was longer in this cohort, MBE (60% *vs.* 89%) and postoperative severe complications (0 *vs.* 8%) (both P<0.001) were less frequent, compared to ORC. At LRA, RARC independently predicted MBE (OR=0.26; 95% CI: 0.09-0.72; P=0.02) but not the need for reintervention. At KM analysis, the minimally invasive approach was associated with a significant advantage in terms of OS (Log Rank =0.03) and this result was confirmed at CRA (HR=0.39; 95% CI: 0.14-0.94; P=0.04).

CONCLUSIONS: RARC with CU may represent the novel standard of care to treat highly comorbid patients with advanced BC as, compared to ORC, it provides significant advantages in terms of transfusion rate and severe postoperative complications while ensuring a prompt recovery and discharge.

SC292
Long-term oncologic outcomes of robot-assisted radical cystectomy: update series from a high-volume robotic center beyond 10 years of follow-up

N. Frego, A. Mottaran, M. Paciotti, A. Piro, C. Bravi, M. Peraire Lores, E. Balestrazzi, L. Nocera, F. Piramide, C. Collà Ruvolo, G. Sorce, M. Ticonosco, S. Rebuffo, R. De Groote, F. D'hondt, A. Mottrie (Aalst)

BACKGROUND: Long-term oncologic data on patients undergoing robot-assisted radical cystectomy (RARC) for non-metastatic bladder cancer (BCa) are limited. We here assessed long-term oncologic outcomes of patients receiving robotic radical cystectomy at a high-volume European Institution.

METHODS: We analyzed data of 107 patients treated with

RARC between 2003 and 2012 at a high-volume robotic center (OLV Hospital, Aalst, Belgium). All surgeries were performed by two high-volume surgeons. Clinical, pathologic, and survival data at the latest follow-up were collected. Clinical recurrence (CR)-free survival, cancer-specific mortality (CSM)-free survival, and overall survival (OS) were plotted using Kaplan-Meier survival curves. Cox proportional hazards models investigated predictors of CR and CSM. Competing risk regressions were utilized to depict cumulative incidences of death from BCa and death from other causes after RARC at long-term.

RESULTS: Pathologic nonorgan-confined BCa was found in 40% of patients, and 7 (7%) patients had positive soft tissue surgical margins. Median (interquartile range [IQR]) number of nodes removed was 11 (6, 14), and 26% of patients had pN+ disease. Median (IQR) follow-up for survivors was 123 (117, 149) months. The 12-year CR-free, CSM-free and overall survival were 55% (95% confidence interval [CI]: 44%, 65%), 62% (95% CI: 50%, 72%), and 34% (95% CI: 24%, 44%) respectively. On multivariable competing risk analysis, nodal involvement at final pathology was associated with higher risk of both CR (Hazard Ratio [HR]: 1.82; 95% CI: 1.06, 3.13, P=0.030) and CSM (HR: 1.70, 95% CI: 1.30, 2.22; P<0.0001). The cumulative incidence of non-cancer death exceeded that of death from BCa after approximately ten years after RARC.

CONCLUSIONS: We provided relevant data on the oncologic outcomes of RARC at a high-volume robotic center, with acceptable rates of clinical recurrence and cancer-specific survival at long term. In patients treated with RARC, the cumulative incidence of death from causes other than BCa is non-negligible and should be taken into consideration for postoperative follow-up.

SC293

Perioperative and functional outcomes of robot-assisted radical cystectomy with totally intracorporeal orthotopic Y ileal neobladder: results from a high-volume institution

R. Schiavina, P. Piazza, E. Tonin, L. Bianchi, M. Presutti, F. Costa, E. Balestrazzi, S. Boschi, A. Angiolini, A. Mottaran, F. Chessa, E. Brunocilla (Bologna)

BACKGROUND: The aim of this study was to describe perioperative, functional and urodynamics findings of our robotic Y intracorporeal neobladder (ICNB) technique.

METHODS: In this retrospective study we analyzed data from 50 patients treated with RARC and ICNB at a single tertiary center from January 2019 to September. All procedures were performed by two highly experienced robotic surgeons. The demolitive phase was conducted according to Karolinska's demolitive technique. The reconstructive phase used 40 cm of small bowel and very limited reconfiguration. Early and late complications were collected and classified according to Clavien-Dindo. Continence, potency, use of clean-intermittent-catheterization and mucus leakage were evaluated at 3, 6 and 12 months. Urodynamic examination, assessing reservoir maximum cystometric capacity, compliance, uroflowmetry and post-voiding residual was performed at 3, 6 and 12 months for patients undergoing Y-ICONB. Mann-Kendall test was used to identify the presence of a monotonic trend in maximum cystometric capacity and neobladder compliance's values.

RESULTS: Median operative time was 335 minutes (294-372), with a median demolitive time of 135 minutes (110-163) and a median diversion time of 170 (150-198) minutes. Overall, 30 postoperative complications were recorded in the early (≤90 days) postoperative period, with 4 patients (8%) experiencing CD≥3 grade adverse events. Thirty-nine (77%) and 32 (64%) patients referred urinary day time and nighttime continence at 12 months after surgery, respectively. At urodynamic examination, median reservoir maximum cystometric capacity was 239, 265 and 291 mL at 3, 6 and 12 months, respectively; reservoir maximum bladder compliance was 14, 17 and 18 mL/cmH_20 at three, six and 12 months after surgery. Reservoir maximum cystometric capacity (τ=0.6; P<0.001) and maximum bladder compliance (τ=0.8; P<0.001) showed a monotonic upward trend over 12 months after surgery.

CONCLUSIONS: Robotic Y ICNB is feasible and safe as shown by the low rate of postoperative complications. Satisfying UD functional outcomes are achievable, both during filling and voiding phase, showing an increasing trend and better results over time.

SC294

Urinary diversions in radical cystectomies: when and why does the surgeon's choice divert from the preoperative planning?

L. Olivera, G. Cianchi, A. Marzocco, A. Pili, V. Livio, F. Peschiera, M. Lo Re, L. Viola, A. Bonutto, S. Serni, A. Minervini, L. Masieri (Florence)

BACKGROUND: This retrospective study describes the urinary diversions (UD) that involved the use of an ileal tract performed in radical cystectomies at our tertiary center. We analyzed if the final UD corresponded to the option counseled in the preoperative planning (PP), and which intraoperative findings caused the change from the planned UD to the performed one.

METHODS: We included all the radical cystectomies from 04/01/17 to 06/03/23. If the PP listed more than one option for the UD, we considered it correspondent when the performed UD was one of the possibilities foreseen in the PP. In the statistical analysis (*t*-test) the level of significance was set at P<0.05.

RESULTS: Eight hundred twenty patients were included, 82% males and 18% females. The mean age was 72.2 yrs (19-96). Five hundred fifty-two (67.3%) patients underwent open (OC), 268 (32.7%) robots assisted (RARC) cystectomy. The diagnosis was: 97.4% bladder cancer, 1.6% neurogenic bladder, 1% others. Four hundred sixty-five (56.7%) patients were counseled for Bricker or neobladder reconstruction (NB) or had a multiple-option PP that included at least one of these options. In this group 80.6% were males, 19.4% were females. The mean age was 67.4 (19-88). In 41 (5%) patients the PP was not present or did not specify a UD. 82.9% of them underwent ureterocutaneostomy (UCS), 9.8% Bricker, 4.9% NB, 2.4% no-UD in anuric pt. In Bricker planned cases (61 patients, 7.4%), 83.6% underwent Bricker as planned; 16.4% UCS. In NB planned cases (306 patients, 37.3%), 88.9% of them underwent NB reconstruction; 5.2% UCS, 5.6 Bricker and 0.3% nephrostomies. In case of multiple options, the final UD was: in UCS *versus* (vs) Bricker (49 patients, 6%), 73.5% underwent UCS and 26.5% Bricker. In UCS *vs.* NB (32 patients, 3.9%), a UCS was performed in 62.4%, NB

in 18.8%; Bricker in 18,8% instead. In Bricker *vs.* NB (17 patients, 2.1%), a NB was realized in 11.8% and a Bricker in 70.6%, while in 17.6% a UCS was chosen. Overall, in the ileal reconstruction group, UCS was the performed UD in 88(18.9%) patients, Bricker in 97 (20.8%), NB in 280 (60.2%). The UD performed matched the PP in 716/820 patients (87.3%). In the Bricker group the adherence rate to the PP was 83.6%; in the NB group 88.9%. There was no significant difference between the RARC *vs.* OC groups in the adherence to the PP (P=0.327). There was no statistically significant difference in the correspondence between the PP and the final UD between the planned-Bricker *vs.* planned-NB groups (P=0.247). The main causes driving a different UD from the PP were: neoplastic findings worse than expected in 21 (33.3%) patients; short mesentery in 10 (15.9%); intestinal adhesions in 7 (11.1%); other reasons in 8 (12.7%); the reason was not specified in the operative note of 17 (27%) patients.

CONCLUSIONS: In more than 12% of our patients the UD carried out during surgery was different than the one planned. Locally advanced neoplasm, short mesentery and intestinal adhesions were the most common causes of non-adherence to the PP.

SMART (SC295-SC302)

Kidney Cancer 8

SC295
Identifying the optimal warm ischemia time cut-off during robot-assisted partial nephrectomy for cT1 renal masses

SC296
Perioperative results of different renal clamping techniques during robot-assisted partial nephrectomy at 5 European robotic centers

SC297
Mid-term oncologic outcomes and predictors of disease recurrence in patients undergoing robot-assisted partial nephrectomy: results from a prospectively maintained dataset of a single tertiary referral center

SC298
Predicting positive surgical margins in patients treated with robot-assisted partial nephrectomy: results from a prospectively maintained dataset of a single tertiary referral center

SC299
Evolution of clampless robot-assisted nephron sparing surgery: functional and oncological outcomes from a monocentric experience over time

SC300
Perioperative assistance during robot-assisted partial nephrectomy using new generation 3D virtual models with perfusional zones allows better pedicle management

SC301
Metastatic renal cell carcinoma with primary tumor size ≤4 cm: assessment of the survival advantage associated to cytoreductive nephrectomy

SC302
Surveillance interruption and need for active treatment in Von Hippel-Lindau disease: a prospective study from a multidisciplinary program

SC295
Identifying the optimal warm ischemia time cut-off during robot-assisted partial nephrectomy for cT1 renal masses

L. Nocera, M. Ticonosco, C.A. Bravi, M. Paciotti, E. Balestrazzi, A. Piro, M. Pereira Lores, F. Piramide, S. Rebuffo, N. Frego, C. Collà Ruvolo, G. Sorce, R. De Groote, G. De Naeyer, A. Mottrie (Aalst)

BACKGROUND: Robot-assisted partial nephrectomy (RAPN) is the gold-standard treatment for T1 renal masses. However, to reduce bleeding, renal artery clamping is often required. Duration of intraoperative ischemia on renal function is subject of significant debate, since several warm ischemia time (WIT) cut-offs have been proposed, but no systematic and detailed analysis has never been performed. We aimed to identify the best WIT cut-off to predict acute kidney injury (AKI).

METHODS: We relied on 305 patients identified in our prospectively maintained renal cancer database and treated with RAPN between 2009 and 2020. All patients were treated by highly experienced surgeons. Patients undergoing clampless RAPN, as well as patients harboring multiple masses, were excluded. The primary endpoint was AKI defined as a rise >0.3 mg/dL between pre- and postoperative creatinine or a 1.5-fold higher value of creatinine at discharge as compared to baseline creatinine. Multivariable Cox regression models examined the impact of WIT on AKI after adjustments for age, sex, preoperative creatinine, solitary kidney, chronic kidney disease, clinical tumor size and PADUA Score. The C-Index was used to identify the WIT cut-off with highest accuracy.

RESULTS: Median age was 63 years (interquartile range [IQR]: 54, 71) and the majority of patients were male (197, 67%). Fifteen (5%) patients had a solitary kidney, 17 (6%) harbored chronic kidney disease, while median preoperative creatinine was 0.9 mg/dL (IQR: 0.8, 1.0). Median tumor size was 3.1 cm (IQR: 2.0, 4.3) and median PADUA Score was 8 (IQR: 7, 10). Median WIT time was 14 minutes (IQR: 10, 18). Overall, 47 (15%) patients experienced AKI before discharge. On multivariable Cox regression models, all variables with the exception of PADUA Score, represented independent predictors of AKI (all P<0.05). The WIT cut-off associated with the highest accuracy in predicting AKI was 19 minutes (C-Index: 83.5%). When individuals were stratified according to the 19 minutes cut-off, AKI was present in 12% *vs.* 28% of those with a WIT time below *vs.* above the threshold.

CONCLUSIONS: Consensus for appropriate duration of ischemia during RAPN for T1 renal masses is lacking. Here, we performed detailed and systematic cut-off analyses of WIT and identified an optimal cut-off of 19 minutes.

SC296
Perioperative results of different renal clamping techniques during robot-assisted partial nephrectomy at 5 European robotic centers

F. Piramide, M. Paciotti, C.A. Bravi, A. Piro, M. Peraire Lores, E. Balestrazzi, C. Collà Ruvolo, G. Sorce, S. Rebuffo, M. Ticonosco, N. Frego, M. Belmonte, D. Amparore, S. Puliatti, R. De Groote, R. Schiavina, C. Fiori, G. De Naeyer, C. Terrone, S. Micali, E. Brunocilla, F. Porpiglia, A. Mottrie (Aalst)

BACKGROUND: In the last years several different techniques for the management of renal pedicle during partial nephrectomy (PN) has been developed and described with the aim to reduce the postoperative impairment of renal function. Nevertheless, it has been rarely reported which are the clamping strategies routinely performed at high volume centers and their perioperative surgical results. Aim of the present study was to describe and report perioperative results of the current renal clamping techniques used at 5 European robotic centers.

METHODS: Five European high-volume robotic centers were involved in this study. Data of consecutive patients underwent robot assisted PN (RAPN) from January 2012 to January 2023 were retrieved from prospectively maintained institutional databases. All patients were treated by highly experienced robotic surgeons. Continuous and categorical variables were reported as median and interquartile range (IQR) or frequencies as appropriate. χ^2 test was performed to test differences in clamping strategy between the different PADUA risk categories and the development of complications and positive surgical margins (PSM). Finally, a multivariate regression analysis (MRA) was built to identify predictors of major postoperative complications.

RESULTS: One thousand four hundred seventy-nine patients were finally included in this study. Overall, median age, BMI and Charlon's Comorbidity Index were 64 (IQR: 55-72) years, 26 (IQR: 23.5-29) and 2 (IQR: 1-3), respectively. Median tumor size and PADUA Score were 35 (IQR: 24-47) mm and 8 (IQR: 7-10). Median operative time was 160 (IQR: 120-206) minutes. Overall, global clamping was used in the 45.3% of cases, off-clamp and selective clamping were performed in the 20.7% and 13.3% whilst early unclamping was adopted in the 20.6% of cases. Stratifying per tumor's surgical complexity, a higher rate of off clamp procedure (31.6%) was recorded in case of low complex masses (PADUA: 6-7), whilst high complex masses (PADUA≥10) were more frequently approached by global (49.3%) or early unclamping (24.9%) strategy (P<0.001). Median ischemia time and blood loss were 15 (IQR: 11-20) minutes and 150 (IQR: 100-300) mL. Overall, major postoperative complication and positive surgical margins (PSM) rates were 16.9%, 3.0% and 6.2% respectively. No differences in terms of major postoperative complication (P=0.18) or PSM rate (P=0.97) were recorded between the different clamping approaches. At MRA lesion's size was found to slightly increase the risk of major postoperative complications (Odds Ratio [OR]=1.02, 95% CI: 1.003-1.047), whilst any clamping approach reached the statistical significance.

CONCLUSIONS: Although global clamping still represents the most used strategy during RAPN, off-clamp and early unclamping techniques are increasingly chosen in case of low and high complex masses, respectively, without increasing the risk of PSM and major postoperative complications.

SC297
Mid-term oncologic outcomes and predictors of disease recurrence in patients undergoing robot-assisted partial nephrectomy: results from a prospectively maintained dataset of a single tertiary referral center

S. Giudici, V. Salamone, M. Bacchiani, L. Lambertini, E. Massaro, A. Sandulli, R. Mariottini, A. Cadenar, A. Grosso, L. Olivera, F. Di Maida, S. Scelzi, G. Vittori, R. Fantechi, L. Masieri, A. Minervini, A. Mari (Florence)

BACKGROUND: This study aimed to evaluate the mid-term oncological results and factors associated with disea-

se recurrence in patients undergoing robot-assisted partial nephrectomy (RAPN) for renal cell carcinoma at a single high-volume institution.

METHODS: The data of 1285 patients who underwent RAPN between January 2017 and March 2021 were analyzed prospectively. A total of 985 patients who were not lost during follow-up were included, and 201 tumors that were found to be benign were excluded. The study evaluated local and distant recurrence rates, recurrence-free survival (RFS), cancer-specific survival (CSS), and overall survival (OS) using Kaplan-Meier and log-rank tests.

RESULTS: The study included 784 patients, with a median age of 63.0 (IQR: 54-71) years, of which 497 (63.4%) were males. The median Charlson Comorbidity Index (CCI) was 1 (IQR: 0-2), and the median clinical tumor dimension was 41 mm. Of the tumors, 547 (70.0%), 43 (5.5%), and 29 (3.7%) were clear cell, papillary, and chromophobe RCC, respectively. The mean±SD pathological diameter was 3.6±1.46 cm, and 102 (13%) cases were reported to be upstaged to pT3a. Positive surgical margins (PSM) were found in 32 (4.1%) patients, and higher nucleolar grade (3-4) was reported in 237 (30.3%) cases. At the last follow-up (median 45 [24-60] months), 102 (13%) patients had disease recurrence, including 36 (35%) systemic, 21 (20%) lymph nodes, and 47 (45%) omolateral or contralateral kidney. Among them, 22 (2.8%) died due to RCC. The 3-year and 5-year recurrence-free survival (RFS) rates were 88.2% and 83.1%, respectively. The 3-year and 5-year cancer-specific survival (CSS) rates were 95.5% and 92.5%, respectively. The 3-year and 5-year overall survival (OS) rates were 92.7% and 89.4%, respectively. Multivariable analysis showed that PSM (HR=2.89, 95% CI: 1.38-6.03, P=0.005), higher nucleolar grade (HR=2.20, 95% CI: 1.31-3.70, P=0.003), and larger pathological diameter (HR=1.20, 95% CI: 1.01-1.44, P=0.036) were significantly associated with worse RFS.

CONCLUSIONS: The study reported favorable oncological outcomes of RAPN for renal cell carcinoma patients with high rates of RFS, CSS, and OS. However, PSM, higher nucleolar grade, and larger pathological diameter were significant predictors of worse RFS. These results can support clinicians in identifying suitable candidates for RAPN and optimizing follow-up strategies and the use of adjuvant systemic therapies for those at higher risk of disease recurrence.

SC298
Predicting positive surgical margins in patients treated with robot-assisted partial nephrectomy: results from a prospectively maintained dataset of a single tertiary referral center

A. Mari, M. Bacchiani, L. Lambertini, E. Massaro, A. Sandulli, V. Salamone, R. Mariottini, A. Cadenar, S. Giudici, L. Olivera, A. Grosso, F. Di Maida, S. Scelzi, G. Vittori, R. Fantechi, L. Masieri, A. Minervini (Florence)

BACKGROUND: This study aimed to evaluate the factors associated with positive surgical margins (PSM) in patients undergoing robot- assisted partial nephrectomy (RAPN) for renal cell carcinoma at a single high-volume institution.

METHODS: We prospectively analyzed the data of 1611 patients who underwent RAPN between January 2017 and December 2022. A total of 22.3% of patients were excluded due to benign histology. The study evaluated the perioperative results of this case series. Uni- and multivariable logistic regression analyses were performed to determine the variables associated with a higher risk of PSM. The Area Under the Receiving Operator Characteristic Curve (AUC) was used to quantify predictive discrimination. A nomogram was created from the multivariable model.

RESULTS: Overall, 1251 patients were included in the study, the median Charlson Comorbidity Index (CCI) was 1 (IQR: 0-2), and the median clinical tumor dimension was 39 mm. Imperative indication at surgery was reported in 49 (3.9%) patients. Of the tumors, 73.7%, 6.2%, and 3.1% were clear cell, papillary, and chromophobe RCC, respectively, and SIB>1 in 218 (17.4%) patients. PSM were found in 57 (4.6%) patients. At multivariable analysis, surgical indication (OR=6.06, 95% CI: 2.58-14.22, P<0.001), SIB>1 (OR=2.37, 95% CI: 1.43-3.92, P=0.001), PADUA Score (OR=1.10, 95% CI: 1.03-1.17, P=0.006), and off-clamp tumor resection (OR=3.00, 95% CI: 1.41-6.39, P=0.004) were significantly associated with PSM. The developed nomogram including these variables showed an AUC of 0.784.

CONCLUSIONS: In this study, surgical indication, SIB>1, PADUA Score, and off-clamp tumor resection were identified as significant predictors of PSM in patients undergoing RAPN. These findings can help clinicians in identifying patients at higher risk of PSM and optimizing surgical techniques to reduce the occurrence of PSM.

SC299
Evolution of clampless robot-assisted nephron sparing surgery: functional and oncological outcomes from a monocentric experience over time

S. Scarcella, E. Beatrici, G. Giglioni, C. Del Prete, S. Cappuccelli, L. Pitoni, L. Papapoj, E. Cappa, G. Gabrielloni, V. Lacetera, V. Beatrici (Pesaro, Pesaro-Urbino)

BACKGROUND: We aimed to describe our experience in robot assisted partial nephrectomies (RAPN) comparing functional and oncological outcomes regarding the introduction of clampless tumor enucleation to standard on-clamp tumorectomy technique.

METHODS: We evaluated 152 patients treated with RAPN from May 2017 to March 2023 with a diagnosis of stage cT1-cT2 renal mass. All demographic, perioperative and postoperative data were retrospectively collected. Patients were divided into two groups according to enucleation technique of choice comparing clampless tumor enucleation (CLT) *vs.* on clamp tumorectomy (OCT). χ^2 test and Student's *t*-test were used to compare categorical and continuous variables respectively.

RESULTS: Overall, 82 (54%) pts were treated with CLT while the remaining 70 (46%) underwent OCT. No differences regarding preoperative demographic characteristics (age P=0.751, sex P=0.772, comorbidities P=0.245, preoperative ASA P=0.804, renal score P=0.078) were evicted between the two groups. After performing tumor enucleation bleeding control and hemostasis were obtained using a 4-0 PDS medullary suture with a 3-0 monocryl cortical reinforced suture with sliding clips technique in 26 (32%) of CLT *vs.* 37 (53%) of OCT P=0.008 with a mean 23 (17-28) min of

warm ischemia time in the OCT group, P<0.001. Only one case of intraoperative complication with ureteral damage was reported in the CLT group P=0.354. Postoperative complications occurred in 12 (15%) CLT *vs.* 16 (23%) OCT patients, P=0.192 with 2 (3%) CLT *vs.* 7 (10%) OCT Clavien-Dindo grading ≥3, P=0.151 and one patient per group respectively required postoperative embolization for acute postoperative bleeding, P=0.910. Mean operative time resulted 146 min (101-192) CLT *vs.* 176 min (136-224) OCT, P<0.001. No differences were detected between the two groups regarding mean intraoperative and postoperative bleeding and preservation of renal function with 7 (9%) CLT *vs.* 11 (16%) OCT patients with temporary worsening of renal function, P=0.172. Trifecta and Pentafecta scores were achieved in 64 (78%) CLT *vs.* 21 (30%) OCT, P<0.001 and 54 (66%) CLT *vs.* 18 (26%) OCT patients. At a mean follow-up time of 36 (28-42) months no recurrences were detected.

CONCLUSIONS: According to our experience the progressive introduction of clampless tumor enucleation technique allows comparable oncological and functional outcomes to traditional on-clamp tumorectomy, with a significative reduction of operative time and the need of hemostatic suture reinforcement and better adherence to both Trifecta and Pentafecta surgical quality scores.

SC300
Perioperative assistance during robot-assisted partial nephrectomy using new generation 3D virtual models with perfusional zones allows better pedicle management

D. Amparore, F. Piramide, P. Verri, E. Checcucci, S. De Cillis, A. Piana, G. Volpi, M. Burgio, G. Busacca, M. Colombo, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: The use of selective clamping techniques during partial nephrectomy (PN) has been studied in recent years to reduce functional impairment brought on by ischemia damage. Recently, 3D virtual models (3DVM) have been shown to improve surgical strategy accuracy, resulting in a greater success rate for selective clamping. However, occasionally this empirical classification of vascular areas based on the orientation of arterial branches fails intraoperatively, leading to the clamping of the main artery. Our goal is to introduce a new generation of 3DVM, which was developed by taking into account the various perfusion volumes of the kidney rather than vascular regions that were empirically estimated, evaluating their accuracy intraoperatively and assessing whether there are factors that affect the tumor location in relation to these perfusion volumes.

METHODS: For all consecutive patients listed in our center for robot assisted PN (RAPN) from 2019 to 2021, we assessed the vascular perfusion zones of the organs using a mathematical tool named the Voronoi diagram and created 3DVMs. A selective clamping strategy was designed and carried out intraoperatively based on the information provided by the 3DVMs. The effectiveness of selective clamping was evaluated using near-infrared-fluorescence imaging (NIRF). By superimposing 3DVMs over the actual endoscopic view, the concordance between the virtual and real perfusion zones was automatically evaluated. The k-Cohen Test was then used to evaluate the comparability between their extensions. At last, a multivariate regression model (MLR) was built to analyze possibly relevant preoperative characteristics. This involved evaluating each lesion location in relation to the number of its crossing perfused zones.

RESULTS: Eighty patients were recruited. In all of them, the preoperatively planned strategy for the management of the renal pedicles was carried out. In 76.25% of cases, clamping was done selectively. The concordance between the 3DVM areas and the NIRF enhanced areas was verified (k=0.91). According to the distribution of perfused areas crossing the tumor, there were 1, 2, 3, 4 and 5 crossing areas, with relative perfusion rates of 13.75%, 35%, 32.5%, 13.75%, and 5%. At MLR, lesions' diameter and mesorenal location were the only two factors related to a higher number (>3) of perfusion volumes crossing the lesion.

CONCLUSIONS: The implementation of mathematical algorithms to 3DVMs allows a precise estimation of the perfusion zone of each arterial branch feeding the organ, leading to perform a safe and effective pedicle management planning.

SC301
Metastatic renal cell carcinoma with primary tumor size ≤4 cm: assessment of the survival advantage associated to cytoreductive nephrectomy

S. Tappero, F. Barletta, M.L. Piccinelli, S. Morra, S. Parodi, P. Dell'Oglio, C. Palumbo, A. Briganti, O. de Cobelli, N. Longo, F. Saad, N. Suardi, M. Borghesi, C. Terrone, P.I. Karakiewicz (Genoa)

BACKGROUND: It is unknown whether the survival benefit of cytoreductive nephrectomy (CN) in metastatic renal cell carcinoma (mRCC) applies to patients with primary tumor size ≤4 cm. The aim of this study was to test the association between CN on overall survival (OS) of mRCC patients with primary tumor size ≤4 cm.

METHODS: Within the Surveillance, Epidemiology, and End Results database (SEER 2006-2018), all mRCC patients with primary tumor size ≤4 cm was identified. Propensity score matching (PSM), Kaplan-Meier plots, multivariable Cox regression analyses and six months' landmark analyses addressed OS according to CN status. Sensitivity analyses examined specific populations of special interest: systemic therapy-exposed *vs.* naïve, clear-cell (ccmRCC) *vs.* non-clear-cell (non-ccmRCC) histology, historical (2006-2012) *vs.* contemporary (2013-2018), and young (≤65 years) *vs.* old (>65 years) patients.

RESULTS: Of 814 patients, 387 (48%) underwent CN. After PSM, median OS was 44 *vs.* 7 months (D=37 months; P<0.001) in CN *vs.* no-CN patients, respectively. CN was associated with higher OS in overall population (multivariable Hazard Ratio [HR]=0.30; P<0.001), as well as in landmark analyses (HR=0.39; P<0.001). In all sensitivity analyses, CN was independently associated with higher OS: 1) systemic therapy-exposed, HR=0.38; 2) naïve, HR=0.31; 3) ccmRCC, HR=0.29; 4) non-ccmRCC, HR=0.37; 5) historical, HR=0.31; 6) contemporary, HR=0.30; 7) young, HR=0.23; and 8) old, HR=0.39 (all P values <0.001).

CONCLUSIONS: The current study validates the association between CN and higher OS in patients with primary tumor size ≤4 cm. This association is robust, controlled for immortal time bias, and valid across systemic treatment exposure, histologic subtypes, years of surgery and patient age.

SC302
Surveillance interruption and need for active treatment in Von Hippel-Lindau disease: a prospective study from a multidisciplinary program

A. Larcher, F. Cei, C. Re, F. Belladelli, G. Fallara, L. Salerno, S. Cusano, F. Iannace, A. Falini, S. Calloni, F. De Cobelli, G. Guazzarotti, P. Mortini, J.F. Capitanio, M. Bailo, F. Bandello, R. Lattanzio, M. Falconi, S. Partelli, F. Muffatti, I. Rowe, F. Montorsi, U. Capitanio, A. Salonia (Milan)

BACKGROUND: Despite surveillance is key for the long-term management of Von Hippel-Lindau (VHL) disease, a paucity of data is available. The aim of the study was to evaluate the surveillance outcomes in a prospective study of VHL patients enrolled in multidisciplinary surveillance program.

METHODS: Since January 2021, patients with VHL diagnosis are enrolled into a prospective, observational surveillance study. Each patient receives diagnostic and clinical evaluation by a multidisciplinary team of physicians. The primary outcome of the study was surveillance status defined as absence of VHL lesions, presence of VHL lesions suitable for surveillance and VHL lesion requiring surveillance interruption and indication for active treatment. VHL lesions were retinal (RHEM) and central nervous system hemangioblastoma (CNSHEM), pancreatic neuroendocrine tumor (NET) or serum cystadenoma (PSC) and clear cell renal cell carcinoma (RCC). Simple cysts were not considered. The secondary outcomes of the study were the incidence of each specific lesion and patient's characteristics at baseline.

RESULTS: Thirty patients were enrolled. The rate of patients without any VHL lesion was 7%, the rate of patients with VHL lesions suitable for surveillance was 40% and the rate of patients with VHL lesion requiring active treatment was 53%. The incidence of each specific lesion was 77% for RHEM, 83% for CNSHEM, 83% for NET or PSC and 72% for RCC. The rate of surveillance interruption was 33% for RHEM, 20% for CNSHEM, 3% for NET or PSC and 13% for RCC. At baseline, median patient's age was 48, 57% patients were male and the median eGFR was 86. The rate of patients with end stage renal disease treated with dialysis or transplant was 7% (N.=2). The rate of previous surgeries was 63% for RHEM and 77% for CNSHEM, 10% for NET or PSC and 43% for RCC. 9 patients received follow up diagnostic and clinical evaluation at one year from enrolment. Among those, the rate of surveillance interruption was 22% for RHEM, 22% for CNSHEM, 0% for NET or PSC and 22% for RCC. The median eGFR was 92.

CONCLUSIONS: The current study provides unique information on clinical management of VHL disease. Patients and clinicians should be aware that in case of VHL disease, the absence of any lesion is uncommon, and surveillance must be interrupted in favor of active treatment in a large proportion of cases.

SMART (SC303-SC316)

Andrology 2

SC303
Clinical characteristics at presentation of Peyronie's disease patients have changed over the last 20 years

SC304
Long-term outcomes of extracorporeal shock wave therapy for acute Peyronie's disease: a 10-year retrospective analysis

SC305
Multi-incision corporal technique with malleable penile prosthesis and collagen sealant matrix graft in Peyronie's disease: an effective lengthening strategy in patients with or without preoperative erectile dysfunction

SC306
Surgical and functional outcomes of the modified shortening corporoplasty for congenital and acquired penile curvature

SC307
The definition of idiopathic male infertility should include sperm DNA fragmentation values: findings from a cross-sectional study

SC308
Paternal age is associated with increased sperm DNA fragmentation in normospermic men

SC309
Systematic review and meta-analysis of serum total testosterone and luteinizing hormone variations across hospitalized COVID-19 patients and healthy controls: a proof of interplay between host immune-response, hypothalamic-pituitary-gonadal axis and severe acute respiratory syndrome Coronavirus 2

SC310
A machine learning-derived nomogram to predict pregnancy in infertile couples with male factor infertility undergoing medically assisted reproduction techniques

SC311
Phase angle at bioimpedance analysis was associated with sperm DNA fragmentation in infertile patients

SC312
Does physical activity influence fertility parameters? A meta-analysis of randomized-controlled trials

SC313
can delayed ejaculation have an impact on psychological health? Findings from a cross-sectional study

SC314
Prevalence of and predictors of unrecognized orgasmic dysfunction in men with new onset erectile dysfunction: findings from a cross-sectional, real-life study

SC315
The clinical profile of men with premature ejaculation at presentation has changed over the last fifteen years: analysis from a longitudinal study

SC316
Long-term follow-up outcomes of pelvic floor rehabilitation in subjects suffering from lifelong premature ejaculation: retrospective multicenter study

SC303
Clinical characteristics at presentation of Peyronie's disease patients have changed over the last 20 years

E. Pozzi, G. Fallara, F. Belladelli, S. Cilio, C. Corsini, F. Lanzaro, A. Bertini, M. Raffo, F. Negri, L. Cella, M. Fantin, L. Candela, P. Capogrosso, L. Boeri, A. d'Arma, F. Montorsi, A. Salonia (Milan)

BACKGROUND: The aim of this study was to detail and explore the changes of clinical and sociodemographic characteristics of a cohort of PD patients over a 17-year period at a single tertiary referral center.

METHODS: Comprehensive data from 616 consecutive patients complaining of PD as their primary complaint between 2005 and 2022 were analyzed. Health significant comorbidities were scored with the Charlson Comorbidity Index (CCI). All patients completed the International Index of Erectile Function (IIEF) baseline. Descriptive statistics was used to detail the entire cohort characteristics. Linear regression models were applied to explore the changes in patterns of sociodemographic and clinical characteristics over a 17-year period (2005-2022). Loess curve was used to graphically display the association between age at first clinical visit and year of assessment.

RESULTS: Overall, the median (IQR) age and IIEF-EF were 56 (45-63) years and 22 (10-28), respectively. Of all, 232 (37.7%) patients reported associated erectile dysfunction (ED) with 89 (14.4%) depicting criteria of severe ED (IIEF-EF<11). A CCI≥1 was found in 145 (23.5%); 193 (31.3%) patients had arterial hypertension and 72 (11.7%) had diabetes mellitus type 1 and 2. Overall, 115 (18.7%) had less than 40 years at first presentation and 124 (20.1%) were active smokers. Over the analyzed timeframe, at linear regression analysis, patients were more likely to be younger (Coeff.=-0.03, P<0.001), to report less comorbidities according to the CCI (Coeff.=-0.38, P<0.02), to have associated ED (Coeff.=1.21, P=0.002), to smoke more (Coeff.=2.88, P<0.001) and to exercise more (Coeff.=1.3, P<0.001).

CONCLUSIONS: The probability of assessing younger PD patients has gradually increased over the last 20 years. In this context, one out of five patients seeking first medical help for PD is younger than 40 years of age.

SC304
Long-term outcomes of extracorporeal shock wave therapy for acute Peyronie's disease: a 10-year retrospective analysis

A. Lecce, L. Spirito, C. Manfredi, C. Qauttrone, F. Bottone, M. Stizzo, M. Terribile, M. Olivetta, A. Rubinacci, G. Della Rosa, S. Papi, L. Napolitano, D. Arcaniolo, R. Autorino, M. De Sio (Naples)

BACKGROUND: The aim of this paper was to describe the long-term outcomes of extracorporeal shock wave therapy (ESWT) in patients with acute Peyronie' disease (PD).

METHODS: An observational retrospective study was conducted in men with acute PD who underwent ESWT between 2009-2013 at a single institution. ESWT protocol consisted of 1 session (3000 shock waves, 0.10-0.25 mJ/mm^2, 4-6 Hz) *per* week for 4 weeks. Penile pain was chosen as the primary outcome. Penile curvature angle, erectile function, and satisfaction with ESWT were selected as secondary long-term outcomes. A total of 194 patients were included. The mean follow-up duration after ESWT was 125.6 months.

RESULTS: Mean penile curvature worsened significantly at 3 months (18.3 *vs.* 21.5 degrees; P=0.023) and 12 months (21.5 *vs.* 28.6 degrees; P=0.001) and stabilized over the long-term (28.6 *vs.* 28.8 degrees; P=0.335). Mean penile pain improved significantly at 3 months (6.5 *vs.* 3.1 points; p <0.001) and 12 months (3.1 *vs.* 1.0 points; P=0.001), remaining stable over time (1.0 *vs.* 1.0 points; P=0.074). The mean five-item version of the International Index of Erectile Function (IIEF-5) increased significantly at 3 months (14.5 *vs.* 17.9 points; P=0.001), remaining stable at 12 months (17.9 *vs.* 18.5 points; P=0.082), and deteriorating in the long-term (18.5 *vs.* 15.8 points; P=0.003). A high satisfaction rate with ESWT was recorded at 3 months (92.3%), remaining similar at 12 months (91.2%) and over the long term (90.2%).

CONCLUSIONS: No new acute phase and low rate of PD surgery (4.1%) were recorded in the long-term analysis. In patients with acute PD, ESWT seems to be associated with early and persistent relief of penile pain, transient improvement in erectile function, no significant effect on penile curvature, and a high rate of patient satisfaction constant over time.

SC305
Multi-incision corporal technique with malleable penile prosthesis and collagen sealant matrix graft in Peyronie's disease: an effective lengthening strategy in patients with or without preoperative erectile dysfunction

G. Maiolino, A. Fraile Poblador, M. Hevia Palacios, E. Fernández-Pascual, E. Mearini, J.I. Martínez Salamanca (Perugia)

BACKGROUND: The aim of this study was to evaluate postoperative outcomes of multi-incision corporal technique with malleable prosthesis and collagen sealant matrix graft in Peyronie's disease (PD) patients with or without preoperative erectile dysfunction (ED).

METHODS: We collected retrospectively data from 46 consecutive PD patients treated with the technique mentioned above in two centers between October 2015 and November 2021. All patients had a stable PD and complained of significant penile shortening. Two surgeons performed all surgeries. A statistical analysis on postoperative outcomes and global satisfaction scores was performed, including a comparison between preoperative ED *vs.* no-preoperative ED patients.

RESULTS: Mean age was 59.1±6.4 years. More than one half of patients (67.4%) had a preoperative normal erectile function. No intraoperative complications were recorded. At a median follow-up of 19±10.7 months, excluding 6 patients who underwent revision surgery, 40/40 (100%) patients reported ability to achieve penetration during sexual intercourse and absence of significant postoperative residual curvature. At the last follow-up visit, mean erectile penile length gained resulted in 2.76±0.63 and 85% of patients reported a very much or much better impression of improvement at Patient Global Impression of Improvement (PGI-I) Scale. No significant difference was reported between patients with and without preoperative ED among preoperative penile length (10.5±2.2 *vs.* 10.4±1.8, P=0.97), patient-reported penile length loss (2.79±0.6 *vs.* 2.71±0.5, P=0.71), postoperative erectile penile length (13.2±1.8 *vs.* 13.3±1.8, P=0.85), penile length gained (2.69±0.6 *vs.* 2.82±0.6) and PGI-I score values (P=0.42). 8 (17.3%) patients experienced a postoperative complication,

6 were graded IIIb according to Modified Clavien-Dindo Classification (1 peri-wound sterile fluid collection: 3 prosthesis infections and 2 prosthesis erosion). Considering the last 30 cases, complications rate results of 3.3%.

CONCLUSIONS: Multi-incision corporal technique with malleable prosthesis and Tachosil graft is an effective long-term lengthening strategy with a high grade of global satisfaction in PD patients with penile length loss complaint, even in patients with normal erectile function at time of first evaluation. Due to the high rate of complications, high experience in penile reconstructive surgery and careful patient counselling is mandatory.

SC306
Surgical and functional outcomes of the modified shortening corporoplasty for congenital and acquired penile curvature

M. Scavone, M. Falcone, M. Preto, L. Cirigliano, F. Peretti, I. Ferro, N. Plamadeala, G. Paolo (Turin)

BACKGROUND: Surgical treatment of penile curvature (PC), both congenital (CPC) and acquired (APC), may rely on many different surgical techniques. Among them, Nesbit corporoplasty is a safe and effective option. We aim to report surgical, functional and patient-reported outcomes (PROs) of a modified shortening corporoplasty.

METHODS: A single-center retrospective analysis was conducted from May 2005 to March 2023. Penile complete straightening, operative time, surgical and postoperative complications were considered as surgical outcomes. Functional outcomes were explored through validated questionnaires administered preoperatively and 12 months after surgery. Furthermore, PROs were assessed through an *ad-hoc* created questionnaire.

RESULTS: One hundred forty-seven patients fulfilled the inclusion criteria. CPC was diagnosticated in 94 patients, whilst APC, secondary to Peyronie's disease, was present in 53 patients. Median follow-up was 83 months (IQR: 28-163). Median age was 30 years (IQR: 20-55). Median PC was 60° (IQR: 45-70). The most frequent curvature was ventral (63.8%) and dorsal (64.2%) in CPC and APC respectively. Median operative time was 120 minutes. A minor residual curvature (<20°) was detected in 14% of patients. Postoperative complications (*e.g.*, bleeding, infection, poor esthetic wound healing etc.) occurred in 8.2% of patients. Postoperative hematoma was more frequent in CPC group (P<0.01). Fifteen percent of patients declared to be dissatisfied of postoperative penile length, with a higher incidence in the APC group (P=0.001). Long-term *de-novo* postoperative erectile dysfunction was observed in 3% of APC patients and in 0% of CPC cases (P=0.001). Multivariate analysis showed hypertension and postoperative complications as independent risk factors for the development of postoperative erectile dysfunction. Overall, a significant improvement in sexual life was observed in both categories with significant improvement of both International Index of Erectile Function (IIEF) and Sexual Encounter Profile (SEP, items 2-3). One hundred seventeen (79.6%) patients reported an overall improvement of sexual life after surgery, while 123 (83.7%) would suggest the surgical procedure to a friend with the same condition.

CONCLUSIONS: The modified shortening corporoplasty may represent an excellent option for PC correction, with limited complications and high patient's satisfaction rate. Overall, CPC patients may experience better surgical and functional outcomes compared to APC.

SC307
The definition of idiopathic male infertility should include sperm DNA fragmentation values: findings from a cross-sectional study

L. Boeri, E. Pozzi, F. Belladelli, G. Fallara, F. Lanzaro, A. Bertini, C. Corsini, S. Cilio, M. Raffo, F. Negri, L. Cella, M. Fantin, L. Candela, P. Capogrosso, A. d'Arma, F. Montorsi, A. Salonia (Milan)

BACKGROUND: Idiopathic male infertility (defined as infertile men with abnormal semen parameters in the absence of possible causal factors) accounts for approximately 40% of cases. Recent evidence has shown that an extensive baseline diagnostic work-up of infertile men reduces the proportion of cases without possible etiologic factor. However, sperm DNA fragmentation (SDF) testing has never been considered among baseline investigations to categorize male infertility. We aimed to investigate the impact of SDF values on idiopathic male infertility definition.

METHODS: Data from 2035 primary infertile men who underwent a thorough diagnostic work-up including detailed medical history, physical examination, hormonal assessment, genetic testing, semen analyses; semen and urine cultures and testis color Duplex US were considered. SDF≥30% was considered pathologic. We excluded: 1) men with genetic abnormalities; 2) men with history of cryptorchidism; 3) men with biochemical hypogonadism; 4) men with clinical varicocele; and 5) men with other factors (either current or history of seminal tract infections, current smokers, BMI>30 kg/m^2). Men without any identified causal factor (792/2035, 38.9%) were considered as idiopathic. Descriptive statistics and logistic regression analyses were used to describe the whole cohort.

RESULTS: Median (IQR) age at presentation was 37 (25, 49) years. Of all, 418 (52.7%) idiopathic infertile men had SDF≥30%. Men with pathologic SDF were older (38 [36-41] *vs.* 37 [35-41] years, P=0.02), had higher FSH (5.0 [2.9-8.9] *vs.* 3.4 [2.3-5.5] mUI/mL, P=0.04) but lower total testosterone values (4.7 [3.4-5.4] *vs.* 5.4 [4.4-6.1] ng/mL, P=0.01) than those with SDF<30%. Sperm concentration (5.5 [1.4-24] *vs.* 14.5 [10.7-50] ×106/mL, P=0.01) and progressive motility (15 [10-28] *vs.* 16 [7-45], P=0.01) were lower in idiopathic infertile men with SDF≥30% than those with normal values. A higher rate of oligo-asthenoteratozooserpmia was found in men with pathologic SDF than in those with SDF<30% (69.8% *vs.* 30.2%, P<0.001). The Homeostatic Model Assessment Index (HOMA) for insulin resistance was higher in men with pathologic SDF values (1.6 [1.1-1.9] *vs.* 0.7 [0.5-1.6], P=0.01). Multivariable logistic regression analysis revealed that older age (OR=1.1, P=0.02) and higher HOMA score (OR=1.8, P=0.03) were associated with SDF≥30%, after accounting for total testosterone and sperm concentration values.

CONCLUSIONS: Findings from this cross-sectional study showed that approximately half of infertile men categorized as idiopathic after extensive baseline diagnostic work-up had pathologic SDF values. Idiopathic infertile men with pathologic SDF showed worse clinical, hormonal and seminal profile than those with normal values. These results suggest that including SDF testing would help identify infertile men with worse characteristics that should not be considered idiopathic

despite the lack of identifiable etiologic factors for semen and SDF impairment.

SC308
Paternal age is associated with increased sperm DNA fragmentation in normospermic men

J. Buratini, M. Orini, P. Piomboni, A. Luddi, D. Turchi, M. Mignini Renzini, M. Dal Canto, E. Panio, S. Maruccia (Sao Paulo)

BACKGROUND: Whilst maternal age has been recognized as the current greatest challenge in reproductive medicine and assisted reproductive technologies (ART), the importance of sperm quality has been somehow neglected. Advanced maternal age (AMA) is associated with advanced paternal age (APA) and sperm donation has been demonstrated to improve ICSI outcomes of AMA age patients with normospermic partners. DNA damage due to increased oxidative stress has been considered a potential major problem associated with paternal age, although well designed studies, particularly in the population of normospermic men, are still needed to clarify whether APA does lead to this defect. Therefore, in this study, by comparing sperm samples from pre-APA and APA men, we tested the hypothesis that APA would be associated with a higher degree of sperm DNA fragmentation.

METHODS: Eleven men aged ≤35 years and twelve men aged ≥42 years composed the pre-APA and APA groups compared in this study. All men were normospermic (WHO, 2021) and provided semen samples after 1-5 days of sexual abstinence. Sperm DNA fragmentation was evaluated by Halosperm® G2 Kit (Halotech DNA, Madrid, Spain), following the manufacturer's instructions. A two-tailed Student's *t*-test was used to compare fragmentation degree between pre-APA and APA groups.

RESULTS: Mean age was 32.6 and 45.3 years for pre-APA and post-APA groups. Semen volume, sperm motility, sperm concentration and morphology did not differ between age groups. Sperm DNA Fragmentation Index was significantly higher in APA (23±10%) as compared with pre-APA men (15±6%; P<0.01).

CONCLUSIONS: The present data suggest that APA is indeed associated with an increase in the percentage of sperm cells with fragmented DNA in normospermic men. Importantly, sperm integrity appears to be compromised by age regardless of a negative impact on the routinely semen parameters evaluated in the andrological examination. The present data thus reinforce the importance of sperm molecular quality in ICSI/IVF application to treat age-related infertility even in the absence of male infertility factor.

SC309
Systematic review and meta-analysis of serum total testosterone and luteinizing hormone variations across hospitalized COVID-19 patients and healthy controls: a proof of interplay between host immune-response, hypothalamic-pituitary-gonadal axis and severe acute respiratory syndrome Coronavirus 2

S. Salciccia, M. Moriconi, V. Asero, V. Canale, E. De Berardinis, G. Di Pierro, G.P. Ricciuti, A. Sciarra, F. Del Giudice (Rome)

BACKGROUND: A growing body of evidence suggests the role of male hypogonadism as a possible harbinger for poor clinical outcomes across hospitalized COVID-19 patients. Accordingly, we sought to investigate the impact of dysregulated hypothalamic-pituitary-gonadal axis on the severity of the clinical manifestations for hospitalized COVID-19 patients matched with healthy controls through a systematic review and meta-analysis.

METHODS: PubMed, Scopus, Web of Science, Embase, and Cochrane databases were searched from inception to March 2022. A standardized mean difference (SMD) meta-analysis focused on hospitalized COVID-19 patients and healthy controls was developed for studies who reported total testosterone (TT) and Luteinizing Hormone (LH) levels at hospital admission. Subgroup analysis was performed to explore the serum hormonal variation across different clinical stages of COVID-19 disease. Sensitivity analysis, cumulative meta-analysis, and meta-regression were implemented to investigate contributions of moderators to heterogeneity.

RESULTS: In total, 18 series with 1575 patients between 2020 and 2022 were reviewed. A significant decrease SMD of TT levels in COVID-19 patients compared to paired controls was observed (-3.25 nmol/L, 95% CI: -0.57 and -5.93, P<0.001). This reduction was even more consistent when matching severe COVID-19 patients with controls (-5.04 nmol/L, 95% CI: -1.26 and -8.82, P<0.001) but similar for COVID-19 survivors and non-survivors (-3.04 nmol/L, 95% CI: -2.04 and -4.05). No significant variation was observed for serum LH levels across studies. Patient related comorbidities, year of the pandemic, and total lymphocyte count were associated with the observed estimates.

CONCLUSIONS: Our study suggests that low serum TT levels may be a useful serum marker of poor outcomes among COVID-19 patients. This would be supported by the non-primary etiology of hypogonadism encountered across COVID-19 population and the more severe clinical manifestations in our analysis. These findings may support the development of *ad-hoc* clinical trials in the COVID-19 risk-group classification and subsequent disease monitoring.

SC310
A machine learning-derived nomogram to predict pregnancy in infertile couples with male factor infertility undergoing medically assisted reproduction techniques

F. Belladelli, E. Pozzi, G. Fallara, S. Cilio, C. Corsini, F. Lanzaro, L. Candela, A. Bertini, M. Raffo, F. Negri, L. Cella, M. Fantin, P. Capogrosso, L. Boeri, A. d'Arma, M. Eisenberg, L. Pagliardini, F. Montorsi, A. Salonia (Milan)

BACKGROUND: It is challenging to predict the probability of a successful assisted reproduction (ART) cycle with adequate accuracy. We sought to develop a predictive nomogram applying machine learning to predict the probability of pregnancy in couples with male infertility undergoing ART.

METHODS: Data from 442 primary infertile couples with pure male factor infertility evaluated at a single academic center from April 2004 to May 2018 and submitted to at least one cycle of ART were included in this study. Male patients were randomly subdivided into a training set (70% of all patients) and a test set (the remaining 30%). Using the training set, fourteen variables were selected for the prediction models: patient's age, BMI, CCI, sex hormonal levels (*i.e.*, FSH, LH,

prolactin, tT), semen parameters (*i.e.*, volume, concentration, total motility, morphology, and sperm DNA fragmentation [SDF]), smoking and alcohol intake. A random survival forest-based classifier was built to predict ART outcomes. The mean decrease in accuracy – defined as the decrease in model accuracy from permuting the values in each variable – was used as a variable importance score. tHUS, A nomogram was developed to predict pregnancy based on a multivariable Cox regression model including the 5ìfive most relevant variables. The Harrel's Concordance Index (C-Index) was used to evaluate the accuracy of ML prediction model and the final nomogram.

RESULTS: Overall, 97 (22%) patients had a successful ART cycle. Median (IQR) age, number of cycles, and time-to-the-last-cycle were 38 (34-41) years, 1 (1-2) cycles, and 1.3 (0.7-2.3), respectively. The ML model's C-Index was 83%. The five most relevant variables selected by the ML model to predict pregnancy were: patients' age, tT, sperm concentration, sperm morphology, and SDF. The nomogram's C-Index was 71%.

CONCLUSIONS: We developed a novel nomogram based on user-friendly infertile men's clinical parameters to predict ART outcomes by applying a ML algorithm. This nomogram might be useful in patients counselling before ART cycle in the everyday clinical practice.

SC311
Phase angle at bioimpedance analysis was associated with sperm DNA fragmentation in infertile patients

G.I. Russo, A. Liprino, S. Cimino, F. Giacone, M.G. Asmundo, A. Lo Giudice, A. Guglielmino, S. Chamayou (Catania)

BACKGROUND: The aim of the study was to demonstrate that the electrical properties of the cell membrane may be affected by the DNA damage in the sperm, which in turn may affect the phase angle values.

METHODS: Patients were consecutively enrolled in this study and undergo BIA (bio-impedance analysis [BIA, Inbody 770; InBody Co., Ltd., Seoul, South Korea]), conventional sperm and SDF analysis. A phase angle between 6 and 7 was considered to be normal, while a value less than 6 indicate a condition of membrane cells rupture. Data are expressed as median and interquartile range (IQR). Participants had demographic data recorded and were weighed on an InBody 770 Scale on the day of oocyte retrieval. The In-Body Scale measures adiposity through multifrequency BIA, quantifying direct impedance measurements from the user's various body compartments. BIA has been demonstrated as having as high as 99% correlation with dual-energy X-Ray absorption in quantifying lean mass measurements and has also been found to have high accuracy in measuring body fat in a healthy population.

RESULTS: A total of 520 consecutive patients affected by primary infertility have been enrolled in this prospective study. Overall, 12 (2.31%) patients had asthenoteratospermia, 224 (43.08) had asthenospermia, 112 (21.54%) had oligoasthenoteratospermia, 76 (14.62%) had oligoasthenospermia, 12 (2.31%) had oligospermia and 84 (16.15%) were normospermic. Median age was 40 years old (interquartile range [IQR]: 37.0-45.0), median phase angle was 6.1 (IQR: 5.8-6.5), median SDF was 22.0% (IQR: 16.0-29.0), median sperm concentration was 25.0 million/cc (IQR: 9.2-48.0), median total sperm was 67.16 million/cc (IQR: 30.8-130.63), median progressive motility was 15.5% (IQR: 5.0-26.0), median morphology was 6.0% (IQR: 4.0-8.0), median BMI was 26.3 kg/m^2 (IQR: 24.2-29.3). At the correlation analysis, age and phase angle were correlated with SDF, 0.25 (P<0.01) and -0.09 (P=0.03), respectively. The univariate linear regression analysis showed a negative between phase angle and SDF (r=-2.15; P=0.03). A total of 44 patients (8.46%) had an SDF≤20%. At the age-adjusted logistic regression analysis we demonstrated that phase angle was inversely associated with SDF>20% (Odds Ratio: 0.2 [95% CI: 0.10-0.41]; P<0.01).

CONCLUSIONS: In conclusion, while further research is needed to fully understand the association between SDF and phase angle, these studies suggest that phase angle may be a useful marker of sperm health and male fertility. Clinicians may consider these results in order to start strategies that my increase phase angle in order to decrease SDF.

SC312
Does physical activity influence fertility parameters? A meta-analysis of randomized-controlled trials

M.G. Asmundo, A. Lo Giudice, S. Cimino, G. Morgia, A. Cocci, M. Falcone, I. Sokolakis, P. Capogrosso, A. Morgado, G.I. Russo (Catania)

BACKGROUND: The aim of this study was to investigate the impact of physical activity on sperm parameters and fertility rate.

METHODS: To investigate if physical activity may affect semen parameters and fertility rate, a systematic literature search on major dataset has been performed. The search terms included: "assisted reproduction therapies," "fertility," "semen parameters," "sperm parameters" and "physical activity." This analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines, and it was registered on PROSPERO (CRD42023384471). Fertility parameters investigated were semen quality parameters and pregnancy rates and live births.

RESULTS: A total of seven studies published from 2014 to 2022 and 2053 patients were finally included in the meta-analysis. A statistically significant relationship between physical exercise and sperm concentration (P=0.02), total sperm motility (P<0.01), total sperm count (P<0.01), normal morphology (P<0.01) has been established. Moreover, the study registered a statistically significant association within physical activity and total pregnancy rate (P<0.01) and live birth rate (P<0.01).

CONCLUSIONS: We demonstrated that physical activity is significantly associated with amelioration of semen parameters and may be crucial in improving or even reverting male infertility. Further studies may be warranted to confirm and strengthen our findings.

SC313
Can delayed ejaculation have an impact on psychological health? Findings from a cross-sectional study

C. Corsini, F. Belladelli, E. Pozzi, G. Fallara, S. Cilio, M. Raffo, F. Negri, L. Cella, M. Fantin, A. Bertini, F. Lanzaro, L. Candela, L. Boeri, P. Capogrosso, A. D'Arma, F. Montorsi, A. Salonia (Milan)

BACKGROUND: Delayed ejaculation (DE) is among the most challenging male sexual dysfunctions. We aimed to explore and compare the sociodemographic and clinical characteristics of men with DE with those complaining of primary premature ejaculation (PE).

METHODS: Data from 555 consecutive men seeking first medical help for DE and/or primary PE between 2005 and 2022 at a single tertiary-referral center were retrospectively analyzed. Complete socio-demographic, clinical and laboratory data were collected. All patients completed the International Index of Erectile Function (IIEF) and the Beck Depression Inventory (BDI) at baseline. We excluded men with known or potential causes responsible for ejaculatory disorders (N.=52). Descriptive statistics was used to detail and compare clinical and sociodemographic characteristics between the two groups (DE *vs.* PE). Linear regression models tested the association between depressive symptoms (BDI) and baseline IIEF domains scores among men with DE.

RESULTS: Of 555 patients, 479 (86%) and 76 (14%) primary PE and DE, respectively. Men with DE were significantly older (44 *vs.* 47, P=0.01) than patients with PE. Conversely, the two groups did not differ in terms of educational/relational status, BMI, comorbidities, and hormonal milieu. At psychosexual interview, men with DE report more frequently symptoms referable to anxiety and depression (9% and 13%) along with higher median baseline BDI scores (8 *vs.* 6), all P<0.01. DE patients reported lower median IIEF-OF, -SD domains (6 *vs.* 9) and (7 *vs.* 8) than patients with PE only, all P<0.05. At linear regression analysis, among DE patients, a higher BDI score was associated with lower IIEF-OS (Coeff.=-1.57, P=0.004) and IS (Coeff.=-0.76, P=0.01) domains. No association between BDI and IIEF-OF, -EF, -SD domains was found.

CONCLUSIONS: Among men with complaining of ejaculatory disorders, one out of ten reports DE. These patients have higher chances to report clinically significant depression considerably impacting on their overall satisfactory sexual life.

SC314
Prevalence of and predictors of unrecognized orgasmic dysfunction in men with new onset erectile dysfunction: findings from a cross-sectional, real-life study

S. Cilio, F. Belladelli, E. Pozzi, G. Fallara, L. Candela, A. Bertini, C. Corsini, F. Lanzaro, M. Raffo, F. Negri, L. Cella, M. Fantin, L. Boeri, P. Capogrosso, A. d'Arma, F. Montorsi, A. Salonia (Naples)

BACKGROUND: Orgasmic phase disorders (OD) in men may negatively impact on satisfactory sexual intercourses. The interrelationship between OD and erectile dysfunction (ED) has been scantly analyzed. We aimed to investigate the prevalence of and the predictors of unreported OD in a cohort of men seeking medical help for new onset ED in the real-life setting.

METHODS: Data from 1107 men seeking first medical help for new-onset ED at a single andrology center between 2010 and 2022 were analyzed. Patients were assessed with a thorough medical and sexual history. Comorbidities were scored with the Charlson Comorbidity Index (CCI). All participants were asked to self-report any OD. Moreover, patients completed the International Index of Erectile Function (IIEF) and the Beck Depression Inventory (BDI). The median value of the IIEF- orgasmic function (IIEF-OF) domain was arbitrarily used to categorize men with (IIEF-OF≤5) and without OD (IIEF-OF>5). The IIEF-Erectile function (IIEF-EF) domain was categorized according to Cappelleri's criteria. Circulating hormones were measured in every patient. Descriptive statistics and logistic regression models tested the association between clinical variables and unreported OD.

RESULTS: Overall, 9 (0.8%) patients self-reported OD and were excluded from further analyses. Of 1098 patients not self-reporting OD, 314 (28.6%) had IIEF-OF≤5. With respect to men with only ED, patients with unreported OD were older (median [IQR] 58 [44-66] *vs.* 51 [40-60] years, P<0.001), had higher BMI (25.8 [23.7-28.1] *vs.* 25.2 [23.3-27.4], P=0.01), higher rates of type 2 diabetes (36 [11.5%] *vs.* 45 [5.7%]; P=0.002), lower scores in IIEF-EF (6 [2-10] *vs.* 18 [11-24]), sexual desire (6 [4-8] *vs.* 7 [6-9]), intercourse satisfaction (3 [0-5] *vs.* 8.5 [5-11]), and overall satisfaction (2 [2-4] *vs.* 6 [4-8]) domains (all P<0.001). Moreover, patients with unreported OD depicted higher rate of severe ED (75.5% *vs.* 25%, P<0.001) and of BDI suggestive for depressive symptoms (22.6% *vs.* 17.9%; P=0.03) compared to men without unreported OD. At multivariable logistic regression analysis, ageing (OR=1.02; P=0.002) and lower IIEF-EF scores (OR=0.83, P<0.001) were independently associated with unrecognized OD, after accounting for BMI, CCI and BDI scores.

CONCLUSIONS: Almost one out of three men seeking first medical help for ED showed unreported OD according to IIEF-OF domain scores. Men with unreported OD were older, had higher rates of severe ED and depressive symptoms than men with adequate orgasmic function. A detailed investigation of the orgasmic phase should be always included in the diagnostic work-up of men with ED, in order to better tailoring patient therapeutic management.

SC315
The clinical profile of men with premature ejaculation at presentation has changed over the last fifteen years: analysis from a longitudinal study

L. Boeri, E. Pozzi, F. Belladelli, G. Fallara, S. Cilio, F. Lanzaro, A. Bertini, L. Candela, C. Corsini, M. Raffo, F. Negri, L. Cella, M. Fantin, P. Capogrosso, A. d'Arma, F. Montorsi, A. Salonia (Milan)

BACKGROUND: Patient's characteristics at first medical evaluation for a specific sexual dysfunction (SD) are strongly correlated to the public awareness towards the specific disease and the availability of novel treatments on the market. We aimed to assess the clinical characteristics of patients presenting for premature ejaculation (PE) as their primary medical complaint over a 15-year time frame.

METHODS: Data from 257 sexually active, heterosexual men seeking first medical help for primary PE at a single sexual medicine academic clinic between 2008 and 2022 were analyzed. Clinical data and serum hormones were collected in each case. At baseline all patients completed the International Index of Erectile Function (IIEF), the Beck Inventory for Depression (BDI), and the Premature Ejaculation Diagnostic Tool (PEDT). Relationship status was categorized as single *vs.* stable sexual relationship. Descriptive statistics and linear regression analyses were used to describe the whole cohort.

RESULTS: Median (IQR) age at presentation was 32 (26-37) years. Of all, 182 (71%) patients reported some degree

of erectile dysfunction (ED) according to IIEF-EF scores. Median baseline PEDT and BDI score were 14 (11-17) and 7 (1-11), respectively. Median total testosterone and TSH values were 5.2 (3.9-6.3) ng/mL and 1.6 (1.2-2.4) mUI/L, respectively. Across the 15-year time frame, patient's age at presentation significantly decreased over time (β: -0.5, P<0.001). Furthermore, depressive symptoms at BDI (β: -0.8, P<0.001) and PE severity as scored with the PEDT (β: -0.6, P<0.001) linearly decreased overtime. When segregating the whole cohort into 5-year groups, age at presentation decreased from 2008-2012 to 2013-2017 (P=0.04) and further decreased between 2018-2022 (P=0.01). Similarly, baseline BDI scores decreased from 2008-2012 to 2018-2022 (all P<0.001). PE severity at first assessment was stable between 2008-2012 to 2013-2017 but decreased thereafter (P<0.01). Patients in a stable couple relationship more frequently asked for medical attention for PE between 2018-2022 compared to 2013-2017 and 2008-2012 (71.7% *vs.* 44.0%; *vs.* 61.8%, P<0.001).

CONCLUSIONS: Findings from this longitudinal real-life study showed that PE patients characteristic at first presentation has significantly changed throughout the last 15 years. Of note, age, PE severity and depressive symptoms showed a significant decline overtime. Men in a stable sexual relationship were more likely to seek medical attention for PE in recent years. These results probably reflect the increased public awareness of PE; therefore, patients request PE consultation at younger age, with initial symptoms and with fewer psychological bother related to this condition.

SC316
Long-term follow-up outcomes of pelvic floor rehabilitation in subjects suffering from lifelong premature ejaculation: retrospective multicenter study

A.L. Pastore, Y. Al Salhi, A. Martoccia, A. Fuschi, O.A. Rera, P.P. Suraci, S. Scalzo, F.M. Valenzi, A. Antonioni, M.B. Sequi, D. Graziabni, G. Martino, F. Gianfrancesco, G. Candita, C. De Nunzio, G. Tema, A. Cicione, A. Carbone, A. Zucchi, S. Maruccia (Latina)

BACKGROUND: The aim of the study was to investigate the long-term follow-up outcomes of pelvic floor muscle (PFM) rehabilitation in males suffering from lifelong premature ejaculation (LPE). To evaluate LPE, patients were investigated with intravaginal ejaculatory latency time (IELT) and the self-report Premature Ejaculation Diagnostic Tool (PEDT). These two collected data represented the primary outcome endpoints.

METHODS: This retrospective study evaluated 227 subjects with LPE diagnosis, and a total of 171 patients out of 227 (75%) completed the training protocol and at least the follow-up of 72 months. At baseline, all participants reported an IELT≤60 s and PEDT score >11. Participants completed a 12-week program of PFM rehabilitation, including physio-kinesiotherapy treatment, electrostimulation, and biofeedback, with three sessions per week, with 20 min for each component completed at each session. The effectiveness of intervention was evaluated by comparing the geometric means of IELT times and PEDT scores observed from baseline, to 6, and 12 months during the intervention, and at 24, 36, 48, 60 and 72 months postintervention, using a paired sample 2-tailed t-test, including the associated 95% confidence intervals.

RESULTS: One hundred seventy-one participants completed the PFM rehabilitation protocol with 36 sessions of PFM. All subjects achieved the control of ejaculation reflex, reporting a mean IELT of 181.4 s and PEDT score of 2.5 at the 12-week endpoint of the intervention, representing an increase from baseline of 54.9 s and 16.6 scores, respectively, for IELT and PEDT (P<0.0001). Of the 171 participants who completed the 60-month follow-up, 80%, 78%, 74%, 69 and 67% reported a satisfactory ejaculation control maintenance through the follow-up evaluations at 24, 36, 48, 60 and 72 months after completing PFM rehabilitation, respectively.

CONCLUSIONS: Our study is the first on LPE treatment with such long-term follow-up (6 years). The results observed are statistically significant and support a role of PFM as an effective and safe therapy in LPE subjects. A prospective randomized study is requested to assess the role of PFM in PE.

SMART (SC317-SC328)

Surgical training

SC317
Trends and incidence of reported events associated with staplers: an analysis of the Food and Drug Administration's Manufacturer and User Facility Device Experience database

SC318
Outcomes of supervised resident compared to attendings in transurethral resection of bladder cancer: the importance of mentoring

SC319
New Hugo™ RAS system robotic Medtronic simulation platform: is it effective to train residents?

SC320
European Training in Urology (ENTRY): quality-assured training for European urology residents

SC321
International experts' consensus on performance metrics for a transurethral resection of bladder (TURB)

SC322
Robotic simulation training with the Hugo™ robot-assisted surgery system: introducing a novel simulation platform to enhance residents training

SC323
Do Hugo™ RAS and Versius system simulators change perception about robotic surgery among undergraduate students? A cross-sectional study from a single center

SC324
Analysis of robotic platform-to-platform skill transfer: preliminary results about influence of prior console expertise on basic skill development at Hugo™ RAS simulator

SC325
Survey of the application of ERAS protocol in Italian Urology University Department: complete adherence or simplified protocol?

SC326
First head-to-head comparison between Hugo™ RAS and Versius in the preclinical setting: cross-sectional analysis on virtual-reality simulators

SC327
Ureteral stents placement in urgency and emergency setting by expert and resident surgeons: a 3-year retrospective comparison

SC328
Laser fiber displacement speed during ureteroscopic lithotripsy: an *in-vitro* assessment of surgical performance

SC317
Trends and incidence of reported events associated with staplers: an analysis of the Food and Drug Administration's Manufacturer and User Facility Device Experience database

N. Ghezzo, D. Fiasconaro, L. Sarcinelli, F. Zammitti, A. Guidotti, G. Gallo, J. Stira, B. Turchi, C. Gravina, L. Rovesti, E. Mancini, A. Franco, S. Riolo, R. Lombardo, G. Tema, A. Cicione, C. De Nunzio, A. Tubaro (Rome)

BACKGROUND: The aim of this study was to summarize medical device reports (MDRs) between 2012 and 2022 relating to staplers within the Manufacturer and User Facility Device Experience (MAUDE) database maintained by The Food and Drug Administration (FDA).

METHODS: The MAUDE database was analyzed for all MDRs relating to each FDA-approved stapler for the last ten years. Event descriptions were reviewed and characterized into specific event types. Outcome measures include specific staplers and reported events as detailed by the MDRs. All data are deidentified and in compliance with the Health Insurance Portability and Accountability Act (HIPAA). No further data was available in the database. Pooled relative risk was used to compare data.

RESULTS: Overall, 712 reports were retrieved in 10 years, between 2013 and 2015 a higher number of events were reported. In all, 413/712 (58%) were reported as malfunction of the device while 292/712 (41%) as injury. The most frequently reported adverse events (AEs) were misfire (111/712: 15.6%), failure to form staple (92/712: 12.9%), mechanical jam (76/712: 10.7%) and failure to fire (72/712: 10.1%). In terms of manufacturer: 401/712 (56%) were Covidien (Dublin, Ireland), 172/712 (24%) were Teleflex Medical (Wayne, PA, USA) and 139/712 (19.5%) were Ethicon Instruments (Bridgewater, NJ, USA). When comparing on disproportional analysis the different manufacturers, in terms of misfire, Covidien presented the better profile when compared to Teleflex Medical and Ethicon (PRR: 0.32-0.65; P<0.05); in terms of failure to form staple Teleflex Medical presented the better profile when compared to Covidien and Ethicon (PRR: 0.27-0.49; P<0.05); in terms of mechanical jam Covidien and Ethicon presented the best profile compared to Teleflex Medical (PRR: 0.10-0.15; P<0.05). Lastly, in terms of failure to fire Teleflex presented the best profile (0% of events).

CONCLUSIONS: Standing to MAUDE database the most frequent complications related to stapler are misfire, failure to form staple, mechanical jam and failure to fire. As well, the reported adverse events vary among the different manufacturers.

SC318
Outcomes of supervised resident compared to attendings in transurethral resection of bladder cancer: the importance of mentoring

P. Diana, A. Gallioli, A. Territo, Ó. Rodriguez-Faba, J.M. Gaya, F. Sanguedolce, J. Huguet, A. Piana, P. Verri, A. Uleri, G. Basile, F. Algaba, J. Palou, A. Breda (Barcelona)

BACKGROUND: Urology residents training programs across Europe are uneven and often unsatisfactory for the residents. Despite, the exposure to surgical procedures is a crucial step in their training, patients' safety is of central importance. The significance of resident mentoring should not be overstated, and trainees should be mentored by training-trained attending urologist even in case of common procedures such as the conventional or en-bloc transurethral resection of bladder tumor (cTURBT or ERBT). The aim of this study was to demonstrate the comparability in performance cTURBT and ERBT between urology residents and attendings.

METHODS: This study is a subanalysis of a prospective, randomized trial enrolling patients diagnosed with BC and undergoing endoscopic intervention. Inclusion criteria were tumor size of ≤3 cm, and ≤3 lesions, and no sign of muscle invasion and/or ureteral involvement. The trial (NCT04712201) was approved by the Institutional Review Board (2017/09c). Surgeons were either urology attendings or supervised residents of the 3rd-5th year. Primary outcome was to compare surgical and postoperative outcomes in both groups. Linear and logistic regression analysis were used to find a correlation between surgical and postoperative outcomes and surgical experience.

RESULTS: From April 2018 to June 2021, 300 patients met inclusion criteria and 248 (83%) of these underwent the assigned intervention. Two hundred (80.6%) patients were males, and median (SD) age was 71.2 (11.2). One hundred eight (44%) and 140 (57%) patients were submitted to TURBT and ERBT. Fifty (20%) and 58 (23%) patients and 84 (34%) and 56 (23%) patients were treated by cTURBT and ERBT by urology attendings and residents, respectively. No statistical differences were found in terms of intra and postoperative outcomes (all P>0.05). Linear and logistic regression analysis resulted comparable for all variables (all P>0.05).

CONCLUSIONS: Supervised urology residents do not put the patient at an increased risk of complications neither perform a suboptimal procedure. Resident mentoring is fundamental in order to reach comparable results in surgical outcomes and pathological diagnosis. A structured standardized program with trained trainers and proficiency evaluations are warranted to gain and maintain these outcomes across European urology residency programs.

SC319
New Hugo™ RAS system robotic Medtronic simulation platform: is it effective to train residents?

F. Esperto, L. Cacciatore, F. Tedesco, F. Prata, A. Minore, N. Deanesi, A. Ragusa, A. Iannuzzi, A. Testa, R.M. Scarpa, R. Papalia (Rome)

BACKGROUND: The use of robotic surgery in urology has grown exponentially in the last decade, but robotic surgery training is lagged behind. The launch of new robotic platforms has paved the way for new robotic training systems. The aim of our study was to test the new training system from Hugo™ RAS system (Medtronic, Minneapolis, MN, USA).

METHODS: From December 2022 to February 2023 urology, gynecology and general surgery residents at our institution attended an advanced integrated robotic simulation training course with Hugo™ RAS system (Medtronic). Information about sex, age, year of residency, hours spent on videogames, laparoscopic or robotic exposure and interest in robotic surgery were collected. Five parameters were evaluated: timing, range of motion, panoramic view, conflict of instruments and exercise completed. Residents were asked

to perform three robotic exercises under the mentorship of a robotic tutor. Their performance was evaluated according to an objective Hugo™ system (Medtronic) form and to a Likert Score motivation evaluation. The rate of improvement was evaluated for the 3 exercises before and after tutorship. After training, residents received a preformed Likert 10 Scale questionnaire to evaluate overall satisfaction. Descriptive and variance analysis was performed through SPSS v.27 (SPSS Inc., Chicago, IL, USA), using Wilcoxon *U* Mann-Whitney Test.

RESULTS: A total of 44 residents, 16 females (36.4%) and 28 males (63.6%), were enrolled. Among these, 12 (27.3%) were general surgery residents, 8 were gynecology residents (18.2%), and 24 (54.5%) were urology residents; 16 at first year (36.4%), 16 at second year (36.4%), 2 at third year, (4.5%), 4 at fourth year (9.1%) and 6 at the last year of residency (13.6%). Eighteen (40.9%) did not spend any time, 26 (59.1%) spent less than 3 hours/day and no one spent more than 3 hours playing video games. 68.2% of residents had laparoscopic experience. 90.9% declared to have interest in robotic. All were statistically significant (P<0.005). Mean overall satisfaction score±SD was 9.4±1.2.

CONCLUSIONS: The highly simulated and adaptable Hugo™ RAS system (Medtronic) may be an effective way to improve residents' surgical skills. This protocol training may be standardized in order to have basic certified robotic surgical skills before operating on a real patient.

SC320
European Training in Urology (ENTRY): quality-assured training for European urology residents

N. Buffi, P. Diana, M. Paciotti, A.G. Gallagher, A. Gallioli, A. Uleri, R. Hurle, R. De Groote, A. Territo, G. Lughezzani, P. Casale, J. Palou, A. Mottrie, A. Breda (Pieve Emanuele, Milan)

BACKGROUND: European (EU) urology residents consider their exposure to surgical procedures and training inadequate, as well as their confidence in the execution of surgeries. The European Training in Urology (ENTRY) project is a collaboration between three EU referral university centers (Humanitas University, Pieve Emanuele, Milan, Italy; ORSI Academy, Melle, Belgium; and Fundació Puigvert, Barcelona, Spain) with the aim to improve the training of urology residents in minimally invasive procedures. The aim of our project was the design of a proficiency-based progression (PBP) based training curriculum including eLearning, simulation training, and a protocol for integration in real-practice in the operating room (OR). This will provide a high-quality standardized program for residents' education before and in the OR.

METHODS: The ENTRY project has been awarded the Erasmus+ grant for EU education (Key Action KA220-HED, Agreement Number: 2020-1-IT02-KA103-078194). It consists in the development of an educational program that articulates in 4 main results: a training curriculum outline (PR1), eLearning material (PR2), hands-on simulation (PR3), and quality-assured methodology for training in the OR (PR4). A well-established and evidence-based methodology, the PBP-training methodology, will be implemented to ensure that training will be effective. A pilot test to prove the feasibility, efficacy, and safety of the curriculum will be performed on 20 trainers and 150 urology residents that will evaluate the curriculum and we will assess its impact on the trainees.

RESULTS: PR1 consisted in the development of a procedure-specific, PBP-based training curriculum outline for the residents and a train-the-trainers course for the trainers involved in the teaching phases. PR1 started in November 2021 and ended in July 2022, and it was divided in 3 main stages comprehending the outline itself (PR1.1), including eLearning, simulation, trainer guidebooks, and PBP-based tests. Nine co-design sessions (PR1.2): in 3 sessions we investigated the needs and perception of EU urology residents in three different countries to elaborate on the procedures of interest, the best methodology and simulation program; in 6 sessions we exposed and discussed about both teaching methodology and simulation with internal and external urology experts and trainers. Finally, two validation workshops (PR1.3): 1) with 6 exponents of the Italian Society of Urology (SIU); and 2) with 15 EU Association of Urology experts from 6 EU countries for the validation of the methodology of the first training curriculum on transurethral resection of bladder tumor. PR2-4 started in July 2022 and will end with the program delivery in November 2024.

CONCLUSIONS: Clinical evidence strongly suggests that the skill of the operating surgeon is related to clinical outcomes. Thus, an adequate training leads to solid positive impact on performance, patients' safety, and healthcare system. The standardization of a training program since urology residency schools is necessary to reach a uniform and high-standard education.

SC321
International experts' consensus on performance metrics for a transurethral resection of bladder (TURB)

M. Paciotti, M. Paciotti, P. Diana, A. Gaglioli, R. De Groote, R. Farinha, V. Ficarra, R. Gaston, P. Gontero, R. Hurle, L. Martínez-Piñeiro, A. Minervini, V. Pansadoro, B. Van Cleynenbreugel, P. Wiklund, P. Casale, G. Lughezzani, S. Mancon, A. Uleri, A. Mottrie, J. Palou, A.G. Gallagher, A. Breda, N. Buffi (Milan)

BACKGROUND: Transurethral resection of bladder (TURB) is one of the most common surgical operations and should be mastered by every urologist. At the same time, a complex equipment and refined skills are required to properly perform this procedure, that entails working in a very narrow space, with limited view and control of the instruments, dealing with delicate structures. Recent surveys reported concerning data about European residents' ability and confidence to perform a TURB. Therefore, there is an imperative to standardize and improve TURB training programs. We are working to establish the first proficiency-based progression (PBP) structured training curriculum for TURB. As first step, we aimed to characterize a reference approach to TURB using performance metrics, and to obtain face and content validity in a modified Delphi meeting.

METHODS: A reference approach to piecemeal TURB was characterize according to the PBP methodology. A core team of three TURB experts and a senior behavioral scientist deconstructed the procedure, characterizing phases, steps, errors, and critical errors of a piecemeal TURB. The identified performance metrics constitute an optimal approach for training purposes. Urological societies guidelines published

peer-review papers and unedited videos of TURB were used for this purpose. Then, the metrics were presented to a group of international procedure experts to obtain face and content validity through a modified international Delphi meeting.

RESULTS: The core team deconstructed the procedure identifying 6 procedure phases, 60 procedure steps, 43 errors, and 40 critical errors. The procedure metrics were presented in a three-hour Delphi meeting where 11 in-person and 3 online experts from 6 countries were included. Through a modified Delphi process, a reference case was identified as a standard elective TURB on a male patient, diagnosed after full diagnostic work-up with ≤4 bladder lesions, the largest one ≤3 cm. The international experts panel added 3 steps, 4 errors, 1 critical error. Moreover, 14 steps, 5 errors and 3 critical errors were edited. At the end of the Delphi, 6 procedure phases, 63 procedure steps, 49 errors, and 38 critical errors were identified. A panel consensus of 100% on the resulting metrics was obtained.

CONCLUSIONS: A core metrics team performed a detailed task deconstruction of a piecemeal TURB. The performance metrics were presented, modified, and approved by an international panel of experts. These metrics are the first common system to objectively assess trainee ability to perform TURB, and they are being used to develop the first PBP-based training curriculum for TURB. Therefore, they are the milestone to change the training paradigm for one of the most common urological procedures.

SC322
Robotic simulation training with the Hugo™ robot-assisted surgery system: introducing a novel simulation platform to enhance residents training

L. Cacciatore, F. Prata, F. Tedesco, A. Minore, A. Testa, N. Deanesi, A. Ragusa, G. Raso, F. Esperto, R. Papalia, R.M. Scarpa (Rome)

BACKGROUND: With the spread of robot-assisted surgery (RAS), novel robotic platforms' availability led the surgical community to a growing interest toward naïve surgeons and residents (res) training by applying these emerging technologies. In this context, Hugo™ RAS System (Medtronic, Minneapolis, MN, USA) is one of the most promising robotic platforms. The aim of this study was to test a new simulation program with Hugo™ (Medtronic) to improve res' robotic surgical skills before in-vivo surgery.

METHODS: From December 2022 to February 2023, 44 res from different areas (urology, gynecology, and general surgery) attended an advanced robotic training with Hugo™ simulator (Medtronic) at our center, under the mentorship of a robotic tutor. Data about sex, age, year of residency, hours spent on videogames, laparoscopic or robotic exposure, and robotic interest were collected. Res performed 3 robotic exercises, namely "endoscope targeting," "cut and coagulation" and "suturing skills," assessing visualization, accuracy and dexterity capacity for each exercise. Five parameters (par) were analyzed for each attempt and evaluated objectively according to the Hugo™ (Medtronic) simulator form (score: 0-200): timing (par A), range of motion (par B), panoramic view (par C), conflict of instruments (par D), and exercise completed (par E). The median value of all scores was calculated and a "proficiency" goal assessed if the score of the single trainer resulted to be better than the median value of the whole trainer cohort. Predictors of proficiency were assessed through a logistic regression analysis. A two-sided $P<0.05$ was considered statistically significant.

RESULTS: Our cohort was composed of 16 females (36.4%) and 28 males (63.6%), with a median age of 28.5 (IQR: 28-30). Among these, 16 were at the first year (36.4%), 16 at the second year (36.4%), 2 at the third year, (4.5%), 4 at the fourth year (9.1%) and 6 at the last year of residency (13.6%). Overall, the majority of them (N.=30, 68.2%) reported previous laparoscopic exposure. Despite no res had previous robotic experience, 90.9% (N.=40) of them declared to be interested in robotic surgery. In the first exercise, year of residency was the only predictor of proficiency for parameter (par) A and B, while for par D male sex was the only potential predictor (pp) of proficiency. In the second exercise, laparoscopic exposure resulted to be a pp of proficiency for par C while interest for robot-assisted surgery was the only pp of proficiency for par E. Concerning the last exercise, interest for robot-assisted surgery was pp of proficiency for par C and par E (all $P<0.04$).

CONCLUSIONS: This training program based on Hugo™ simulator (Medtronic) has proved to be an effective, adaptable, and reproducible method. Year of residency, gender, previous laparoscopic exposure, and interest toward RAS resulted to be potential predictors of aptitude to robotic surgery. The standardization of a robotic simulation program and the external validation of our results may allow res to improve robotic skills before surgery and shorten the learning curve.

SC323
Do Hugo™ RAS and Versius system simulators change perception about robotic surgery among undergraduate students? A cross-sectional study from a single center

E. Panio, M.C. Sighinolfi, S. Terzoni, E. Scanferla, A. Ramondo, P.P. Bianchi, G. Formisano, G. Gaia, A.M. Marconi, D. Chiumello, V. Patel, M.C. Moschovas, F. Turri, P. Dell'Orto, S. Maruccia, A. Grasso, M. Sangalli, S. Centanni, M. Stocco, S. Assumma, L. Sarchi, T. Calcagnile, G. Bozzini, S. Micali, B. Rocco (Milan)

BACKGROUND: The spread of robotic surgery and the introduction of new platforms increasingly demands the creation of a structured learning program for future robotic surgeons, which is often lacking. As a consequence, among medical and nurse students, there is not always a full awareness about recent technological developments in surgery. In this study, we aimed to assess, through the creation of hands-on training sessions with Hugo™ RAS (Medtronic, Minneapolis, MN, USA) and Versius System (CMR Surgical, Cambridge, UK) simulators, undergraduate students' knowledge and curiosity in robotics.

METHODS: Forty-one volunteers among medical and nurse students from a single institution were enrolled in a cross-sectional study. Initially, the participants were asked to respond anonymously to questions regarding their understanding of robotics and how much they were interested in it. Then, a summary lecture about robotic surgery and a presentation of the new surgical platforms was performed, followed by a practical session at the Versius System (CMR Surgical) and Hugo™ RAS (Medtronic) simulators. In the end, the students had to fill a second questionnaire to allow comparisons

on how their perception about robotics changed. Data were recorded and analyzed through Mann-Whitney *U* test, Fisher's Exact Test and Mc Nemar Test (to compare the results before and after the session).

RESULTS: Overall, 18 out of 41 participants were medical students, the others were nursing students. Before the practical session took place, less than half of the medical (36.6%) and nurse students (44%) declared to be interested in surgery and in robotics. Nevertheless, few of them showed to already have basic information about robotic surgery also before the lecture. After the hands-on session, all the undergraduates (100%) expressed a strong interest in the subject, with some requiring a dedicated internship (P<0.001). The second questionnaire included also questions about the perceived ease-of-use of Hugo™ RAS (Medtronic) and Versius System (CMR Surgical) simulators: on a scale between 0 and 10, the median score resulted 8 (IQR: 7-8); no differences were noted between the two groups of undergraduate students (P=0.482).

CONCLUSIONS: The present study attests the strong interest in robotic surgery among medical and nurse students. In addition, the use of robotic simulators and the presentation of new robotic surgical systems was recognized as a reinforcement in both the backgrounds. Further studies are needed to check if the development of structured training programs at all levels of education could contribute to the creation of high-level professional figures involved in robotic surgery.

SC324
Analysis of robotic platform-to-platform skill transfer: preliminary results about influence of prior console expertise on basic skill development at Hugo™ RAS simulator

T. Calcagnile, M.C. Sighinolfi, S. Terzoni, E. Scanferla, P.P. Bianchi, G. Formisano, G. Piccolo, M. Barabino, A. Pisani Ceretti, A. Salaj, G. Gaia, A.M. Marconi, F. Turri, M. Sangalli, A. Pathak, R. Darisi, E. Pozzi, S. Centanni, M. Stocco, D. Chiumello, C. Verrusio, A. Baisi, N.M. Mariani, A. Grasso, E. Panio, L. Sarchi, S. Assumma, P. Dell'Orto, G. Bozzini, S. Micali, B. Rocco (Milan)

BACKGROUND: New robotic systems have recently received CE approval and were introduced in the market as a result of the expiry of the da Vinci patent (Intuitive Surgical, Inc., Sunnyvale, CA, USA). The use of simulators is considered an essential step to approach new platforms and to allow an analysis about skill acquisition for operators with and without prior robotic expertise. The aim of the present study was to evaluate which factors contribute to build up basic skills of Hugo™ RAS simulator (Medtronic, Minneapolis, MN, USA).

METHODS: Seventy-one participants with different surgical background (medical/nurse students, residents, robotic and laparoscopic surgeons), but no prior expertise with Hugo™ RAS (Medtronic), were invited to a hands-on session at the simulator and enrolled in a cross-sectional study. "Pick-and-Place" was chosen as the exercise to be analyzed. All participants underwent a first "warm up" exercise; then, the metrics of a second round were collected and evaluated. The variables recorded were demographics, information about previous surgical experience (no expertise, no experience with robotic console but with laparoscopy, experience with different robotic console) and videogame use.

RESULTS: Between the participants, 77.5% had no previous surgical experience, 14.1% had prior robotic console expertise and 8.5% were laparoscopists. Pick-and-Place exercise was completed by all the 71 individuals involved. Prior robotic surgeons required considerably less time (38 s, IQR: 34-45; P<0.001) than both novices (61 s, IQR: 53-71) and laparoscopists (93 s, IQR: 53-162). In general, increase in age had negative impact on the exercise's overall score (P=0.046). Nonetheless, across all age categories, total scores were considerably and consistently increased among surgeons with previous console experience (P=0.006). Gender (P=0.7) and videogame playing (P=0.9) were found not to statistically influence the metrics.

CONCLUSIONS: The analysis of the features influencing the acquisition of basic skills at the simulator may represent a key factor in approaching new robotic systems. Previous robotic experience with different surgical platforms was found to be the most influential element towards skill learning process on novel simulators, supporting the platform-to-platform transferability hypothesis. Nevertheless, further research is needed to investigate this preliminary finding.

SC325
Survey of the application of ERAS protocol in Italian Urology University Department: complete adherence or simplified protocol?

G. Tulone, N. Pavan, C. Minasola, A. Costanzo, R. Giaimo, A. Simonato (Palermo)

BACKGROUND: The Enhanced Recovery After Surgery (ERAS) protocol was created with the aim of guaranteeing, after surgery, optimal recovery, and an early and safe return to daily activities. The aim of this study was to conduct the first national survey among the Italian University Urology Units on the degree of application of the ERAS protocol and the consequences in clinical practice.

METHODS: We have developed a cross-sectional survey based on 34 questions carried out *via* an electronic platform from October 6, 2022, to October 27, 2022, for the evaluation of the application of the ERAS protocol in different centers. The questions concerned the 21 ERAS elements, the incidence and type of both early and late complications, in-hospital stay, time to flatus and evacuation.

RESULTS: The survey was completed by 30 out of 31 directors of university departments of urology. In general, approximately 20 to 40 radical cystectomies are performed per year. In 73.3% of cases, ureteroileocutaneostomy is the most common urinary diversion, followed by orthotopic neobladder with open technique in 56.7% of cases. From the gathered information it emerged that 66% of the participating centers in the survey follow the ERAS protocol. Forty-four percent of centers do not perform oral mechanical bowel preparation and 13 centers do not perform any ileus prevention. One hundred percent of the participants stated that they have a standardized anesthesiologic protocol, but rather the postoperative analgesic therapy is not performed routinely. In more than 50% of the centers, early patient mobilization and early oral diet are applied. The in-hospital stay is between 9 and 11 days in more than 50% of the centers. Times to flatus and stool are substantially similar in all centers. Ileus is reported as the most frequent early complication (33%) followed by urinary tract infections (30%).

CONCLUSIONS: From the data collected it emerges that

in Italy the ERAS protocol is applied heterogeneously in the diverse university hospital centers. Despite this, postoperative complications, the average length of hospital stay, and the outcome do not seem to show significant differences. Considering this, a revise and simplified ERAS protocol could be considered once more large-scale data is obtained.

SC326
First head-to-head comparison between Hugo™ RAS and Versius in the preclinical setting: cross-sectional analysis on virtual-reality simulators

S. Terzoni, M.C. Sighinolfi, T. Calcagnile, S. Assumma, E. Panio, A. Pathak, R. Darisi, E. Pozzi, M. Petix, A. Ramondo, I. Piacentini, A. Grasso, M. Sangalli, L. Sarchi, F. Turri, G. Bozzini, S. Micali, A. Del Nero, P. Dell'Orto, B. Rocco (Milan)

BACKGROUND: Hugo™ RAS (Medtronic, Minneapolis, MN, USA) and Versius (CMR Surgical, Cambridge, UK) are amongst the new robotic systems that entered the market after da Vinci's patent expiry (Intuitive Surgical, Inc., Sunnyvale, CA, USA). Since October 2022, they both became simultaneously available at a single referral center in Milan, Italy. Whereas outcomes of a clinical comparison between new systems are yet to come, an evaluation throughout simulators is already achievable. We report the first head-to-head comparison of the two robotic systems in the preclinical setting.

METHODS: We performed a cross-sectional study recruiting, on a voluntary basis, medical students, who were invited to join a hands-on practice simulation with the Hugo™ RAS (Medtronic) and/or Versius trainer simulator (CMR Surgical). Demographic baseline and habits of participants were recorded (including videogame and musical instrument use). After the hand-on exercise, students were asked to fulfill a questionnaire addressing face and content validity of the simulators. To this purpose, we used the survey from the article of Hertz *et al.* (JSLS, 2018) providing a Likert-Scale graded outcome. Furthermore, the occurrence of symptoms after console practice was addressed throughout the Simulator Sickness Questionnaire and other specific questions addressing pain at different sites. Data were recorded; after a descriptive analysis of the variables (median values and IQR), frequencies were compared with the Fisher's Exact Test.

RESULTS: Twenty-eight undergraduates agreed to participate, 7 males and 21 females, in their third (82.9%) fourth (2.9%) or fifth (14.3%) year of medical school, with a median age of 21 (1.5) years. Twenty-four simulator practices were performed on Hugo™ RAS (Medtronic; 49.0%) and 25 on the Versius (CMR Surgical; 51.0%). Eighteen students (64.3%) used both simulators. Hugo RAS simulation system was found easier to use (P=0.036) independently from experience with musical instruments (P=0.079), previous videogame experience (P=0.082) and having used different controllers other than gamepads (P=0.131). No significant differences were found in other items of face and content validation questionnaires. Both platforms obtained a majority of low scores ("not at all fatiguing" or "slightly fatiguing" on a four-point Likert Scale where the lower was the better) regarding tiredness of the hands, wrists, neck, shoulders, upper and lumbar spine and lower-sacral spine. Similarly, general discomfort was low, with 62.5% and 64.0% of the responders indicating "no discomfort at all" with Hugo™ RAS (Medtronic) and Versius (CMR Surgical), respectively (P=0.323).

CONCLUSIONS: This is the first article comparing Hugo™ RAS (Medtronic) and Versius (CMR Surgical) in the preclinical setting, based on simulator practice. From this preliminary experience, Hugo™ RAS (Medtronic) simulator was found easier to use than Versius (CMR Surgical) one; no other differences were evident. The involvement of participants naïve to robotic surgery lowers the possible bias arising from prior surgical habits in the virtual simulation; however, it may not reproduce live surgical performance, an issue that should be further addressed in real-life practice.

SC327
Ureteral stents placement in urgency and emergency setting by expert and resident surgeons: a 3-year retrospective comparison

R. Danuso, P. Cabas, F. Zorzi, F. Traunero, S. Sartori, G. Rossin, A. Biasatti, G. Rebez, M. Rizzo, S. Bucci, F. Claps, G. Liguori, C. Trombetta (Trieste)

BACKGROUND: The aim of this study was to assess the differences in terms of clinical outcome, intraoperative and postoperative complications between experienced surgeons and residents in positioning ureteral stents in urgency and emergency settings.

METHODS: Retrospective clinical records of patients that underwent Double-J stent placement or replacement in urgency and emergency settings between January 1, 2018, and December 31, 2020, in a single center were collected. All the procedures were performed by expert surgeons or resident urologists without assistance from a supervisor. Clinical outcomes such as failure of the procedure, intraoperative and perioperative complications were analyzed and compared among the group of residents. Complications rate cos as the degree of ureteral injury (divided into mild lesion or severe lesion), and onset within 30 days of early dislocation or early obstruction of the catheter. Intraoperative time was compared by the two groups. The occurrence of ureteral strictures was also assessed at the time of data collection. The Mann-Withey *U* Test was used to compare operative time between the two groups. A linear regression statistical model was used to investigate any differences in intraoperative and postoperative complications between the two groups.

RESULTS: Two hundred fifty patients that underwent ureteral stent placement or replacement in urgency and emergency settings were included, 129 men (51.6%) and 121 women (48.4%). In 206 patients (17.2%) the procedure was performed on one side only (82.4%), while in 43 patients bilaterally. In 154 interventions (61.6%) the first surgeon was an expert urologist, while in 95 (38.0%) a resident urologist doctor. One hundred forty-four (93.5%) procedures were successfully performed by an expert urologist, while 91 (95.78%) were by residents. Failure was noticed in 6 procedures (3.89%) performed by seniors and in 3 procedures (3.15%) by residents. Moreover, for both groups in 3 cases (1.95% for urologists and 3.16% for residents, respectively) it was not possible to complete the procedure bilaterally. Intraoperative ureteral mild injuries occurred in 5 cases (3.24%) in the urologist group *vs.* 1 case in the resident group (1.05%); no serious ureteral lesions have been collected. Postoperative complications occurred in 6 patients (3.89%) *vs.* 3 patients (3.15%)

operated by residents. The median operative time was 20′ (25th percentile 12′, 75th percentile 30′) *vs.* 18′ (25th percentile 15′, 75th percentile 29′). Of the total 3 ureteral strictures were found (1.94%), all in the urologist group. No significant differences in operating times (P=0.777), intraoperative and postoperative complications (P=0.272 and P=0.763, respectively) were recorded between the two groups.

CONCLUSIONS: Ureteral stent placement represents the first step of the trainee's approach to urological surgery and our preliminary data demonstrate that the procedure, performed under expert supervision, can be completed safely without complications by a resident.

SC328
Laser fiber displacement speed during ureteroscopic lithotripsy: an *in-vitro* assessment of surgical performance

C. Corsini, D. Robesti, M. Fantin, M. De Angelis, R. Aiuto, F. Montorsi, I.K. Goumas, O. Traxer, L. Villa, A. Salonia, E. Ventimiglia (Milan)

BACKGROUND: The aim of this study was to propose an *in-vitro* simulation model for the assessment of laser fiber displacement speed during flexible ureteroscopy for stone disease, in order to provide benchmark values for *in-vitro* study and for surgical training.

METHODS: We used a portable bench-training model for fURS, the Key-box (K-Box, Porgès-Coloplast, Humlebæk, Denmark), submerged in saline in order to simulate the renal cavities of an ideal right kidney. A 1 cm³ BegoStone stone phantom model was used in every case and placed in a cavity resembling an upper calix. Flexible ureteroscopy was performed using a single-use digital ureteroscope (LithoVueTM, Boston Scientific, Marlborough, MA, USA). A Ho:YAG laser generator (CyberHo 150 W; Quanta System, Samarate, Varese, Italy) with a 200 micron laser fiber set at 0.2 J, 10 Hz, low peak power was used. Two expert endourologist and 7 residents in training were instructed to laser following a 10x2mm straight line on the BegoStone surface for 10 consecutive attempts, simulating the so called "dusting-painting" technique. Two different ureteroscopic movements were tested for each attempt, *i.e.*, scope deflection and wrist prono-supination. Time from the first laser emission at the edge of the BegoStone until the end of the straight line was recorded. Displacement speed was measured dividing the length of the straight line (10 mm) by the laser time. Each attempt was considered valid whenever remaining withing the boundaries of the line and in case of distance between two consecutive laser hits on the stone <1 mm.

RESULTS: Mean (SD) laser displacement for expert endourologist was 1.1 (0.2) mm/s and 1.1 (0.2) mm/s during deflection and prono-supination, respectively. Considering residents in training, mean (SD) displacement speed was 0.6 (0.3) mm/s and 0.5 (0.7) mm/s for deflection and prono-supination, respectively (both P<0.01 *vs.* expert endourologists). Global failure rate was considerably higher for residents in training *vs.* expert endourologists, 42% *vs.* 18% (P=0.02).

CONCLUSIONS: The average laser fiber displacement speed for expert endourologists is 1.1 mm/s, much lower than what is usually considered in *in-vitro* studies of automated displacement of laser fiber. This study provides a benchmark model for the assessment of *in-vitro* displacement speed as well as for attesting progress during endourological training.

SMART (SC329-SC336)

Prostate cancer: surgical treatment 1

SC329
Defining the optimal target-to-background count rate to identify positive lymph nodes in patients undergoing robot-assisted 99MTC-PSMA-radioguided surgery for prostate cancer: a per-region analysis of a prospective, phase II study

SC330
A novel model integrating clinical, MP-MRI, and epigenomic features to predict lymph node invasion in prostate cancer patients undergoing radical prostatectomy and pelvic lymph node dissection

SC331
Outcomes of prostate cancer patients with seminal vesicle invasion at multiparametric MRI managed with radical prostatectomy: do all patients really need a multimodal approach?

SC332
Validation of novel preoperative risk categories on the prediction of clinical recurrence in patients' candidate to radical prostatectomy for clinically-localized prostate cancer: results of a large, multi-institutional series

SC333
Can we rely on available models to identify candidates for extended pelvic lymph node dissection (ePLND) in men staged with PSMA-PET? External validation of the Briganti nomograms and development of a novel tool to identify optimal candidates for ePLND

SC334
Role of inflammatory markers and Frailty Index as predictors of adverse pathological outcomes in patients undergoing radical prostatectomy: a multicenter analysis

SC335
Safety and efficacy of cytoreductive radical prostatectomy in hormone-sensitive oligometastatic prostate cancer: preliminary results of a prospective single-arm study

SC336
Intense surveillance for patients treated with radical prostatectomy and adverse pathologic features: early results from Early Salvage Radiotherapy-1 (EASY-1) protocol

SC329
Defining the optimal target-to-background count rate to identify positive lymph nodes in patients undergoing robot-assisted 99MTC-PSMA-radioguided surgery for prostate cancer: a per-region analysis of a prospective, phase II study

L. Mattia, E. Mazzone, G. Giorgio, S. Armando, R. Giuseppe, G. Sorce, F. Pellegrino, S. Scuderi, F. Barletta, D. Robesti, R. Leni, M. De Angelis, A. Pellegrino, P. Scilipoti, G. Brembilla, F. De Cobelli, A.M. Samanes Gajate, M. Picchio, L. Gianolli, F.W. Van Leeuwen, M.N. Van Oosterom, F. Montorsi, A. Briganti (Milan)

BACKGROUND: PSMA radio-guided surgery (PSMA-RGS) could help identifying lymph node invasion (LNI) both in primary and salvage extended lymph node dissections (eLND). Although previous studies suggested that a target-to-background rate of 2 should be used to identify patients with positive nodes at PSMA-RGS, the impact of different cut-offs on the performance characteristics of RGS is still unknown. Defining an optimal cut-off is key to optimize the detection of the affected node(s) while sparing unnecessary nodal dissections without compromising staging.

METHODS: Twenty-one patients from a phase-II study enrolling men with intermediate- or high-risk cN0cM0 prostate cancer at conventional imaging with a risk of LNI>5% at a single center were analyzed. Eighteen patients underwent PSMA-RGS between June 2021 and September 2022. All patients received a 68Ga-PSMA PET preoperatively. 99mTc-PSMA I&S was synthesized and administered the day before surgery. A drop-in gamma probe was used for *in-vivo* measurements during RGS. An eLND was performed and different definitions of positive uptake during RGS (*i.e.*, target-to-background count rate ≥2 *vs.* ≥3 *vs.* ≥4) were compared in terms of diagnostic accuracy.

RESULTS: Five (27%) patients had LNI. Overall, 20 out of 116 regions (14%) were positive including an overall number of 64 positive LN out of 446. At preoperative per-region analyses of 116 nodal areas, 68Ga PSMA PET/MRI identified 10 positive spots in 7 patients and missed 9 pathological positive regions. Using count rate ≥2, PSMA-RGS identified 19 additional suspicious nodal areas which were not previously identified by 68Ga-PSMA PET/MRI with a 76% concordance rate. However, of these additional suspicious areas, 13 (68%) resulted negative at final pathology. The sensitivity, specificity, positive (PPV) and negative predictive value (NPV) of count rate ≥2 at a per-region analysis were 70%, 85%, 46%, and 94% (accuracy 84%). When using a count rate ≥3 and ≥4, the same figures for PSMA-RGS at a per-region analysis were 47%, 97%, 72%, 91% (accuracy 89%) and 33%, 99%, 86%, 90% (accuracy 88%), respectively.

CONCLUSIONS: A cut-off of ≥3 target-to-background count rate provides higher accuracy and lower false positive findings when compared to ≥2 count rate at the cost of missing a higher proportion of positive nodes. The suboptimal sensitivity of RGS with virtually all target-to-background count rate cut-offs should not preclude an anatomically defined LND.

SC330
A novel model integrating clinical, MP-MRI, and epigenomic features to predict lymph node invasion in prostate cancer patients undergoing radical prostatectomy and pelvic lymph node dissection

M. Bandini, R. Lucianò, F. Giannese, G.M. Scotti, C. Oneto, F. Barletta, G.O. Cirulli, V. Cucchiara, A. Stabile, E. Mazzone, G. Sorce, N. Tenace, F. Scarfò, G. Brembilla, A. Esposito, M. Morelli, D. Lazarevic, F. De Cobelli, C. Doglioni, G. Tonon, G. Gandaglia, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Multivariable models should be used to identify prostate cancer (PCa) patients' candidates for extended pelvic lymph node dissection (ePLND) during radical prostatectomy (RP) to spare unnecessary ePLNDs without missing lymph node invasion (LNI). Improving LNI detection in PCa is key in reducing ePLND-related morbidity. We hypothesized that LNI can be better predicted by integrating clinical, radiologic and epigenomic information.

METHODS: We recruited 172 PCa patients with a risk of LNI>5% diagnosed by target + systematic biopsy undergoing RP + ePLND between 2014-2021. Epigenetic profiles of tumor DNA biopsy cores were sequenced *via* reduced representation bisulfite conversion. MethylKit R package (Bioconductor) assessed the percentage methylation differences among CpG sites of patients with and without LNI. A 50% cut-off methylation difference (50-MD) identified significant (false discovery rate <0.001) CpGs. Enrichment analysis tested for gene pathways that were expressed among patients with and without LNI by using differentially methylated (50-MD) CpGs. Analyses were performed for target and systematic biopsy samples independently. Two signatures were created from hypermethylated CpGs from target + systematic samples and integrated with PSA, mpMRI stage, and grade group at target biopsy to develop two models predicting LNI which underwent 500 internal train- test validations and were compared with existing tools.

RESULTS: Overall, 37 patients (21.5%) had LNI. We identified 508 and 511 CpGs sites within target and systematic samples that were differentially methylated among patients with and without LNI. Gene pathways involved in the transcription of potassium channels were associated with LNI in target samples. The epigenetic signatures including only hypermethylated CpGs were correlated with LNI on univariable regression (target samples LogOdds: 0.12, P<0.001; systematic samples LogOdds :0.08, P<0.001). Clinical and mpMRI variables (PSA, mp-MRI stage, and ISUP grade group at target biopsy) were associated with LNI (all P≤0.01). An AUC of 86% and 83% was achieved for the target model and systematic model. Both models outperformed the previous versions of the Briganti nomogram at any LNI threshold risk.

CONCLUSIONS: We developed two LNI prediction models that integrated clinical, mpMRI and epigenetic features which outperformed available tools. Epigenetic features from target tumor samples appeared to better predict LNI compared to their systematic counterparts.

SC331
Outcomes of prostate cancer patients with seminal vesicle invasion at multiparametric MRI managed with radical prostatectomy: do all patients really need a multimodal approach?

L. Quarta, F. Barletta, G. Gandaglia, A. Stabile, G. Ploussard, M. Giancarlo, M. Valerio, R. Campi, A. Mari, A. Minervini, S.

Serni, A. Marquis, J.B. Beavaul, A. Rakauskas, F. Sessa, R. van den Bergh, R. Rahota, T. Soeterik, M. Roumiguiè, L. Afferi, J. Zhuang, H. Guo, A. Mattei, P. Gontero, F. Montorsi, A. Briganti (Milan)

BACKGROUND: The presence of seminal vesicle invasion (SVI) at multiparametric MRI (mpMRI) represents one of the strongest risk factors for disease recurrence after radical prostatectomy (RP). According to international guidelines, in patients with suspicion of SVI surgery can be offered only in the context of a multimodal approach. We hypothesized that a subset of men with SVI at imaging might be instead managed with RP only.

METHODS: Overall, 4334 patients diagnosed with MRI-targeted and concomitant systematic biopsy who underwent radical prostatectomy (RP) with or without an extended pelvic lymph node dissection (PLND) at 10 tertiary referral centers worldwide. Among those, we selected men with SVI at mpMRI who did not receive neoadjuvant or adjuvant treatments (N.=169). Clinical and preoperative imaging variables were available for all patients. Biochemical recurrence (BCR) was defined as two consecutive PSA≥0.2 ng/mL. Kaplan-Meier analyses assessed time from surgery to BCR. Cox regression analyses assessed the impact of preoperative imaging and clinical characteristics on the risk of BCR.

RESULTS: Median PSA at diagnosis was 11.5 ng/mL. The median maximum diameter of the index lesion was 20 mm. Overall, 49 (29%) patients had multifocal disease at mpMRI. A total of 62 (37%) and 28 (17%) patients had grade group 4-5 and cT3 disease at DRE, respectively. The median follow-up for survivors was 20 months. Overall, 27 patients experienced BCR. The 3-year BCR-free survival was 75%. Biopsy grade group 4-5 (HR=2.2; 95% CI: 1.1-4.8; P=0.04) and the presence of cT3 at DRE (HR=2.3; 95% CI: 1.1-5.5; P=0.04) were significant predictors of BCR after adjusting for PSA value at diagnosis and maximum diameter of the index lesion. The BCR-free survival rate was significantly higher for those with biopsy Grade Group 1-3 organ-confined disease (N.=79, 47%) compared to their counterparts with biopsy grade group 4-5 or cT3 (N.=88, 53%; 3-year BCR-free survival: 87% *vs.* 61%; P=0.015).

CONCLUSIONS: The prognosis of patients with SVI at mpMRI managed by RP alone is not invariably poor. Men with biopsy grade group ≤3 with organ-confined disease have a substantially lower risk of BCR compared to grade group >3 or cT3 and can be considered as the ideal candidates for surgery as monotherapy.

SC332
Validation of novel preoperative risk categories on the prediction of clinical recurrence in patients' candidate to radical prostatectomy for clinically-localized prostate cancer: results of a large, multi-institutional series

L. Nocera, E. Mazzone, G. Gandaglia, A. Stabile, D. Robesti, A. Necchi, D. Raggi, L. Marandino, G.O. Cirulli, S. Scuderi, F. Barletta, M. De Angelis, V. Cucchiara, A. Pellegrino, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Most of the preoperative risk tools predicting prostate cancer (PCa) recurrence after radical prostatectomy (RP) considered biochemical recurrence (BCR) as the main endpoint when developed. However, not all patients with a BCR ultimately progress to clinical recurrence (CR). We aimed at internally validating a novel preoperative risk classification in predicting CR in patients treated with RP.

METHODS: Overall, 2901 patients treated with RP and received preop mpMRI between 2014-2022 at eight referral centers were identified. The study outcome was 5-yr CR defined as positive imaging after BCR. Kaplan-Meier and multivariable Cox regression models tested time and predictors of CR. Predictors consisted of PSA, biopsy grade group, MRI stage (organ-confined *vs.* extracapsular extension *vs.* seminal vesicles invasion) and maximum diameter of lesion at MRI. These variables defined four risk groups based on the novel classification. The tool accuracy was compared to the EAU risk classification and CAPRA score in predicting 5-year CR using Harrel's C-Index. Decision curve analyses (DCA) compared the net-benefit associated with each of the risk tools.

RESULTS: Overall, 937 (32%), 1006 (35%), 848 (30%) and 110 (3%) had low, intermediate, high and very-high risk disease according to the novel classification. Median follow-up was 43 months. At KM analyses, 5-year CR-free survival rates were 94, 90, 83 and 71% in, respectively, low, intermediate, high and very-high risk groups (P<0.01). The novel model tested for prediction CR in Cox regression analyses depicted good discrimination at internal validation (C-Index 76%). After testing the accuracy of the EAU risk groups and the CAPRA score in our cohort, the novel model showed higher C-Index (78 *vs.* 69 *vs.* 73%). At DCA, our novel model showed a higher net-benefit compared to other models.

CONCLUSIONS: We internally validated a novel preoperative risk tool to predict CR after RP. Our model exhibited higher accuracy as compared to available tools in the prediction of stronger oncologic endpoints at mid-term follow-up. This data reinforces the utility of this patient stratification for preoperative counselling and outcome predictions.

SC333
Can we rely on available models to identify candidates for extended pelvic lymph node dissection (ePLND) in men staged with PSMA-PET? External validation of the Briganti nomograms and development of a novel tool to identify optimal candidates for ePLND

G. Gandaglia, D. Robesti, L. Bianchi, R. Schiavina, E. Brunocilla, L. Afferi, A. Mattei, F. Zattoni, P. Rajwa, S. Shariat, C. Kesch, J. Moreno-Sierra, P. Gontero, G. Marra, H. Guo, J. Zhuang, J. Gomez-Rivas, D. Amparore, F. Dal Moro, F. Porpiglia, C. Darr, W. Fendler, M. Picchio, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Nomograms to identify prostate cancer (PCa) patients' candidate for extended pelvic lymph node dissection (ePLND) during radical prostatectomy (RP) do not account for PSMA-PET. We hypothesized that available tools may be suboptimal and be recalibrated in cN0 disease at PSMA-PET due to its high negative predictive value (NPV) for lymph node invasion (LNI).

METHODS: Six hundred sixty-two PCa patients who received a PSMA-PET and subsequent RP+ePLND at 9 referral centers between 2016-2022 were identified. All patients received ePLND regardless of PSMA-PET. Information on preoperative MRI, biopsies and pathologic data were available for all patients. Calibration and discrimination of available

nomograms predicting LNI (Briganti 2012, Briganti 2017, and Briganti 2019) was assessed at external validation. The same process was repeated in men with cN0M0 disease at PSMA-PET. The Briganti 2019 model was recalibrated using the multivariable logistic regression coefficients of the variables included in the nomogram in men cN0MO disease at PSMA-PET. Calibration plots, the ROC-derived AUC, and decision-curve analyses were used to determine calibration, discrimination, and net benefit associated with the recalibrated nomogram and compare it with available tools.

RESULTS: Overall, 115 (17.4%) patients had positive pelvic spots at PSMA PET/CT. LNI rate was 19.5%. The discrimination of the Briganti 2012, 2017, and 2019 nomograms was 75, 75, and 71%. In patients with negative PSMA-PET (N.=537, LNI rate: 10%), the discrimination of the Briganti 2012, 2017, and 2019 nomograms was even lower (72, 72, and 70%). In these patients, the maximum index lesion diameter, seminal vesicle invasion at MRI, and a target biopsy ISUP group 4-5 were associated with a risk of LNI (all P<0.05). A nomogram based on the coefficients of this multivariable regression had a discrimination of 80%, superior calibration characteristics and higher net-benefit compared to other models. A 7% cut-off in the recalibrated nomogram in cN0M0 disease at PSMA-PET would have spared 55% ePLNDs (*vs.* 29% for the Briganti 2019 nomogram), missing only 3.4% (*vs.* 2.9%) of LNIs.

CONCLUSIONS: Due to its elevated NPV, in men staged with PSMA-PET the Briganti nomogram results in a high number of unnecessary ePLNDs. A novel recalibrated version of the nomogram should be used to identify candidates for ePLND, reducing unnecessary procedures, without missing additional LNIs in men with cN0M0 PCa at PSMA-PET.

SC334
Role of inflammatory markers and Frailty Index as predictors of adverse pathological outcomes in patients undergoing radical prostatectomy: a multicenter analysis

S. Riolo, R. Lombardo, L. Sarcinelli, A. Cicione, G. Guarnotta, V. Baldassarri, O.A. Voglino, L. Antonelli, E. Scarrone, L. Costantino, A. Fuschi, A.L. Pastore, A. Carbone, Y. Al Salhi, M. Ferriero, A. Brassetti, R. Mastroianni, G. Simone, G. Tuderti, A. Nacchia, R. Papalia, F. Prata, F. Esperto, C. De Nunzio (Rome)

BACKGROUND: The aim of this study was to assess patient frailty index and inflammatory state as predictors of adverse pathological outcomes after radical prostatectomy.

METHODS: We performed an analysis of prospectively collected data of consecutive patients undergoing radical prostatectomy in 5 primary care Italian urology centers. Charlson Comorbidity Score and Frailty Index was measured using a simplified Frailty Index (sFI) with a 5-item score including: 1) diabetes mellitus; 2) functional status; 3) chronic obstructive pulmonary disease; 4) congestive cardiac failure; and 5) hypertension, with a maximum 5-item score meaning high level of frailty. Inflammatory status was evaluated with Neutrophil/Lymphocyte Ratio (NLR), Monocyte to Lymphocyte Ratio (MLR), Platelets to Lymphocyte Ratio, fibrinogen and albumin levels. Adverse pathological outcomes were defined as pT≥3a, upgrading of grade group and positive surgical margins. Logistic regression analysis was used to evaluate the role of frailty index and inflammatory status as predictors of adverse pathological outcomes, upgrading and positive surgical margins.

RESULTS: Two hundred sixty-eight patients with a median age of 66 years (60/70) were enrolled. On RP specimens, 105/258 (39%) presented advanced disease (pT≥3a), 59/258 (23%) presented an upgrading in grade group and 67/268 (25%) presented positive surgical margins. On logistic regression analysis neither Frailty Index neither inflammatory markers (NLR, MLR, PLR, albumin and fibrinogen) were predictors of adverse pathological outcomes.

CONCLUSIONS: In patients undergoing surgery for prostate cancer frailty index, inflammatory mediators and comorbidities are not predictors of adverse pathological outcomes. Further studies are needed to explore the role of inflammatory markers in PCa carcinogenesis.

SC335
Safety and efficacy of cytoreductive radical prostatectomy in hormone-sensitive oligometastatic prostate cancer: preliminary results of a prospective single-arm study

E. Checcucci, D. Amparore, S. De Cillis, F. Piramide, A. Piana, M. Sica, M. Manfredi, G. Volpi, D. Zamengo, E. Cisero, C. Gatti, M. Mandaletti, A. Sterrantino, G.A. Mesterca, C. Fiori, A. Mosca, A. Galla, P. Rescigno, G. Belli, F. Porpiglia (Candiolo, Turin)

BACKGROUND: In *de-novo* oligometastatic hormone-sensitive prostate cancer (omHSPC) systemic treatment with androgen deprivation therapy (ADT) represents the standard of care. Furthermore, in the last years local treatment such as radiotherapy (RT) to the primary tumor can be considered. The primary endpoints of this study were to evaluate the safety and the efficacy of ADT and radical prostatectomy (RP) + extended pelvic lymph node (LN) dissection in omHSPC.

METHODS: omHSPC patients (≤5 bone metastasis, none of which outside the axial skeleton), with absence of retroperitoneal LN or visceral metastasis and absence of bulky LN (>3 cm) were included. From April 2019 to September 2022, the enrolled patients underwent 6 months of ADT prior to surgery. Preoperative response to ADT in order to verify hormone sensitive status and a re-staging with CT scan and bone scan were evaluated. Robot assisted RP (RARP) with previously described total anatomical reconstruction technique + extended LN dissection was performed by a single surgeon. After surgery, the ADT was maintained for 2 years. The follow-up schedule included PSA and T every three months and CT-scan and bone scan every 6 months. Concomitant stereotactic body radiation therapy (SBRT) on metastasis was allowed according to multidisciplinary team (MDT) indications. Progression free survival (PFS) was defined as the time free of progression as per RECIST 1.1 or PCWG3 criteria. Quality of life (QoL) was evaluated with EPIC questionnaire. This study was approved by our local ethical committee. All results for continuous variables were expressed as the median and interquartile range (IQR) and the frequencies and proportions were reported as percentages.

RESULTS: Ten patients were enrolled, up to date. Median age was 62 (IQR: 57, 73), ISUP grade was 3, 4 or 5 in 50%, 20%, 20% of the cases, with median PSA at diagnosis of 17 ng/mL (IQR: 6, 56). Median number of bone metastatic lesions was 3 (IQR: 1, 4). At preoperative re-staging no new

metastatic lesions arose; median preoperative PSA and T were 0.5 (IQR: 0.2, 1.4) and 0.25 (IQR: 0.16, 0.28) ng/mL. Three and 7 patients had pT2, pT3 and 8 and 2 pN0 pN1. Median follow-up was 15 (IQR: 3- 24) months. Three patients underwent to SBRT. None of the patients has progressed during the follow-up period; or died for PCa or other causes. Nonadditional surgery related side effects or incontinence was registered at 12 months. No major complications occurred. At EPIC questionnaire the all the patients revealed to be satisfied/extremely satisfied with the treatment received.

CONCLUSIONS: Our findings revealed a good safety and oncological results in terms of overall survival, cancer-specific survival, and PFS by cytoreductive RP and ADT in omHSPC. The trial will continue recruiting until the target of 30 patients is reached.

SC336
Intense surveillance for patients treated with radical prostatectomy and adverse pathologic features: early results from Early Salvage Radiotherapy-1 (EASY-1) protocol

S. Tamburini, L. Bianchi, A. Mottaran, M. Droghetti, P. Piazza, F. Chessa, C. Catanzaro, M. Ntreta, G. Siepe, R. Schiavina, A.G. Morganti, E. Brunocilla (Bologna)

BACKGROUND: Postoperative treatment in patients with prostate cancer (PCa) treated with radical prostatectomy (RP) and adverse pathology is still matter of debate since adjuvant (aRT) and early salvage radiotherapy (esRT) showed comparable biochemical recurrence free survival (BCR-FS). The aim of this work was to evaluate the early oncologic benefit of intense surveillance and esRT in the postoperative management of PCa patients with intermediate-high risk of recurrence after surgery.

METHODS: We prospectively enrolled 721 PCa patients who underwent to RP between March 2018 and December 2022 in a specific approved follow-up protocol (Early Salvage Radiotherapy-1; EASY-1). Inclusion criteria were: 1) biopsy proven PCa patients treated with RP; 2) pT2 with positive surgical margins (R1) or pT3a regardless surgical margins status or pT3b with negative surgical margins (R0); and 3) PSA undetectable at 40 days after surgery (<0.01). Lymph node invasion was considered as an exclusion parameter. The intense surveillance protocol included PSA dosage every 2 months after surgery during the first year, every 3 months during the second and third year, followed by PSA every 4 months until the fifth year, then every 6 months until the tenth year after surgery. EsRT has been performed in case of biochemical relapse (BCR, two consecutive values of PSA≥0.2 ng/mL). 68Ga-PSMA PET/CT was performed before esRT. Kaplan Meier curve depicts the BCR-free survival rates. Overall, 32 patients were excluded due to incomplete follow-up data, leading a final population of 689 men. Kaplan-Meier curves were plotted to assess BCR-FS and multivariate Cox regression model was used to assess independent predictors of BCR.

RESULTS: Overall, 262 (38%), 251 (36.4%), 121 (17.6%) and 53 (7.7%) patients revealed pT2R1, pT3aR0, pT3aR1 and pT3bR0 disease, respectively. Patients with R1 were 383 (55.6%). Considering R1 patients, a positive surgical margin ≥3 mm has been found in 59% of men. Gleason Grade at margin was 3, 4, 5 in 178 (46.1%), 139 (36%) and 5 (0.3%), respectively. Overall, 64 (9.3%) patients experienced BCR at median follow-up of 39 months. The median time to BCR was 15 months (IQR: 8-21), and the median PSA at BCR was 0.21 ng/mL (IQR: 0.18-0.32). Out of 64 patients with BCR, 60 (90%) were submitted to esRT. The BCR-FS at 5 years was 85.5%. Patients with pT2R1+ISUP 4-5 and those with pT3+ISUP 4-5 regardless margin status had significantly lower BCR-FS compared to men with pT2R1+ISUP 1-3 and pT3+ISUP 1-3 (namely, 90% and 70.6% vs. 94.5% and 75%; all P≤0.007). At multivariate analysis, pathologic ISUP 4-5 (HR=2.2) and pT3R1 (HR=2.56) were independent predictors of BCR (all P≤0.003).

CONCLUSIONS: Intense surveillance with PSA monitoring after RP and early detection of BCR with esRT can avoid 90% of potentially harmful aRT in patients with PCa with intermediate-high risk of recurrence disease. pISUP 4-5 and pT3aR1 status were independent predictors of BCR and should be considered in patients management.

SMART (SC337-SC347)

Kidney cancer 5

SC337
Feasibility of active surveillance in the management of Boniak IV renal cysts
SC338
Clinical benefit and cost-effectiveness of a biopsy-all strategy in patients diagnosed with renal mass: simulation of a randomized controlled trial
SC339
Effectiveness of radiomic tumor zone of transition features in the automated discrimination of oncocytoma from clear cell renal cancer
SC340
Prospective evaluation of interobserver variability of the spare and comparison with traditional nephrometry scores in patients undergoing robotic-assisted partial nephrectomy
SC341
The association between the mutation MET c.3328g>a p. Val1110Ile and renal cell carcinoma
SC342
Effect of race/ethnicity on survival in surgically-treated intermediate/high risk non-metastatic clear cell renal carcinoma
SC343
Temporal trends and utilization rates of lymph node dissection in patients with renal cell carcinoma: implications for adjuvant therapies
SC344
Best treatment for oligometastatic renal cancer: a quasi- individual patient data analysis
SC345
Minimally invasive anesthesia during laparoscopic partial nephrectomy: our initial experience
SC346
Perioperative and long-term oncological outcomes after local tumor ablation for complex (Padua score ≥10) ct1a renal tumors: a multicenter analysis
SC347
Active surveillance for very small renal masses: analysis from an observational-prospective trial (NCT03804320)

SC337
Feasibility of active surveillance in the management of Boniak IV renal cysts

E. Morini, D. Perri, F. Mazzoleni, A. Paulesu, U. Besana, A. Pacchetti, L. Berti, M.C. Sighinolfi, B. Rocco, S. Micali, A.S. Gozen, A.L. Pastore, E. Liatsikos, G. Bozzini (Como)

BACKGROUND: We performed a multicenter retrospective analysis of Bosniak IV renal lesions surgically removed in order to increase evidence supporting the feasibility of active surveillance in this setting.

METHODS: Forty-two patients with a single Bosniak IV renal cyst suspected of malignancy were considered. A preoperative contrast-enhanced computed tomography (CT) scan or magnetic resonance imaging (MRI) detected in all cases a solid component with contrast enhancement inside the cyst. Patients with a predominantly solid renal mass with a small cystic component were excluded. In no case a preoperative percutaneous biopsy was performed. A radical (9, 21.4%) or partial (33, 78.6%) nephrectomy was performed in all cases either with laparoscopic (14, 33.3%) or robot-assisted (28, 66.7%) approach. Preoperative data were collected, and analysis of the final pathology was performed. Patients were followed-up according to their prognostic factors. No specific predictive nomogram was used to schedule controls.

RESULTS: Mean lesion size was 54.7±32.6 mm. A solid tumor was detected in 40 patients overall (95.2%), whereas in 2 cases (4.8%) a benign cyst without the presence of a neoplastic component inside was diagnosed. Final pathology revealed a low-grade (Fuhrman 1-2) clear cell renal cell carcinoma (ccRCC) in 16 cases (38.0%), a multilocular cystic renal neoplasm of low malignant potential in 6 cases (14.3%), a papillary RCC (pRCC) type I in 4 cases (9.5%), a clear cell papillary RCC (ccpRCC) in 10 cases (23.8%) and an oncocytoma in 2 cases (4.8%). A high-grade (Fuhrman 3-4) ccRCC was detected in 2 cases (4.8%), whereas no patients had a pRCC type II. In all cases surgical margins were negative. Mean follow-up was 22.6 months and no local or systemic recurrence occurred.

CONCLUSIONS: Despite evidence regarding low malignant potential and good prognosis, surgery is still the recommended treatment for Bosniak IV renal cysts according to international guidelines. The results of our study increase evidence between Bosniak IV class and favorable histology, potentially supporting the role of active surveillance in this setting.

SC338
Clinical benefit and cost-effectiveness of a biopsy-all strategy in patients diagnosed with renal mass: simulation of a randomized controlled trial

F. Belladelli, C. Re, F. Cei, G. Musso, G. Fallara, G. Basile, G. Rosiello, D. Cignoli, D. Canibus, R. Bertini, A. Bertini, R. Lucianò, N. Tenace, A. Necchi, D. Raggi, L. Marandino, F. Montorsi, A. Salonia, A. Briganti, G. Guazzarotti, G. Brembilla, F. De Cobelli, U. Capitanio, A. Larcher, U. Capitanio (Milan)

BACKGROUND: In renal cancer, the indication for surgery upfront (SUR) without previous renal biopsy (RB) invariably results in the overtreatment of patients with benign histology. The aim of the study was to investigate the clinical benefit and cost-effectiveness of a biopsy-all strategy for patients with a renal mass.

METHODS: After exclusion of contraindications to RB (angiomyolipoma or cystic mass), 1680 patients with cT1-2 cM0 renal mass treated with SUR were included. To simulate a randomized clinical trial comparing patients SUR *vs.* RB and subsequent treatment based on RB histology, a random binary variable assigned patients to arm a-SUR and arm b-RB. In arm a-SUR, patients are all treated with SUR; postoperative complications and cost are those recorded after surgery. In arm b-RB, we have assumed a 0.8% uncertain RB histology rate and a 0.07% RB-related complication rate to build our simulation model. Patients are elected for RB and subsequently for SUR in case of malignant or uncertain RB histology; complications are those recorded after surgery in case of malignant or uncertain RB histology but 0% in case of benign histology. The average per-patient cost is defined as costs of RB + cost of SUR in case of malignant or uncertain RB histology but cost of RB only in case of benign histology. Health care expenditures related to surgery type and approach and post-procedural complication were imputed to build our simulation model. The outcomes of the study were rate of SUR avoided, the rate of Clavien-Dindo specific grade complications (CD) avoided and the net difference in per-patient cost in arm b-RB relative to arm a-SUR. Ten thousand individual iterations of the simulation model were performed and among all iterations, the median and mean value and 95% confidence interval (CI) were computed.

RESULTS: If a biopsy-all strategy is implemented, the expected rate of SUR avoided is 13.3%, the rate of CD1, CD2, and CD3 avoided is 2.8%, 2.3%, and 0.5%, respectively, and the average net difference in per-patient cost was 612 USA $.

CONCLUSIONS: The non-selective use RB in patients with renal mass avoid a significant number of SUR, a marginal but existing number of complications and is associated with decreased health care expenditures.

SC339
Effectiveness of radiomic tumor zone of transition features in the automated discrimination of oncocytoma from clear cell renal cancer

E. Balestrazzi, L. Bianchi, E. Tonin, P. Piazza, A. Mottaran, G. Carlini, C. Gaudiano, R. Golfieri, N. Curti, R. Schiavina, F. Giunchi, R. Bondi, D. Caruso, E. Giampieri, A. Merlotti, D. Dall'Olio, C. Sala, S. Pandolfi, D. Remondini, A. Rustici, L.V. Pastore, L. Scarpetti, B. Bortolani, E. Marcelli, F. Coppola, G. Castellani, E. Brunocilla (Bologna)

BACKGROUND: Benign renal tumors, such as renal oncocytoma (RO), can be erroneously diagnosed as malignant renal cell carcinomas (RCC), because of their similar imaging features. Computer-aided systems leveraging radiomic features can be used to better discriminate benign renal tumors from the malignant ones. The aim of this study was to build a machine learning model based on CT-derived radiomic features to discriminate RO from clear cell RCC (ccRCC), focusing on tumor zone of transition (ZOT) features capturing tumor characteristics which are usually overlooked.

METHODS: We collected CT images of 77 patients with a single T1a renal mass, who underwent partial nephrectomy at a single tertiary urologic center from January 2019 to December 2021. Radiomic features were extracted both from the tumor volumes identified by the clinicians and from

the tumor ZOT, after images segmentation performed to carry out 3D virtual model. We used a genetic algorithm (GA) to perform feature selection, identifying the most descriptive set of features for the tumor classification. We built a decision tree classifier to distinguish between ROs and ccRCCs. We proposed two versions of the pipeline: in the first one the feature selection was performed before the splitting of the data, while in the second one the feature selection was performed after on the training data only. We evaluated the efficiency of the two pipelines in the cancer classification.

RESULTS: Overall, 30 cases had RO (39%) and 47 cases had ccRCC (61%) confirmed at final pathologic specimens. The ZOT features were found to be the most predictive by the genetic algorithm. The pipeline with the feature selection performed on the whole dataset obtained an average ROC AUC score of 0.87±0.09. The second pipeline, in which the feature selection was performed on the training data only, obtained an average ROC AUC score of 0.62±0.17. In both cases, eight of the top ten selected features were tumor ZOT features.

CONCLUSIONS: The obtained results highlight the efficiency of tumor ZOT radiomic features in capturing the characteristics of pT1a renal tumors, and particularly in discriminating RO from ccRCC. The use of tumor ZOT features in radiomic analyses should be further investigated, as it may lead to important clinic implication with regards of better selection of patients for active treatment (surgery or ablation) *vs.* active surveillance.

SC340
Prospective evaluation of interobserver variability of the spare and comparison with traditional nephrometry scores in patients undergoing robotic-assisted partial nephrectomy

G. Garofano, C. Saitta, P. Diana, A. Uleri, E. Beatrici, F. Dagnino, A. Piccolini, G. Lughezzani, M. Lazzeri, R. Hurle, A. Saita, P. Casale, N.M. Buffi (Pieve Emanuele, Milan)

BACKGROUND: Robotic-assisted partial nephrectomy is now considered the gold standard for the treatment of small renal masses. Nephrometry scores have recommended in both European (EAU) and American (AUA) guidelines to be used before surgery in order to evaluate the complexity of the procedure. R.E.N.A.L. and PADUA score are traditional tools that have shown their efficacy in predicting complications, despite they show a low interobserver agreement. The new SPARE score was designed in order provide an easier-to-use tool compared to the traditional ones and only a few evidence are available regarding the precision of the scoring system. Aim of our study was to prospective evaluate SPARE interobserver variability and compare it with the PADUA and RENAL score.

METHODS: This is an analysis of our institutional prospective database on renal cancer. We enrolled consecutive patients undergoing RAPN between October 2019 and August 2022. Different statistical tests were used based on the distributions of the value of the parameters distinguishing between normal and not normal. The descriptive part of the analysis was carried out by computing absolute frequencies and percentages for the qualitative variables. For the quantitative analysis, mean and standard deviation were computed if the variable under consideration was normally distributed, while median and interquartile range (IQR) were used for variables not normally distributed. Two senior radiologists (R) and two senior urologists (U) were enrolled in reading and scoring each renal mass. Each evaluation was carried out blindly. Cohen's κ test was performed to test the agreement between urologist and radiologist to calculate each score.

RESULTS: One hundred eighty-one patients were enrolled. Of 181 patients, 109 were males; the median age was 59 years (IQR: 52-66). The median clinical size was 30 mm (IQR: 20-41). Median warm ischemia time was 12 minutes (IQR: 9-16); median estimated blood loss was 70 mL (IQR 37.5-100). Scores stratification according to R and U were as follows: PADUA (low risk 34% *vs.* 40.2%; intermediate 46.3% *vs.* 46.1; high risk 19.7% *vs.* 13,6%), RENAL (low risk 34.2% *vs.* 47.8%; intermediate risk 60.2% *vs.* 48.4%; high risk 5.6% *vs.* 3.8%), SPARE (low risk 59.3% *vs.* 68.1%; intermediate risk 34.1% *vs.* 28.6%; high risk 6.6% *vs.* 3.3%). SPARE, RENAL, and PADUA agreement were respectively 84.6%, 82.7% and 80% (P<0.001).

CONCLUSIONS: The SPARE Score has the statistically higher concordance rate between physicians belonging to different disciplines compared to both RENAL and PADUA scores. The SPARE Score appears to be more precise and reproducible, as well as easier to use.

SC341
The association between the mutation MET c.3328g>a p. Val1110Ile and renal cell carcinoma

M. Rinaldi, A. Porreca, A. Crestani, L. Di Gianfrancesco, A. Amodeo, E. Miglioranza, D. De Marchi, G. Lista (Castelfranco Veneto, Treviso)

BACKGROUND: Among the renal cell carcinomas, the most frequent is the clear cell carcinoma, followed by the papillary forms and finally by the chromophobic ones. An increased understanding of the molecular basis has driven an improvement in therapeutic options such as targeted therapy and immunotherapy. Von Hippel Lindau gene inactivation is frequently found in clear cell renal cell carcinoma (ccRCC), and other common mutations have also been identified including those of BAP-1, PBRM1, SETD2 and PIK3CA. Papillary renal cell carcinoma (pRCC) showed a high level of mutations in mesenchymal transition epithelial (MET) genes. Chromophobic renal cell carcinoma (chRCC) has also been shown to have association with mutations in the proto-oncogene MET, although much smaller than papillary forms. In pRCC the mutation of the MET gene (amplification/overexpression) may have an important role for the target therapy. In our study we report the histological results of patients who were subjected to research into the mutation of the oncogene MET.

METHODS: Fifty-eight patients were subjected to mutation MET c.3328G>A p. Val1110Ile research of the proto-oncogene MET. Among the patients presenting the mutation and subjected to surgical removal of renal cancer we collected histological results. Some of these patients have undergone more than one renal surgical treatment due to the presence of monolateral or contralateral recurrence and/or metacrine kidney tumors.

RESULTS: Twenty-six patients (44.8%) had wild type form of MET and 32 patients (55.2%) had the mutation MET c.3328G>A p.Val1110Ile. The patients with MET mutation

underwent enucleation, renal enucleoresection, partial or radical nephrectomy. Among these 32 patients, 8 patients (25%) had a papillary renal cell carcinoma (pRCC) type II, 17 (53.1%) had a pRCC type I, 5 (15.6%) had both type I and type II pRCC and 2 patients (6.3%) had a chromophobic RCC.

CONCLUSIONS: Our data, although on a small number of patients, suggest that *MET* is a gene often mutated in both type I and type II pRCC, with greater frequency in the type I. These results encourage further exploration of the benefit of targeted anti-MET therapies for the pRCC. Moreover, the expression of the mutation also in two cases of chromophobic RCC encourages any targeted therapies in chRCCs that show this mutation of the proto-oncogene MET.

SC342
Effect of race/ethnicity on survival in surgically-treated intermediate/high risk non-metastatic clear cell renal carcinoma

M.L. Piccinelli, G. Musi, C. Cano Garcia, A. Panunzio, S. Tappero, F. Barletta, R. Incesu, S. Luzzago, F.A. Mistretta, M. Ferro, Z. Tian, F. Saad, S. Shariat, M. Graefen, A. Briganti, C. Terrone, A. Antonelli, F. Chun, O. de Cobelli, P.I. Karakiewicz (Milan)

BACKGROUND: It is unknown to what extent 10-year overall survival of radical nephrectomy treated intermediate/high-risk nonmetastatic clear cell renal carcinoma patients differ from age- and sex-matched population-based controls, especially when race/ethnicity is considered (Caucasian *vs.* African American *vs.* Hispanic *vs.* Asian/Pacific Islander).

METHODS: We relied on the Surveillance Epidemiology and End Results database (2004-2018) to identify newly diagnosed (2004-2008) radical nephrectomy treated intermediate/high risk non-metastatic clear cell renal carcinoma patients. For each case, we simulated an age- and sex-matched control (Monte Carlo simulation), relying on Social Security Administration Life Tables with ten years of follow-up. We compared overall survival between radical nephrectomy treated intermediate/high risk non-metastatic clear cell renal carcinoma cases and population-based controls. Smoothed cumulative incidence plots displayed cancer-specific mortality *vs.* other-cause mortality. Multivariable competing risks regression models tested for predictors of cancer-specific mortality *vs.* other-cause mortality.

RESULTS: Of 6877 radical nephrectomy treated intermediate/high risk non-metastatic clear cell renal carcinoma patients, 5050 (73%) were Caucasian *vs.* 433 (6%) African American *vs.* 1002 (15%) Hispanic *vs.* 392 (6%) Asian/Pacific Islanders. At ten years, overall survival difference between radical nephrectomy treated intermediate/high risk nonmetastatic clear cell renal carcinoma patients *vs.* population-based controls was greatest in African Americans (51 *vs.* 81%, Δ=30%), followed by Hispanics (54 *vs.* 80%, Δ=26%), Asian/Pacific Islanders (56 *vs.* 80%, Δ=24%) and Caucasians (52 *vs.* 74%, Δ=22%). In competing risks regression, only African Americans exhibited significantly higher other cause mortality (hazard ratio: 1.3; 95% confidence interval: 1.1-1.6; P=0.01) than others.

CONCLUSIONS: Relative to Life Tables' derived sex- and age-matched controls, radical nephrectomy treated intermediate/high-risk non-metastatic clear cell renal carcinoma patients exhibit worse overall survival, with worst overall survival recorded in African Americans of all race/ethnicity groups.

SC343
Temporal trends and utilization rates of lymph node dissection in patients with renal cell carcinoma: implications for adjuvant therapies

D. Cignoli, G. Rosiello, G. Fallara, C. Re, F. Cei, G. Basile, G. Musso, D. Canibus, F. De Cobelli, G. Brembilla, R. Lucianò, N. Tenace, R. Matloob, R. Bertini, A. Briganti, F. Montorsi, A. Salonia, A. Larcher, U. Capitanio (Milan)

BACKGROUND: The role of lymph node dissection (LND) in renal cell carcinoma (RCC) patients is still controversial. Despite several studies demonstrated no survival benefits of LND in RCC, performing accurate LND may be still important for staging purposes, in the light of new emerging and promising adjuvant treatments in locally advanced disease. In this scenario, we aimed at assessing the trend of LND over the last 30 years.

METHODS: We relied on a prospectively maintained database including 2880 patients treated with radical (RN) or partial nephrectomy (PN) for non-metastatic RCC at a single high-volume center between 1990 and 2021. High-risk disease was defined as patients harboring pT3-4, and/or pN1 and/or Fuhrman grade 3-4 RCC. Temporal trend analyses using estimated annual percentages changes (EAPC) were performed. Multivariable logistic regression analyses (MVA) tested the effect of year of surgery on LND, after adjusting for age at surgery, clinical tumor size, clinical tumor stage, clinical nodal stage, type of surgery and surgical approach.

RESULTS: Overall, 2880 patients underwent either PN or RN for RCC. Of these, 1135 (39%) underwent LND, but only 161 (5.6%) showed pathologically confirmed LN invasion. Patients treated with LND were younger (61 *vs.* 63 years; P<0.001), more frequently symptomatic (51 *vs.* 24%; P<0.001), with higher clinical size (7 *vs.* 3.8 cm; P<0.001) and higher rates of suspicious cN+ disease (25 *vs.* 6.8%; P<0.001). Time trends analyses revealed a reduction in LND over time, both in the overall population (from 74 to 33%; EAPC: -3.7%; P<0.001) and in high-risk patients (from 72 to 50%; EAPC: -1.4%; P<0.001). Moreover, the median number of LNs removed also decreased over time, from 6 (interquartile range [IQR]: 3-5) to 2 (IQR: 1-4; P<0.001). At MVA, patients undergoing surgery for RCC in the most recent years were less likely to receive LND (OR=0.96; 95% CI: 0.95-0.98; P<0.001).

CONCLUSIONS: Over the last 30 years, the rates of LND performed in RCC patients significantly decreased over time. Such trend was also shown in high-risk patients, regardless of tumor characteristics or surgical approach. Given the importance of LND for staging purposes, the observed phenomenon may potentially increase the proportion of patients with unknown locally advanced disease at time of surgery and their inclusion in protocols for adjuvant therapies.

SC344
Best treatment for oligometastatic renal cancer: a quasi- individual patient data analysis

G. Fallara, G. Rosiello, A. Martini, G. Musso, F. Cei, C. Re, F. Belladelli, A. Necchi, D. Raggi, L. Marandino, R. Bertini, P.I. Karakiewicz, A. Mottrie, F. Montorsi, A. Briganti, A. Salonia, A. Larcher, U. Capitanio (Milan)

BACKGROUND: Oligometastatic renal cell carcinoma is a frequent diagnosis for which very few randomized con-

trol studies (RCTs) have been conducted and still represent a challenge for clinicians. Over the past few years, the results of two Phase I/II trials on this issue, the RESORT (sorafenib + SBRT) and the RAPPORT (pembrolizumab + SBRT) have been published. In addition, at ASCO23 the Kaplan Meier curves regarding the M1-NED group of the KEYNOTE-564 (surgery on metastases + pembro) has been presented. In this hypothesis generating work, we aimed to assess which of these approaches has the best outcomes.

METHODS: A comprehensive search for all published trials which included survival data on treatment for oligometastatic RCC was conducted in PubMed, EMBASE, Web of Science, and Scopus databases up to October 2022. We reconstructed the survival data from published Kaplan-Meier curves on overall survival (OS) meta-analyzed pembrolizumab + SBRT *versus* sorafenib + SBRT *versus* surgery pembro. The outcomes of interest were assessed using differences in restricted mean survival time (ΔRMST) at different time points and Cox regression.

RESULTS: Three studies were included in the final analysis (RESORT, RAPPORT and KEYNOTE-564). Overall, 91 patients were included in the meta-analysis. In all the trials, patients had histologically confirmed clear cell RCC (nephrectomy in all the patients out of 3/30 in the RAPPORT) with ECOG≤2 and a number of one to five sites of metastatic disease at the time of enrollment. The small number of patients and the incomplete reporting of data did not allow statistical meaningful comparison among the studies. Pembrolizumab + NED obtained the higher OS benefit (HR=0.37 compared to sorafenib + SBRT and 0.33 compared to pembro + SBRT, all P<0.05), with ΔRMST at 24 months of 1.4 months (1.0-1.8) compared with sorafenib +SBRT and of 1.2 months (0.9-1.3) compared to pembro + SBRT.

CONCLUSIONS: Despite lack of baseline differences, lack of power and presence of confounding, this hypothesis generating meta-analysis support the use of the combination of surgery + pembro for oligometastatic ccRCC.

SC345
Minimally invasive anesthesia during laparoscopic partial nephrectomy: our initial experience

J. Lauria, A. Piana, G. Zappalà, F. Chiaradia, A. Greco, F. Chiaravalloti, M. Di Dio, F. Porpiglia, S. Alba (Rocca di Neto, Crotone)

BACKGROUND: Since we entered in the "precision surgery era," a tailored organ sparing approach is frequently planned in order to provide a minimal anatomical impact along with ensuring optimal oncological outcomes. In this scenario, a new concept of being minimally invasive relies on the possibility of performing abdominal surgery using pneumoperitoneum while having the patient awake for minimizing the impact of anesthesia and thus accelerating postoperative recovery. The aim of this study was to assess the feasibility and safety of neuroaxial anesthesia (NA) during partial nephrectomy (PN).

METHODS: From May 2021 to September 2022, we performed laparoscopic transperitoneal PNs with NA in our Institution. We included organ-confined renal masses amenable of nephron sparing surgery in motivated patients with an acceptable performance status. Intraoperative vital parameters were constantly monitored, and patients were asked to alert the physicians whenever any discomfort occurred. Patients were informed about the possibility of switching to general anesthesia, if necessary. Pre- and postoperative data were collected. Follow-up data were registered.

RESULTS: 10 patients were prospectively enrolled in this study, 7 males and 3 females with a median age (IQR) of 70 years (64-76) and BMI 28 (25-31). Median (IQR) preoperative serum creatinine (sCr) level was 0.9 (0.8-1.1) mg/dL and hemoglobin (Hb) level was 14.4 (13.9-14.8) g/dL. Median (IQR) PADUA Score of the renal masses was 8 (7-9) with tumor size of 3 (3-3.7) cm. 8 (80%) cTa and 2 (20%) cT1b masses were treated. Four PNs, 3 enucleoresections and 3 enucleations with a median (IQR) warm ischemia time of 16 (15-20) minutes (min) and operative time of 150 (134-181) min were performed. From a surgical point of view, procedures appeared not to be affected by the anesthesia performed. A case of bleeding from resection bed was recorded and needed an intraoperative blood transfusion. One Clavien-Dindo 1 postoperative complication (Hb drop) was observed and managed conservatively. Patients were eating normally at the end of the same day of the operation and were able to stand up and walk during the following day. Median (IQR) postoperative length of stay was 4 days (3-5) with a sCr at discharge of 1.0 (0.8-1.3) mg/dL and Hb of 11.6 (10.8-12.4) g/dL. At final pathology, 1 pT3a, 1 pT1b and 7 pT1a RCCs were observed. One the masses was an oncocytoma. All specimens were R0. Median (IQR) sCr level at 6 month was 0.9 (0.85-1) mg/dL. With a median (IQR) follow-up of 6 (3-9) months, no relapses, complications or disease progressions were observed, and all the patients were alive.

CONCLUSIONS: We aimed to describe a new concept of minimally invasive surgery. The clinical impact in terms of faster postoperative recovery without side effects of general anesthesia while not compromising the results of surgery seems considerable and might expand the indication for surgery in fragile patients.

SC346
Perioperative and long-term oncological outcomes after local tumor ablation for complex (PADUA Score ≥10) ct1a renal tumors: a multicenter analysis

P. Piazza, L. Bianchi, S. Luzzagi, M. Bandini, A. Mottaran, S. Amirassankhani, B. De Concilio, A. Celia, C. Serra, A. Cappelli, R. Golfieri, G. Musi, A. Gallina, M. Rizzo, G. Liguori, C. Trombetta, F. De Cobelli, G. Mauri, F. Orsi, U. Capitanio, R. Schiavina, O. De Cobelli, F. Montorsi, E. Brunocilla (Bologna)

BACKGROUND: Complex renal masses have a non-negligible risk of perioperative complications due to their inherent anatomical characteristics. Local tumor ablation (LTA) could be a useful tool to approach these tumors in patients unfit for surgery or with hampered renal function. However, oncological and perioperative outcomes of these patients remain underreported. The aim of this study was to report the perioperative and long-term oncologic outcomes of LTA (including radiofrequency ablation [RFA], Cryoablation [Cryo], Microwave ablation [MW]) for complex masses (PADUA Score ≥10).

METHODS: We retrospectively evaluated 102 patients treated with LTA for complex (PADUA≥10) cT1a renal tumors at 5 European tertiary centers. Categorical and continuous variables were reported as proportions and median±interquartile ranges (IQR), respectively. Multivariable logistic regression

was used to identify predictors of postoperative complications. Kaplan-Meier estimate was used to investigate 5-year recurrence free survival (RFS). Multivariate Cox's proportional hazard regression was used to identify predictors of local recurrence.

RESULTS: Overall, 40 (39%), 37 (36%) and 25 (25%) patients underwent RFA, Cryo and MW ablation, respectively. Of those, 55 (54%), 24 (24%), 22 (22%) and 1 (1%) had a PADUA Score of 10, 11, 12 and 13, respectively. Median tumor size was 3 (2.2-3.7). At biopsy, 71 (70%), 12 (12%), 3 (3%) and 2 (2%) had clear cell, papillary, chromophobe and mixed renal carcinoma, respectively. In the perioperative period, 26 (25%) patients experienced postoperative complications. At multivariable logistic regression, the use of RFA (OR=2.56, 95% CI: 1.58-8.6, P=0.045) was the only independent predictor of perioperative complications. During a median follow-up of 60 months (IQR 49-87), 22 (24%) and 9 (12%) patients experienced local and systemic recurrence, respectively, with a 5-years RFS of 57.3%. At multivariable Cox's analysis, papillary histology (HR=0.15, 95% CI: 0.01-0.88, P=0.032) was the only independent predictors of RFS.

CONCLUSIONS: LTA is a viable treatment even for patients with complex (PADUA≥10) renal masses, who are considered at higher risk for surgery. However, patients should be accurately counseled due to the higher rates of complication and disease recurrence.

SC347
Active surveillance for very small renal masses: analysis from an observational-prospective trial (NCT03804320)

G. Musso, W. Cazzaniga, F. Castiglione, A. Larcher, A. Nini, C. Carenzi, L. Villa, G. Conti, C. Maccagnano, C. Simeone, A. Antonelli, E. Montanari, G. Albo, R. Salvioni, S. Stagni, M.A. Catanzaro, F. Montorsi, U. Capitanio, R. Bertini (Milan)

BACKGROUND: Small renal masses (SRMs) have become increasingly common due to the extensive adoption of imaging exams. Numerous treatment approaches such as surgical interventions, tissue ablation and active surveillance have all been proved to play a role in the management of SRMs. In this study, we report the updated descriptive results from this prospective, non-randomized, multi-institutional protocol for the active surveillance of SRMs≤2 cm.

METHODS: The protocol has been introduced in April 2014 in 5 Italian centers. Patients with monolateral SRM (£ 2 cm of diameters), with more than 50 years of age and without symptoms related to the mass have been enrolled in the protocol. Patients with previous history of renal cancer, single kidney, hereditary tumors, presence of metastasis, immunodepressant therapy or with a life expectancy lower than 1 year have been considered not eligible. All the patients underwent a standardized follow-up scheme and collection of urine and blood samples for the creation of a biobank of biological samples.

RESULTS: To date, 65 patients have been enrolled in the protocol, 2/65 (3.1%) have dropped out from the study and 0/65 have died in the study period and 2/65 were lost at FU. The mean follow-up time was 29.0 months (SD=11.16). No patients have developed symptoms or paraneoplastic syndromes during the follow-up period. At the enrolment, the mean linear diameter was 1.3 cm (SD=0.36), and the mean volume was 1.8 cm^3 (SD=1.22). The mean annual increase in the linear growth has been 0.15 cm/year and the mean annual increase in the volumetric growth has been 1.00 cm^3/year. 3/61 (6%) have been submitted to percutaneous biopsy and the cause was the tumor growth. Overall, 4/61 (6.2%) patients have required active treatment.

CONCLUSIONS: Our preliminary data suggests the feasibility and the safety of the introduction of an active surveillance protocol for small renal masses. Also in our experience, this approach may represent a valuable option to offer to patients older than 50 years old and diagnosed with a SRM £ 2 cm. The biomolecular aspects of these masses will be evaluated in future studies.

SMART (SC348-SC363)

Prostate cancer: staging

SC348
Impact of radiologist expertise on PIRADS distribution and detection of clinically significant prostate cancer: results from a single, high-volume center

SC349
Improving prediction of local stage by PSMA-PET: development of a novel integrated tool for extracapsular extension and seminal vesicle invasion combining clinical and imaging features in localized prostate cancer

SC350
PSMA-PET for recurrent prostate cancer and guidance of salvage treatments: is the sooner always the better ("shoot blind" or "sharpshooting")?

SC351
Which men with CN1 prostate cancer at PSMA PET/CT represent the ideal candidate to radical prostatectomy? Development of a novel risk stratification tool for individualized approaches based on a large, multi-institutional series

SC352
PSMA-PET in high-risk prostate cancer patients suitable for radical treatments: scenario of detection and clinical impact for staging setting

SC353
Comparison between preoperative GA68-PSMA PET lymph nodes involvement, in intermediate/high-risk prostate cancer, and histopathological lymphadenectomy results after robotic-assisted radical prostatectomy

SC354
The prognostic role of preoperative PSMA PET/CT for men with cN0M0 conventional imaging and pN+ prostate cancer: a multicenter study

SC355
Comparison of four validated nomograms (Memorial Sloan Kettering Cancer Center, Briganti 2012, 2017, and 2019) predicting lymph node invasion in patients with high-risk prostate cancer candidates for radical prostatectomy and extended pelvic lymph node dissection

SC356
Identifying the optimal candidates for a super-extended staging pelvic lymph-node dissection in prostate cancer patients treated in the PET-PSMA era: results from a multi-institutional series

SC357
Real-life performance of imaging *vs.* nomograms for the assessment of lymph-node involvement in prostate cancer: should we trust radiology?

SC358
Defining the most informative intermediate clinical endpoint in patients treated with metastasis directed therapy for a positive 68GA-PSMA PET/CT after biochemical recurrent prostate cancer. results of a large, single-institution series

SC359
Overall survival of metastatic prostate cancer patients according to location of visceral metastatic sites

SC360
Development of a microultrasound-based nomogram to predict extracapsular extension in patients with prostate cancer undergoing robot-assisted radical prostatectomy

SC361
Peritumoral inflammation in prostate biopsy core predict biochemical recurrence after active treatment for prostate cancer

SC362
Computer-aided diagnosis in prostate cancer: a retrospective evaluation of the Watson Elementary® system for preoperative tumor characterization in patients treated with robot-assisted radical prostatectomy at a tertiary referral center

SC363
Are EAU risk groups to stratify men with biochemical recurrence after radical prostatectomy reliable in patients restaged with PSMA-PET?

SC348
Impact of radiologist expertise on PIRADS distribution and detection of clinically significant prostate cancer: results from a single, high-volume center

F. Pellegrino, A. Stabile, G. Gandaglia, V. Cucchiara, E. Mazzone, R. Leni, G. Sorce, S. Scuderi, F. Barletta, D. Robesti, A. Pellegrino, M. De Angelis, L. Quarta, P. Zaurito, G. Brembilla, E. Zaffuto, A. Esposito, F. De Cobelli, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Radiologist experience has an important role on prostate mpMRI diagnostic accuracy. However, it is still unclear whether radiologist expertise may have an impact on PIRADS distribution and detection of clinically significant prostate cancer (csPCa). Here, we assessed the relationship between radiologist expertise and detection of csPCa according to change in PIRADS distribution.

METHODS: We identified 352 consecutive patients undergoing mpMRI, which were read by three uro-radiologists. All patients with a positive MRI (PIRADS score ≥3) received MRI-targeted biopsy. The outcome was the detection of csPCa at prostate biopsies. We plotted the proportion of each PIRADS score against radiologist experience (defined as the progressive number of scans performed) using the LOWESS function. Multivariable model (MVA) was used to assess whether radiologist experience was associated with the risk of csPCa in patients with positive MRI. We then plotted the risk of csPCa by radiologist experience and PIRADS scores, using the LOWESS function.

RESULTS: Overall, 265 patients (75%) had a positive mpMRI. PIRADS 3, 4, and 5 were found in 16, 36, and 23%, respectively. The proportion of PIRADS 3 decreased from 35 to 20% according to radiologist experience. Conversely, the proportion of PIRADS 4 and 5 increased from 23 to 38%, and 38 to 43%, respectively. At MVA, radiologist experience was associated with a higher risk of csPCa at biopsy in patients with positive MRI (OR=1.01, P<0.01), after accounting for PIRADS score and other confounders. Fig 1b plots the probability of csPCa by radiologist experience, which shows increasing detection of csPCa for each incremental PIRADS score. csPCa for PIRADS 4 and 5 lesions was constant after 100 mpMRIs, whereas the risk of csPCa for PIRADS 3 lesions increased during the study period.

CONCLUSIONS: We confirmed that radiologist experience affects MRI accuracy in detecting csPCa. Suspicious MRI scans reported by experienced radiologists are more likely to harbor csPCa. Radiologists reach a learning curve plateau after roughly 100 MRIs. Moreover, the proportion of PIRADS 3 lesions are less common among mpMRI scans reported by experienced radiologists, supporting the prevalence of PIRADS 3 as a proxy of a radiologist expertise.

SC349
Improving prediction of local stage by PSMA-PET: development of a novel integrated tool for extracapsular extension and seminal vesicle invasion combining clinical and imaging features in localized prostate cancer

S. Scuderi, G. Gandaglia, F. Barletta, L. Bianchi, F. Zattoni, F. Dal Moro, G. Reitano, P. Rajwa, N. Hübner, S. Shariat, C. Kesch, C. Darr, W. Fendler, J. Gomez-Rivas, J. Moreno-Sierra, G. Marra, H. Guo, J. Zhuang, D. Amparore, E. Checcucci, F. Porpiglia, R. Schiavina, E. Brunocilla, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Validated models predicting extracapsular extension (ECE) and seminal vesicle invasion (SVI) based on clinical parameters and mpMRI are available for prostate cancer (PCa) patients undergoing radical prostatectomy (RP). However, their performance in the PSMA era are still unknown, where the inclusion of PSMA-PET might improve their discrimination.

METHODS: One hundred ninety-five patients staged with PSMA PET scan and treated with RP±pelvic lymph node dissection (pLND) at 9 referral centers between 2016 and 2022 were identified. Men with nodal or extra-nodal spots at PSMA PET and those who received neoadjuvant treatments were excluded. Two existing models predicting ECE and SVI based on preoperative PSA, clinical stage, ISUP Grade Group at mpMRI, ECE and SVI at mpMRI, the maximum diameter of the index lesion at mpMRI, and the percentage of cores with significant PCa at systematic biopsy were externally validated. Logistic regression analyses tested whether intraprostatic SUV_{max} was associated with ECE and SVI at final pathology. We then developed a new model predicting pathological ECE (model 1) and SVI (model 2) based on the coefficients of the previously mentioned variables with the addition of SUV_{max} at PSMA PET. Calibration plots, ROC-derived Area Under the Curve (AUC), and decision-curve analyses (DCAs) determined the calibration, discrimination, and net benefit of the new models.

RESULTS: The median SUV_{max} was 12. Overall, 128 (66%) and 34 (18%) patients had ECE and SVI after RP. The existing model's discrimination was 72% for ECE and 78% for SVI at external validation. Nonlinear associations between SUV_{max} and ECE and between SUV_{max} and SVI were observed using non-parametric curves. Two nomograms based on the new model including SUV_{max} considered as a restricted cubic spline showed higher discrimination for ECE (81 *vs.* 72%) and SVI (90% *vs.* 78%), and a higher net benefit compared to the available ones. Using a nomogram cut-off of 80%, the sensitivity and specificity for ECE were substantially higher for model 1 (44% and 96%) than for mpMRI alone (31% and 94%). Moreover, for model 2, a 40% cut-off led to higher sensitivity for SVI than mpMRI (61% *vs.* 52%, respectively), with similar specificity (92% *vs.* 95%).

CONCLUSIONS: Two novel predicting models including SUV_{max} values showed higher performances in the prediction of ECE and SVI after RP than the currently available ones. These models showed increased sensitivity for ECE and SVI when compared to mpMRI alone.

SC350
PSMA-PET for recurrent prostate cancer and guidance of salvage treatments: is the sooner always the better ("shoot blind" or "sharpshooting")?

M. Droghetti, L. Bianchi, E. Balestrazzi, F. Ceci, F. Costa, A. Pissavini, M. Presutti, R. Scarlatti, L. Lampariello, A. Farolfi, R. Mei, P. Castellucci, S. Puliatti, G. Gandaglia, A. Larcher, A. Mottrie, A. Briganti, A.G. Morganti, S. Fanti, F. Montorsi, R. Schiavina, E. Brunocilla (Bologna)

BACKGROUND: Prostate specific membrane antigen-positron emission tomography (PSMA-PET) is currently

recommended to restage prostate cancer (PCa) and to guide the delivery of salvage treatments. Metastases-directed therapy (MDT) however takes a positive PET to be done which often comes at higher PSA levels, potentially worsening outcomes compared to early salvage treatments. We aimed to evaluate the oncologic outcomes of patients with recurrent PCa according PSMA-PET results.

METHODS: Data of 134 hormone-sensitive PCa with first PSA relapse after radical prostatectomy who underwent PSMA-PET in 3 high-volume European Centres were retrospectively analyzed. Patients with oligorecurrent (≤3 lesions) PSMA-positive disease underwent PSMA-directed treatments: whole pelvis salvage radiotherapy (sRT) plus MDT (including stereotactic body radiotherapy [SBRT]). Patients with polirecurrent (>3 lesions) PSMA-positive disease were treated with combinations of systemic therapies. Patients with negative PSMA-PET were treated with whole pelvis sRT or systemic therapies or observation according to the treating physician preferences. Progression-free survival (PFS) was evaluated through Kaplan-Meier curves, according to PSMA-PET results and compared with log-rank test. Multivariable Cox regression models explored the impact of PSMA-PET results on PFS. Model was adjusted for pathological stage, ISUP grade and PSA level at PET scan.

RESULTS: Median follow-up after PSMA-PET was 15 (4-30) months. Overall, 69 (51.5%) patients were found positive at PSMA-PET. Men with positive PSMA-PET had more advanced disease (pT3a-b: 82.6 *vs.* 52.3%), higher lymph node involvement (38% *vs.* 18.5%), worse ISUP grade (ISUP 4-5: 65.2% *vs.* 30.8%) and higher median PSA at PET (0.8 *vs.* 0.33 ng/mL) as compared to negative ones (all P<0.01). Overall, 6/69 (8.7%) patients had a polimetastatic disease at first recurrence, while 63 were oligometastatic (91.3%). Median number of positive spots was 2 (1-3). The PFS estimates at 2 years were 75.6% *vs.* 48.7% in patients with negative *vs.* positive PSMA-PET, respectively (P=0.3). After adjusting for confounders, at multivariable analyses PSMA-PET result didn't show up to be an independent predictor for higher risk of disease progression after salvage therapies (HR=1.07; 95% CI: 0.87-1.34; P=0.5).

CONCLUSIONS: Considering pathological stage, ISUP grade and PSA levels at recurrence, having a positive PSMA-PET at first recurrence is not related with poor prognosis. These findings might suggest a more important role for MDT even in the first recurrence setting.

SC351
Which men with CN1 prostate cancer at PSMA PET/CT represent the ideal candidate to radical prostatectomy? Development of a novel risk stratification tool for individualized approaches based on a large, multi-institutional series

M. Longoni, F. Barletta, E. Mazzone, G. Gandaglia, L. Bianchi, R. Schiavina, L. Afferi, A. Mattei, F. Zattoni, G. Reitano, P. Rajwa, S. Shariat, C. Kesch, L. Ibañez, J. Gomez-Rivas, G. Marra, H. Guo, J. Zhuang, D. Amparore, E. Cisero, F. Porpiglia, M. Picchio, E. Checcucci, N. Huebner, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Limited data is available to identify men who would benefit the most from radical prostatectomy (RP) in prostate cancer (PCa) patients with clinical lymphadenopathies (cN+) at PSMA PET and, on the other hand, to select patients for proper management. We aimed at assessing predictors of early recurrence in surgically managed PCa patients with cN+ at PSMA PET scan by integrating clinical, magnetic resonance imaging (MRI) and PET parameters.

METHODS: We identified 662 patients treated with RP and lymph node dissection who received preoperative PSMA PET between 2017 and 2022 at nine referral centers. We selected 93 patients with positive nodal uptake at preoperative PSMA PET. The study outcome was PSA persistence, defined as a PSA≥0.1 ng/mL at first postoperative measurement. Multivariable logistic regression tested predictors of persistence. Covariates consisted of biopsy ISUP grade group (IGG) (2-3 *vs.* 4-5), stage at MRI (organ-confined disease [OC] *vs.* extracapsular extension [ECE] *vs.* seminal vesicles invasion [SVI]) and number of positive spots at PET scan. Regression tree analysis stratified patients into risk groups based on their preoperative characteristics.

RESULTS: Median number of positive spots at preoperative PET was 2. LNI was detected in 64 patients (69%). Comparing PSMA PET and final pathology, concordance of positive nodes location was 85%. 32 patients (34%) experienced PSA persistence after RP. At multivariable analyses, biopsy IGG 4-5 represented the strongest predictor of PSA persistence (OR=2.44; P=0.001). At regression tree analysis, patients were stratified in four risk group according to IGG, number of positive spots at PET and stage at MRI. This model depicted a good discrimination (AUC=78%). Notably, patients in high and very-high risk groups showed higher PSA persistence (62 and 83%, respectively) compared to low-risk group (27%).

CONCLUSIONS: Patients with IGG 2-3, as well as patients with IGG 4-5 but with OC or ECE at MRI and a single positive spot at PET are those where RP may achieve the best oncological. Conversely, patients with high GG and SVI or >1 spots at PSMA PET should be considered as potentially affected by a systemic disease upfront.

SC352
PSMA-PET in high-risk prostate cancer patients suitable for radical treatments: scenario of detection and clinical impact for staging setting

A. Pissavini, L. Bianchi, M. Droghetti, M. Pugliese, M. Presutti, R. Scarlatti, E. Balestrazzi, S. Tamburini, L. Lampariello, C. Mignogna, R. Mei, A. Farolfi, L. Vetrone, F. Serani, L. Calderoni, M. Ntreta, A.G. Morganti, R. Schiavina, P. Castellucci, S. Fanti, E. Brunocilla (Bologna)

BACKGROUND: PSMA-PET improves the diagnostic performance in staging high-risk PCa patients. However, no data are available concerning the potential benefit of treatment changes due to PSMA-PET. We aimed to depict the scenario of positive PSMA-PET distribution in high-risk PCa patients scheduled for radical approach, the treatment's changes and the impact of effective treatments performed according to PSMA-PET.

METHODS: Patients were enrolled according to the following criteria: histopathologic diagnosis of high-risk PCa suitable for radical treatment and PSMA-PET performed for staging proposal. We analyzed the overall detection rate stratified according to miTNM staging and the clinical impact of PSMA-PET on the intention-to-treat based on PSMA-PET findings: 1) major treatment's change was defined as the tran-

sition from radical prostatectomy (RP) to radiotherapy (RT) and vice versa or from radical treatments to systemic therapies and vice versa; and 2) minor treatment's change was defined as any additional treatment to those planned. The effective treatments are described according to PSMA-PET results.

RESULTS: Overall, 207 high-risk PCa patients were enrolled. Overall, 175 patients had available data concerning treatments after PMSA-PET. Prior to PSMA-PET, the scheduled treatment was: 149 (85.1%) RP±ePLND, 17 (9.7%) RT+ADT and 9 (5.1%) systemic treatments, respectively. After PSMA-PET, the effective treatments consisted in 131 (75%) RP±ePLND; 2 (1%) RP+ePLND+SBRT; 23 (13%) RT+ADT; 2 (1%) RT+SBRT+ADT, 17 (10%) systemic treatment (ADT±docetaxel/ARTA). Overall, 19 (10.9%) patients had major treatments change, while 3 (1.7%) had minor treatment's change. Considering miM1 patients, 20 (69%), 3 (10.3%) and 6 (20.7%) underwent RP+ePLND±SBRT, RT±SBRT+ADT and systemic treatments, respectively. Out of the 20 miM1a-b patients who underwent surgery, only 4 (20%) had PSA persistence and were treated with SBRT target to positive PSMA-PET spots, while 16 (80%) had undetectable PSA after surgery alone.

CONCLUSIONS: PSMA-PET for staging high-risk PCa patients increase the detection of distant suspicious lesions. The overall effective treatment change by PSMA-PET is approximately 10%; however, still we do not know whenever findings of PSMA-PET should be taken into account for treatment change.

SC353
Comparison between preoperative GA68-PSMA PET lymph nodes involvement, in intermediate/high-risk prostate cancer, and histopathological lymphadenectomy results after robotic-assisted radical prostatectomy

G. Spena, T.B.C. Moretti, F.S. Dávila, F.P. Calace, A. Tufano, V. Mirone, S. Perdonà, A. Izzo, K. Maes (Naples)

BACKGROUND: The aim of this study was to evaluate the strength of PET-PSMA as a preoperative staging exam and its usefulness to predict lymph nodes involvement in order to best plan lymph node dissection.

METHODS: Fifty patients who underwent 68Ga-PSMA PET/CT and following radical prostatectomy plus robotic lymphadenectomy were included in this retrospective analysis. Nuclear medicine doctor considered the standardized uptake value (SUV) of the metastatic lesions. Diagnostic tests were performed through per-patient analysis in a 2×2 table with ePLND results considered as the gold standard and PET/PSMA as a diagnostic method to be tested. Correlation analysis between continuous variables were performed using the Spearman's Rank Test.

RESULTS: The clinical characteristics of the 50 patients included in the analysis showed a mean age of 63.3 years (SD=8.2), a median total PSA of 7.7 ng/dl (IQR=5.4), and 44% were classified in the staging biopsy as ISUP≥4 and 28% as pT3. Patients were recruited during 5 years from 2018 to 2022. Descriptive and comparative analysis of the global population and separated into two groups (pN0 or pN1) was performed. Among them, 43 patients (86%) submitted to ePLND did not present lymph node metastases (pN0), and 8 patients (14%) were positive for locoregional lymph node metastases (pN1). A low prevalence of patients with positive nodes (16%) was found, reducing the value of PPV (28.6%) and increasing of NPV (86.0%). In this sample, PET-PSMA showed low sensitivity in detecting lymph node disease (S=25%) and good ability to exclude disease (E=88.1%). There was a significant positive correlation between the Total SUV_{max} of the prostate with initial total PSA (r=0.38; P=0.019) and the percentage of tumor involvement (r=0.383; P=0.022).

CONCLUSIONS: Despite PET-PSMA is an excellent study to identify extraprostatic disease, has a high accuracy in excluding lymph node involvement and may be a good option as preoperatory staging, it is not yet validated to limit the performance of lymphadenectomy in patients with intermediate/high risk prostate cancer or high predictive nomograms score. The positive correlation between SUV and prostate involvement indicates that PET-PSMA could reflect, with a good approximation, the pathological features of the prostate.

SC354
The prognostic role of preoperative PSMA PET/CT for men with cN0M0 conventional imaging and pN+ prostate cancer: a multicenter study

G. Montefusco, P. Rajwa, C. Filippini, G. Ploussard, I. Puche-Sanz, J. Olivier, F. Zattoni, F. Dal Moro, A. Magli, C. Dariane, A. Affentranger, J.B. Grogg, T. Hermanns, P.K. Chiu, B. Malkiewicz, K. Kowalczyk, R.C. Van den Bergh, S.F. Shariat, A. Bianchi, A. Antonelli, S. Gallina, W. Berchiche, R. Sanchez-Salas, X. Cathelineau, L. Afferi, C.D. Fankhauser, A. Mattei, R.J. Karnes, S. Scuderi, F. Montorsi, A. Briganti, M. Oderda, P. Gontero, G. Gandaglia, G. Marra (Turin)

BACKGROUND: Up to 10% of patients with negative preoperative conventional staging harbor lymph-node positive (pN+) prostate cancer (PCa) at radical prostatectomy (RP); the optimal management of these patients is still unknown. The advent of new imaging modalities such as PSMA PET/CT, are increasing detection of lymph-node involvement. However, their clinical impact and prognostic value remains not yet clear. We aimed to investigate the prognostic value of preop PSMA PET/CT in patients with cN0M0 conventional imaging subsequently found with pN+ PCa at RP.

METHODS: We retrospectively identified cN0M0 patients at conventional imaging (CT and/or MRI, and bone scan) who were diagnosed with pN+ PCa at RP at 17 referral centers. Patients with cN+ at PSMA/Choline PET/CT but cN0M0 at conventional imaging were also included. Our primary outcome was systemic progression. Cox proportional hazards model were used for multivariate analysis.

RESULTS: We included 1163 men. ISUP grade was ≥4 in 66.6%. Overall, 42% of patients had postop PSA persistence (≥0.1 ng/mL). Postoperative management included initial observation (34%), ADT (22.7%) and adjuvant RT±ADT (42.8%). Median follow-up was 42 months. Patients with cN+ on PSMA PET/CT had an increased risk of systemic progression (52.9% *vs.* 13.6% cN0 PSMA PET/CT *vs.* 27% cN0 at conventional imaging only; P<0.01); cN+ PSMAPET/CT was associated to an increased risk of systemic progression on multivariate analysis (HR=5.179, 95% CI: 2.781-9.645; P<0.001). No significant associations for PET types were found for local progression, biochemical recurrence and overall mortality (all P>0.05). Observation as an initial management strategy instead of adjuvant treatments was related with an increased risk of distant metastases (HR=1.804; 95% CI: 1.045-3.113; P<0.05).

CONCLUSIONS: PSMA PET/CT cN+ patients with negative conventional imaging may have an increased risk of systemic progression after RP. Further studies are needed to confirm our findings and assess the benefit from radical treatment and/or multimodal adjuvant therapy in these men.

SC355
Comparison of four validated nomograms (Memorial Sloan Kettering Cancer Center, Briganti 2012, 2017, and 2019) predicting lymph node invasion in patients with high-risk prostate cancer candidates for radical prostatectomy and extended pelvic lymph node dissection

G. Di Pierro, S. Salciccia, M. Frisenda, A. Tufano, A. Sciarra, E. Scarrone, F. Del Giudice, V. Asero, G. Bevilacqua, M. Moriconi, A. Carbone, A. Pastore, S. Signore, P. Bove, F. Forte, P. Emiliozzi, A. Tubaro, C. De Nunzio, V. Canale (Rome)

BACKGROUND: The indication for extended pelvic lymph node dissection (ePLND) at the time of radical prostatectomy (RP) is based on nomograms predicting the risk of lymph node invasion (LNI). However, limited data are available on the comparison of these predictive models in high-risk prostate cancer (PC) patients. Therefore, the aim of our study was to compare the accuracy of the most used nomograms (MSKCC, Briganti 2012, 2017, and 2019) in the setting of high-risk PC patients who underwent ePLND+RP.

METHODS: One hundred fifty patients with high-risk PC disease from 2019 to 2022 were included. Before RP, we assessed the MSKCC, Briganti 2012, 2017, and 2019 nomograms for each patient and we compared the prediction of LNI with the final histopathological analysis of the ePLND. Pearson correlation analysis was performed; regression coefficients were used to calculate risk of LN positivity; sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were assessed.

RESULTS: Mean age was 64.7 years, mean preoperative total PSA=17.0ng/mL, 71.3% of patients were cT2, 84% were cN0. LNI was found in 39 patients (26%). After RP, 26.2% was pT2, 45.1% was pT3a, 28% was pT3b. Mean number of removed lymph nodes was 23.8 in pN0 e 25.0 in pN+. Considering nomograms' results as continuous variables, mean±SD estimated risk for pN+ showed some differences among MSKCC (33.5±19.7), Briganti 2012 (26.1±19.7), Briganti 2017 (43.3±25.4) and Briganti 2019 (24.9±20.0) nomograms, even though their results did not show statistically significant differences between pN0 and pN+ patients (P>0.08; 0.20; 0.09 and 0.10, respectively. Seventy-four percent of patients with MSKCC estimated risk >7% showed pN0 compared to 71% with Briganti 2012 >5%, 69% with Briganti 2017 >7% and 70% with Briganti 2019 >7%. The percentage of patients at risk of LNI, according to Briganti Nomogram (2012, 2017, and 2019), was significantly higher in pN+ cases than in pN0 (reaching 100% for Briganti 2012, P<0.03), while MSKCC prediction did not vary significantly between pN0 and pN+ groups (P=0.2). All nomograms showed high sensitivity (Se>0.90), low specificity (Sp<0.20) and similar AUC (range: 0.526-0.573) in predicting pN+. PPV was 0.248, 0.285, 0.352 and 0.301, respectively, for MSSKC, Briganti 2012, 2017 and 2019. pT stage, ISUP grading and surgical margins significantly correlated with pN status. At multivariate analysis only pT3a and pT3b significantly increased the risk of pN+, respectively of 6 and 11 times (P=0.005; P=0.002).

CONCLUSIONS: Although we considered only high-risk PC cases eligible for ePLND, a high percentage of them continues to show no LNI at final histopathology. We observed similar predictive value in terms of LNI estimation among the four most frequently used validated nomograms, with similar high sensitivity but low specificity.

SC356
Identifying the optimal candidates for a super-extended staging pelvic lymph-node dissection in prostate cancer patients treated in the PET-PSMA era: results from a multi-institutional series

D. Robesti, F. Barletta, G. Gandaglia, L. Bianchi, R. Schiavina, L. Afferi, A. Mattei, F. Zattoni, G. Reitano, P. Rajwa, S. Shariat, C. Kesch, J. Gomez Rivas, G. Marra, H. Guo, J. Zhuang, D. Amparore, E. Cisero, F. Porpiglia, M. Picchio, F. Montorsi, A. Briganti (Milan)

BACKGROUND: An extended pelvic lymph node dissection (ePLND) represents the gold standard for nodal staging in prostate cancer (PCa). However, patients with higher risk of lymph-node invasion (LNI) at final pathology might benefit from a staging super-extended PLND (sePLND) given the risk of nodal metastases in the common iliac and/or presacral sites. However, these results have been obtained in pre-PSMA era. We hypothesized that PET-PSMA findings might improve the identification of candidates for a sePLND.

METHODS: We relied on 662 PCa patients with PET-PSMA performed before RP treated at 9 referral centers between 2016 and 2022. Patients receiving neoadjuvant treatments were excluded. We identified 57 men with PET-PSMA detected suspicious nodal pelvic lesions (cN1) who underwent sePLND at the time of radical prostatectomy (RP) with complete data. The sePLND was defined as a LND including the presacral and common iliac nodal landing sites. The outcome was LNI in the common iliac and/or presacral stations. Preoperative risk of LNI was calculated using the Briganti nomogram. Uni- and multivariable logistic regression (MLR) models tested the association between the number of positive nodes at PET-PSMA (1-2 vs. >2) and common iliac and/or presacral positive nodes after accounting for baseline risk of LNI.

RESULTS: Overall, 38 (66%) patients exhibited pN1 disease while 10 (18%) had LNI in the common iliac or presacral landing sites. The median preoperative risk of LNI and the number of positive nodes at PET-PSMA were 23% (9-40%) and 2 (1-3). After stratification according to the preoperative LNI risk, the positivity rates in the common iliac and/or presacral nodes were 15 and 22% in patients with an LNI risk ≤30% and >30%. When stratifying according to the number of positive nodes at PET-PSMA, the rates of LNI in the common iliac and/or presacral stations were 6 and 35%, in patients with 1-2 and >2 positive nodes at imaging. In MLR models, the number of positive nodes at PET-PSMA (namely >2 vs. 1-2; OR=7.81, P=0.019) achieved independent predictor status for LNI in the common iliac and/or presacral nodal regions after adjusting for the risk of LNI.

CONCLUSIONS: The extent of nodal burden at PET-PSMA was associated with higher risk of LNI in the common iliac and/or presacral landing sites. Patients with >2 suspicious lymph nodes at PET-PSMA are those who could benefit the most from a staging sePLND regardless of the baseline risk of LNI.

SC357
Real-life performance of imaging vs. nomograms for the assessment of lymph-node involvement in prostate cancer: should we trust radiology?

F. Chierigo, G. Felici, A. Porcaro, N. Pavan, D. Amparore, R. Bertolo, C. A. Bravi, G. Bozzini, C. Trombetta, E. Mearini, E. Montanari, P. Ditonno, A. Simonato, P. Bove, C. De Nunzio, A. Tubaro, R. Schiavina, E. Brunocilla, A. Antonelli, A. Galosi, A. Mottrie, F. Porpiglia, C. Terrone, M. Borghesi (Genoa)

BACKGROUND: The aim of this study was to assess the performance of different imaging modalities and nomograms for lymph node staging in clinical node positive (cN1) prostate cancer (PCa) patients treated with radical prostatectomy (RP) and pelvic lymph node dissection (PLDN).

METHODS: We relied on a multicentric database of 336 consecutive cN1 patients from 16 Academic institutions treated with RP+PLND from 2009 to 2022. We calculated sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy and AUC (Youden's J) of abdominal CT scans, MRIs, Choline-PET, PSMA-PET, Briganti's nomogram and Gandaglia's nomogram. For both nomograms, a cut-off of nodal involvement of 7% was used to define clinical lymph node positivity, according to previous literature.

RESULTS: Overall, median age was 67 years, median PSA at diagnosis was 10 ng/mL and harbored biopsy grade group 1, 2, 3, 4, and 5 in respectively 12%, 14%, 21%, 32% and 21%. LND was extended to obturator + external iliac artery (OA+EIA) in 21%, to internal iliac artery (OA+EIA+IIA) in 29%, until common iliac artery (OA+EIA+IIA+CIA) in 28%, and to presacral artery (OA+EIA+IIA+CIA+PreSA) in 22%. At final pathology, 193 (57%) patients were pN0 vs. 143 (43%) pN1. Sensitivity for CT, MRI, Choline-PET, PSMA-PET, Briganti and Gandaglia was 75% (67-82%), 16% (10-23%), 4% (1-8%), 13% (8-19%), 94% (87-98%), and 94% (85-98%), respectively. Specificity for CT, MRI, Choline-PET, PSMA- PET, Briganti and Gandaglia was 26% (20-33%), 84% (78-89%), 97% (94-99%), 85% (80-90%), 29% (21-39%), and 28% (19-38%), respectively. Performance, measured by Youden's J, was 51% (50-51%), 50% (50-51%), 50% (50-51%), 49% (48-49%), 62% (61-63%), and 61% (60-62%) for respectively CT, MRI, Choline-PET, PSMA-PET, Briganti and Gandaglia.

CONCLUSIONS: Our study suggests that clinical nodal staging in PCa is still suboptimal. In this context, Briganti's and Gandaglia's nomograms, when used to define cN1 PCa, might outperform imaging modalities. Therefore, nomograms should be considered in treatment planning, even outside the surgical context.

SC358
Defining the most informative intermediate clinical endpoint in patients treated with metastasis directed therapy for a positive 68GA-PSMA PET/CT after biochemical recurrent prostate cancer. Results of a large, single-institution series

G. Cirulli, E. Mazzone, G. Gandaglia, A. Stabile, D. Robesti, A. Necchi, D. Raggi, L. Marandino, S. Scuderi, F. Barletta, M. de Angelis, E. Balestrazzi, S. Fanti, V. Cucchiara, A. Farolfi, L. Bianchi, R. Schiavina, N. Fossati, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Metastasis directed therapy (MDT) represents a potential curative treatment for positive PSMA-PET patients with biochemical recurrence (BCR) of prostate cancer (PCa) after radical prostatectomy (RP). Since long-term follow-up is still needed to evaluate the effect of MDT in this setting, we aimed at identifying the most informative intermediate clinical endpoint (ICE) after MDT in a large single center series of patients with BCR of PCa and a positive PSMA PET.

METHODS: We retrospectively identified 226 patients evaluated with 68Ga-PSMA PET/CT for BCR after RP between 2016 and 2022 who had positive spots. MDT was delivered in 109 (48%) patients and consisted of stereotactic ablative radiation therapy (SABR) on positive spots, either nodal, bony or visceral. Salvage radiotherapy (sRT) was delivered according to the judgement of each treating physician. PSA was measured every 3 months after MDT. Biochemical recurrence (BCR) was defined as a first post-MDT PSA higher than pre-MDT PSA, or a PSA rise of 25% from the nadir after MDT, as previously published. CR was defined as any new metastases detected at imaging after a first PSMA PET/CT. Associations of BCR within 3, 6, and 12 months after MDT with the risk of CR were evaluated using multivariable Cox regression analyses at 3, 6, and 12 months after MDT. The discriminative ability of each model for predicting CR was assessed using Harrell's C Index. Covariates consisted of adverse pathological features (*i.e.*, grade group 4-5 with ≥pT3a stage and/or lymph node invasion), oligometastatic status (≤3 *vs.*≥3 mets) and sRT use.

RESULTS: Overall, 76 patients (69%) had adverse pathological features and 25 patients (23%) received additional sRT at MDT. Median follow-up for survivors was 30 months after the PSMA PET/CT. Overall, 37 patients had CR, while 42 experienced BCR after MDT. The 3-year CR-free survival rate was 51% since MDT. At 3, 6, and 12 months, 100, 86 and 64 patients, respectively, were alive and not censored. At Cox analyses, progression to BCR within 6 months from MDT (HR=4.70, P<0.001) was the most informative ICE for predicting CR (C Index 0.75) compared to BCR within 3 and 12 months (C Index: 0.71, and 0.67).

CONCLUSIONS: We demonstrated that progression to BCR within 6 months after MDT represents the most informative ICE for prediction of CR. This information could be applied for future study design and could potentially support earlier release of results from ongoing randomized controlled trials.

SC359
Overall survival of metastatic prostate cancer patients according to location of visceral metastatic sites

S. Tappero, F. Barletta, M.L. Piccinelli, S. Morra, S. Parodi, P. Dell'Oglio, C. Palumbo, A. Briganti, O. de Cobelli, N. Longo, F. Saad, S.F. Shariat, N. Suardi, M. Borghesi, C. Terrone, P.I. Karakiewicz (Genoa)

BACKGROUND: It is unknow whether specific locations of visceral metastatic sites affect overall survival (OS) of metastatic prostate cancer (mPCa) patients. We tested the

association between specific locations of visceral metastatic sites and OS in mPCa patients.

METHODS: Within Surveillance, Epidemiology and End Results database (2010-2016), survival analyses relied on specific locations of visceral metastases: lung only *vs.* liver only *vs.* brain only *vs.* ≥2 visceral sites. Kaplan-Meier plots and Cox regression models were fitted.

RESULTS: Of 1827 patients, 1044 (57%) harbored lung only visceral metastases *vs.* 457 (25%) liver only *vs.* 131 (7%) brain only *vs.* 195 (11%) ≥2 visceral sites. Median OS was 22 months in all patients *vs.* 33 months in lung only *vs.* 15 months in liver only *vs.* 16 months in brain only *vs.* 15 months in patients with ≥2 visceral sites. Highest OS was recorded in lung only visceral metastases patients, especially when concomitant non-visceral metastases were located in lymph nodes only (median OS=57 months) *vs.* bone only (26 months) *vs.* lymph nodes and bone (28 months). Liver only, brain only or ≥2 visceral sites exhibited poor OS, regardless of concomitant non-visceral metastases type (median OS from 13 to 19 months).

CONCLUSIONS: In mPCa patients, lung only visceral metastases, especially when associated with lymph node only non-visceral metastases, portend the best prognosis. Conversely, visceral metastatic sites other than lung portend poor prognosis, regardless of concomitant non-visceral metastases type.

SC360
Development of a microultrasound-based nomogram to predict extracapsular extension in patients with prostate cancer undergoing robot-assisted radical prostatectomy

N. Frego, R. Contieri, D. Maffei, V. Fasulo, P.P. Avolio, P. Arena, G. Chiarelli, E. Beatrici, F. Sordelli, F. De Carne, F. Dagnino, M. Aljoulani, A. Saita, M. Lazzeri, N.M. Buffi, P. Casale, G. Lughezzani (Rozzano, Milan)

BACKGROUND: The identification of prostate cancer (PCa) patients at higher risk of extracapsular extension (ECE) at robot-assisted radical prostatectomy (RARP) is essential for preoperative treatment planning, guiding the plane of dissection and the grade of nerve-sparing (NS). We aimed to build a nomogram including clinicopathological parameters and microultrasound (mUS) findings to predict non-organ confined disease.

METHODS: Data of consecutive patients undergoing RARP between September 2020 and October 2021 were prospectively collected. All patients underwent mUS the day prior to RARP and the operators were blinded for both mpMRI and biopsy results. ECE on definitive pathology was the primary outcome. Variables significantly associated with ECE at univariable analysis were used to build the logistic multivariable models, and the regression coefficients of the model with the higher Area Under the Receiver Operating Curve (AUC) were used to develop the nomogram. Calibration plot was used to assess the extent of over- and under-estimation of the model. The model was subjected to 1000 bootstrap resamples for internal validation. The performance of the microUS model were evaluated using the AUC of the ROC curve, calibration plot, and Decision Curve Analysis (DCA). Sensibility, specificity, and negative predictive value (NPV) for each cut-off was evaluated.

RESULTS: Overall, 98/244 patients showed signs of ECE at mUS assessment before RARP, and 107/244 (43.8%) cases had a diagnosis of ECE on definitive pathology. MicroUS correctly identify ECE in 75/107 cases showing a sensitivity and a specificity of 76.5% and 78.1%, with an AUC of 76.6%. The mUS-based nomogram for the prediction of ECE had an AUC of 83.5%. The calibration plot showed a satisfactory concordance between predicted probabilities and observed frequencies of ECE, with a slightly tendency to underestimation. After 1000 bootstrap resamples, the predictive accuracy of the model was 82.5%. DCA showed a higher clinical net-benefit compared to the model including only clinical parameters. Considering a 5% cut-off NS was recommended in 143 (58.6%) patients and EPE was detected in 31 (21.7%) of them; while among the 101 (41.4%) patients where NS was not recommended organ-confined disease was documented in 25 (24.7%) patients. Finally, among patients with positive surgical margins at final pathological examination, 31 (62%) out of 50 cases were above the 5% threshold.

CONCLUSIONS: We developed a mUS-based nomogram for the prediction of ECE. Its high accuracy and NPV make it a promising tool in planning the surgical approach. External validation and a direct comparison with mpMRI-based nomogram is crucial to corroborate our results.

SC361
Peritumoral inflammation in prostate biopsy core predict biochemical recurrence after active treatment for prostate cancer

F. Guzzi, U. Falagario, A. Fanelli, A. Ninivaggi, L. Montrone, O. Selvaggio, P. Annese, G.M. Busetto, C. Bettocchi, F. Sanguedolce, G. Carrieri, L. Cormio (Foggia)

BACKGROUND: The relationship between prostate inflammation (PI) and prostate cancer is still unclear. In order to evaluate the prognostic role of PI on BPH (Benign prostatic hyperplasia) symptoms and prostate cancer outcomes we recently developed the Prostate Inflammation Score (PIS) as a readily available parameter that can be assessed by the pathologist during microscopic evaluation of the prostate. This study aimed to assess the association of the PIS with biochemical recurrence after radical prostatectomy.

METHODS: Since 2013, we prospectively enrolled all patients undergoing prostate biopsy at our institution in this observational study. Grade and aggressiveness of prostatic inflammation were prospectively assessed by a dedicated uropathologist. The PIS (prostate inflammation score) was used to categorize patients in 3 group, routed on the dual classification of grade and aggressiveness of prostatic inflammation described by Irani et al.: 1) PIS 1 – no inflammatory cells or scattered inflammatory cell infiltrate without nodules; 2) PIS 2 – interstitial Inflammatory cell infiltrate organized in lymphoid nodules but no glandular disruption; and 3) PIS 3 – interstitial infiltrate with glandular disruption. For the present study we included all those patients with a positive prostate biopsy who consequently underwent radical prostatectomy and were followed-up with repeated PSA measurements. Patients with detectable PSA after surgery were excluded. Biochemical recurrence defined as PSA≥0.2 ng/mL in two consecutive measurements was our primary outcome. Competing risk regression was used to evaluate predictors of BCR, Kaplan Mayer method to estimate BCR free survival (BCRFS).

RESULTS: A total of 4065 patient were screened. Five hundred ninety-five patients were ultimately included and stratified by the PIS (prostatic inflammation score) into 3 groups. The average follow-up time was 32 months. Patients with PIS 1 (N.=439) were younger and with lower prostate volumes compared to PIS 2 (N.=101) and PIS 3 3 (N.=52) patients. No difference was found in Gleason Score, clinical stage, and PSA at diagnosis. Five-year BCRFS was 80%, 90% and 95% for patients with PIS 1, PIS 2 and PIS 3 respectively (P=0.0025). At multivariable Cox regression analysis adjusting for age, Gleason Score, clinical stage and PSA at diagnosis, HAZARD ratios for BCRFS were 0.40 (95% CI: 0.18,0.87) and 0.20 (95% CI:0.05,0.83) for patients with PIS 2 and 3 respectively compared to PIS 1 patients.

CONCLUSIONS: Peritumoral inflammation assessed by the prostate inflammation score in prostate biopsy cores is associated with Biochemical recurrence after RP and may represent a readily available parameter to improve prediction of aggressiveness of prostate cancer and its clinical evolution.

SC362
Computer-aided diagnosis in prostate cancer: a retrospective evaluation of the Watson Elementary® system for preoperative tumor characterization in patients treated with robot-assisted radical prostatectomy at a tertiary referral center

M. Bacchiani, A. Mari, S. Giudici, A. Cadenar, E. Massaro, A. Sandulli, V. Salamone, A.A. Grosso, M.R. Raspollini, L. Righi, S. Agostini, F. De Nisco, L. Masieri, A. Minervini, G. Vittori (Florence)

BACKGROUND: This study aimed to evaluate the performance of the Watson Elementary® ([WE®] Oncology Systems Limited, Shrewsbury, UK) computer-aided diagnosis (CAD) system in detecting and characterizing prostate cancer (PCa) in patients undergoing robot-assisted radical prostatectomy (RARP) at a tertiary referral center.

METHODS: A total of 61 patients who underwent RARP at this institution between 2020 and 2022 were included. The WE® system (Oncology Systems Limited) analyzed multiparametric-magnetic resonance imaging (mpMRI) data to calculate the Malignancy Attention Index (MAI) and predict the presence of PCa, the location and size of the dominant lesion, and the likelihood of extraprostatic extension (EPE). The results of the WE® system (Oncology Systems Limited) were compared with the pathological data obtained by an expert uro-pathologist who was blinded to the mpMRI and WE® results (Oncology Systems Limited). Positive and negative agreements between mpMRI and WE® (Oncology Systems Limited) were calculated, and the accuracy of WE® (Oncology Systems Limited) and mpMRI in determining the largest diameter of the pathologic lesion was compared using the Wilcoxon Signed Rank Test. The relationship between MAI, ADC, Gleason Grade, and EPE was analyzed using point-biserial and Pearson's product-moment correlations.

RESULTS: At pathological evaluation, 54/61 patients presented a clear dominant lesion of PCa. The WE® system (Oncology Systems Limited) identified an intraprostatic red area in 50 (82%) PCa cases, while in 11 cases WE® (Oncology Systems Limited) did not obtain a positivity. The overall positive agreement between WE® (Oncology Systems Limited) and mpMRI was 92%. The sensitivity and specificity of WE® (Oncology Systems Limited) in detecting EPE were 81.3% and 56.4%, respectively, while the positive predictive value and negative predictive value were 87.4% and 42.9%, respectively. The corresponding values for mpMRI were 71.3%, 60.7%, 84.2%, and 39.8%, respectively. The WE® system (Oncology Systems Limited) showed a 2.54 mm median delta of diameter with pathology in determining the largest diameter of the pathologic lesion, compared with a 3.9 mm of mpMRI *versus* pathology. The median diameter of the dominant lesion was 16.7 mm at pathology, 15.5 mm at WE® (Oncology Systems Limited), and 15.1 mm at mpMRI assessment. The correlation analysis showed that the quantitative WE® (Oncology Systems Limited) parameter MAI of the dominant lesion was not significantly correlated with Gleason risk group or tumor EPE. The correlation of mpMRI with Gleason risk group and tumor EPE was lower compared to WE® (Oncology Systems Limited). The analysis of apparent diffusion coefficient (ADC) of the dominant lesion at mpMRI showed a not significant correlation with both Gleason risk group and tumor EPE. The positive and negative predictive values of the WE® system (Oncology Systems Limited) in predicting the presence of PCa were 98.3% and 75.4%, respectively, while the corresponding values for mpMRI were 93.8% and 66.8%, respectively.

CONCLUSIONS: The WE® system (Oncology Systems Limited) is accurate in detecting, localizing, and characterizing the dominant lesion of PCa in patients undergoing RARP. The system provides additional information concerning EPE prediction and may improve the detection and characterization of PCa.

SC363
Are EAU risk groups to stratify men with biochemical recurrence after radical prostatectomy reliable in patients restaged with PSMA-PET?

G. Gandaglia, D. Robesti, E. Mazzone, A.M. Samanes Gajate, A. Stabile, V. Cucchiara, L. Quarta, P. Zaurito, A. Pellegrino, S. Scuderi, F. Barletta, F. Pellegrino, G. Sorce, E. Zaffuto, U. Capitanio, A. Necchi, D. Raggi, M. Picchio, L. Gianolli, F. Montorsi, A. Briganti (Milan)

BACKGROUND: The EAU prostate cancer (PCa) guidelines introduced risk groups to stratify men with biochemical recurrence (BCR) after surgery. However, they do not account for PSMA-PET, which is recommended in this setting. We aimed to assess the rates of positive PET after BCR and to evaluate the prognostic role of BCR risk groups.

METHODS: Overall, 299 men restaged with PSMA-PET at PSA persistence or BCR after radical prostatectomy (RP) between 2016 and 2022with BCR risk groups information were identified. Patients were restaged during follow-up according to the judgement of the treating physician. Clinical recurrence (CR) was defined as any new metastases after PET. Kaplan-Meier analyses assessed the impact of the risk groups vs. PET (negative vs. local recurrence, prostatic fossa and pelvis, vs. distant recurrence) on CR-free survival. The accuracy of multivariable models including risk groups vs. PET was assessed using the c-index after accounting for salvage therapies. Decision-curve analyses assessed the net benefit associated with models including EAU BCR risk groups vs. PET.

RESULTS: Overall, 58 (19.4%) vs. 241 (80.6%) patients were low- vs. high-risk according to the BCR risk groups and 199 (66.6%) patients had a positive PET. Median PSA at PET was 0.7 ng/mL (0.5 vs. 0.7 ng/mL for low vs. high-risk). Median PSA doubling time was 8 months. Overall, 57% vs. 21% patients had a negative vs. positive PET, 24 vs. 12% received salvage radiotherapy, 0% vs. 43% received MDT and 19% vs. 23% received systemic therapies in low and high-risk groups. Overall, 67.2% vs. 66.4% patients had a positive PSMA-PET in low vs. high-risk (P=0.5). The rate of local and distant spots at PET was 29.3% and 37.9% vs. 22. 2% and 43.6% in low vs. high-risk patients (P=0.5). Median follow-up was 16 months and 87 patients had CR. No differences were detected in 2-year CR-free survival according to risk groups (58% vs. 65%, P=0.6). When patients were stratified according to PET, the 2-year CR-free survival rates were 75.2% vs. 54.3% (P<0.01). A positive PET (HR=2.3; P=0.01) but not the BCR risk groups (P=0.8) was associated with CR. The inclusion of PET improved the discrimination of models predicting CR (53% vs. 65%) with a higher net benefit.

CONCLUSIONS: In patients staged with PSMA-PET, the EAU risk groups lose their prognostic importance. More than 60% of men with low risk BCR had positive PET which was significantly associated with higher risk of CR. When imaging is available, PET overrules the prognostic impact of clinical risk stratification of BCR.

SMART (SC364-SC369)

Andrology 3

SC364
The risk of cardiovascular and cerebrovascular disease in men with a history of priapism
SC365
Association between priapism and HIV disease and treatment
SC366
Surgical and functional outcomes of urethral lengthening in the context of genital gender affirming surgery in AFAB patients
SC367
Sexual satisfaction in transgender women undergoing peritoneum-vaginoplasty: comparison of techniques
SC368
Scrotovaginoplasty with peritoneal flap reduces the risk of cystitis in transexual women who previously had undergone to surgical sexual assignment surgery
SC369
Surgical and functional outcomes following total penile reconstruction with split-thickness skin graft for buried penis

SC364
The risk of cardiovascular and cerebrovascular disease in men with a history of priapism

E. De Berardinis, V. Asero, C.M. Scornajenghi, P. Dipinto, A. Sciarra, S. Basran, M.L. Eisenebrg, B.I. Chung, E. Mulloy, F. Del Giudice (Rome)

BACKGROUND: Priapism is a debilitating condition that affects sexual function. As a majority of cases are idiopathic, investigators have hypothesized underlying vascular dysfunction which may predispose men to priapism. We sought to determine if men are at risk for other sequelae of vascular dysfunction such as cardiovascular and thromboembolic disease after a priapism event.

METHODS: Using a large commercial insurance claims data warehouse, we evaluated all men (age ≥20) with a diagnosis of priapism from 2003-2020 and matched them to a cohort of men with other urological disorders of sexual dysfunction (erectile dysfunction, Peyronie's disease, and premature ejaculation). We identified incident disease (cardiovascular disease, heart disease, embolism, thrombosis, cerebrovascular disease) for all cohorts.

RESULTS: A total of 10,459 men with priapism were identified and were matched to men with erectile dysfunction, Peyronie's disease, or premature ejaculation. The mean age was 51.1 years old. Men with priapism showed increased incidence of heart disease, both ischemic (HR=1.24, 95% CI: 1.09-1.42) and other heart disease (HR=1.24, 95% CI: 1.12-1.38) in the years following the priapism diagnosis. Incident cerebrovascular disease was also more likely in men with a history of priapism (HR=1.33, 95% CI: 1.15-1.55). Men requiring treatment for ischemic priapism had a higher hazard of cardiovascular and cerebrovascular disease. In addition, men with more priapism episodes had a higher rate of cardiovascular disease and thromboembolic events.

CONCLUSIONS: Men with priapism are at increased risk for cardiovascular and cerebrovascular events in the years following a priapism.

SC365
Association between priapism and HIV disease and treatment

E. De Berardinis, V. Asero, C.M. Scornajenghi, P. Dipinto, A. Sciarra, S. Basran, M.L. Eisenebrg, B.I. Chung, F. Del Giudice (Rome)

BACKGROUND: We sought to identify medical conditions and pharmaceutical treatments that are associated with priapism using data-mining techniques.

METHODS: Using deidentified data in a large insurance claims database, we identified all men (age ≥20 years) with a diagnosis of priapism from 2003 to 2020 and matched them to cohorts of men with other diseases of male genitalia: erectile dysfunction, Peyronie disease, and premature ejaculation. All medical diagnoses and prescriptions used prior to first disease diagnosis were examined. Predictors were selected by random forest, and conditional multivariate logistic regressions were applied to assess the risks of each predictor.

RESULTS: An overall 10,459 men with priapism were identified and matched 1:1 to the 3 control groups. After multivariable adjustment, men with priapism had high associations of hereditary anemias (Odds Ratio [OR]=3.99; 95% CI: 2.73-5.82), use of vasodilating agents (OR=2.45; 95% CI: 2.01-2.98), use of HIV medications (OR=1.95; 95% CI: 1.36-2.79), and use of antipsychotic medications (OR=1.90; 95% CI: 1.52-2.38) as compared with erectile dysfunction controls. Similar patterns were noted when compared with premature ejaculation and Peyronie disease controls.

CONCLUSIONS: Using data-mining techniques, we confirmed existing associations with priapism (*e.g.*, hemolytic anemias, antipsychotics) and identified novel relationships (*e.g.*, HIV disease and treatment).

SC366
Surgical and functional outcomes of urethral lengthening in the context of genital gender affirming surgery in AFAB patients

I. Ferro, M. Falcone, M. Preto, L. Cirigliano, F. Peretti, N. Plamadeala, M. Scavone, C. Ceruti, P. Gontero (Turin)

BACKGROUND: Genital gender affirming surgery is a rarely addressed topic in scientific literature. Among the most delicate phases of this surgery there is urethral reconstruction. The purpose of our study was to present surgical and functional results of urethral reconstruction within the framework of genital affirmation surgery in AFAB patients.

METHODS: A retrospective monocentric cohort study was conducted. From 2015 to 2022, 80 patients underwent metoidioplasty or phalloplasty in our center, and 33 of them subsequently underwent urethral lengthening. Outcomes and postoperative complications have been reported. Furthermore, four questionnaires were administered to patients: CCO-EPIC, ICIQ-SF to evaluate a patient's urinary function, BDI (scale of depression) and a questionnaire with six items approved by Ethics Committee of University of Turin.

RESULTS: Thirty-three patients were included in the study. Eleven underwent metoidioplasty (group 1), while 22 underwent phalloplasty with different techniques (group 2). The descriptive characteristics between the two groups were found to be comparable, except for BMI resulting greater in group 2 (P=0.02) and smoke, which resulted more frequent in group 2 (P=0.04). Average follow-up was 10 months (IQR: 4-20). No intraoperative complications have been detected. Forty-two percent of the patients had postoperative complications. The different incidence of complications between the two groups did not result to be statistically significant (P=0.08). The most frequent complications observed were urinary fistulas. 85% of the fistulas healed spontaneously with conservative treatment. Overall, only 6 patients (18%) needed a re-do surgery do address urethral surgical complications. From a functional point of view, confronting CCO-EPIC and ICIQ-SF before and after 1 year from surgery, there was a worsening in both tests (10% and 31% of the total score). BDI score did not show significant difference before and after surgery. Despite the test scores, 85% of the patients after 1 year follow-up were satisfied of the procedure and 85% declared that surgery had a positive impact on their quality of life.

CONCLUSIONS: Urinary reconstruction in genital gender affirmation surgery is still burdened by high complication rates, but it is an important element which can contribute to the psychological well-being of AFAB patients. These outcomes have to be confirmed by multicentric studies, with more patients involved and a more extended follow-up.

SC367
Sexual satisfaction in transgender women undergoing peritoneum-vaginoplasty: comparison of techniques

E. Sollazzi, M. Boccadamo, F. Carli, G. Tornabene, A. Zucchi, R. Bartoletti, A. Perotti (Pisa)

BACKGROUND: Penile inversion vaginoplasty is currently the most widely used and reliable surgical technique for surgical sex affirmation in transsexual women. In some cases, this technique cannot be used, due to the lack of native penile and scrotal tissue or following obliteration of the neovagina as a post-surgical complication. Up to now in these cases there was an indication to perform colovaginoplasty, a very complex surgical operation that can be burdened by even very serious complications and cannot always be performed. We therefore proposed to these patients the execution of peritoneovaginoplasty, instead of colovaginoplasty.

METHODS: Between 2018 and 2021, we selected 19 transgender patients with no comorbidities or history of abdominal or pelvic surgery. Peritoneovaginoplasty was proposed to patients who would have been instructed to perform a colovaginoplasty. These patients were compared with those undergoing traditional vaginoplasty. All patients were evaluated 6 months after surgery. We assessed general sexual satisfaction, the quality of orgasm, the speed of reaching orgasm, the number of sexual intercourse and genital erogenous sensitivity, by completing an online questionnaire.

RESULTS: The mean age of the patients was 37 years (range: 22-66). All the elements evaluated (general sexual satisfaction, quality of orgasm, speed of reaching orgasm, number of sexual intercourse and genital erogenous sensitivity), were significantly improved compared to before surgery, with no statistically differences between the two groups (traditional vaginoplasty *vs.* peritoneovaginoplasty).

CONCLUSIONS: Since all the parameters evaluated were found to be superimposable, the peritoneovaginoplasty can therefore be considered an excellent surgical alternative to be offered to patients with the need for extension of the neovagina, instead of colovaginoplasty. In fact, peritoneovaginoplasty has shown to be, in our study, a technique with excellent results, comparable to the technique that represents the gold standard (penile inversion vaginoplasty), but it is not burdened by all the complications of the colovaginoplasty.

SC368
Scrotovaginoplasty with peritoneal flap reduces the risk of cystitis in transexual women who previously had undergone to surgical sexual assignment surgery

G. Macrì, A. Perotti, E. Sollazzi, A. Zucchi, M. Pacini, F. Gregori, R. Bartoletti (Pisa)

BACKGROUND: In order to investigate the potential role of the urethral length and the circulating estrogen serum levels as risk factors for the recurrence of cystitis in transgender women who previously had undergone to sexual affirmation surgery with two different methods of neovaginal reconstruction.

METHODS: Forty consecutive transgender women were investigated in a retrospective observational study (RetroCT SAPLT 2019/896@dsbmc.uniroma1.it). Patients who had had cystitis before surgery, infectious comorbidities, or conditions of defective immune integrity were excluded. The number of episodes of cystitis before and after the starting of estrogen therapy and the trans gender sexual affirmation surgery were evaluated. Moreover, differences between patients who received simple scrotovaginoplasty or scroto-peritonealvaginoplasty were also investigated.

RESULTS: 21/40 patients were excluded from the study because not fulfill the exclusion criteria or refused a urine culture test in the case of cystitis. 19/40 transsexual women were evaluated. Seventy-four percent of them experienced significant UTIs after surgery; *E. coli* was the bacterial strain most frequently isolated. The number of infective episodes was greater in patients who had at least 10 or more sexual intercourse for month. (3 *vs.* <1 episodes per year). The administration of estrogenic therapy did not impact on the frequency of cystitis episodes. However, patients who had undergone to simple scrotovaginoplasty had a significant greater number of episodes of cystitis than the group that who received scroto-peritonealvaginoplasty (P=0.033).

CONCLUSIONS: The prevalence of cystitis in transexual women is due to the urethral shortening and the number of sexual intercourses per month. Peritoneal vaginoplasty has a protective effect against urinary infections.

SC369
Surgical and functional outcomes following total penile reconstruction with split-thickness skin graft for buried penis

A. Buffardi, M. Graziani, A. Gillo, F. Bardari, M. Silvani, E. Berdondini (Turin)

BACKGROUND: Buried penis is a relatively rare condition that causes the penis to become hidden beneath the skin. It has a significant impact on quality of life and can present in a variety of ways, with lower urinary tract symptoms and erectile dysfunction being common. We present our experience of total penile reconstruction for buried penis.

METHODS: We report our experience of 5 patients with buried penis treated from 2019 to 2022. The inclusion criteria were buried penis while the exclusion criteria were the presence of penile cancer. Diagnostic workup was based on medical history, physical examination and in the case of urethral stricture urethrocistography was made. Follow-up included outpatient medical review, physical examination, and uroflowmetry. Success was defined as the restoration of the penis, the recovery of sexual function and the restoration of urinary flow in pts who underwent urethroplasty.

RESULTS: Mean age was 63 years (range: 60 to 68). All patients referred impossibility to sexual intercourse and 2 patients reported LUTS due to urethral stricture of the distal penile urethra. The cause was Lichen sclerosus (LS) in 3 patients and previous penile surgery in 2 patients. The LS disease was confirmed by a histologic exam. The median skin graft harvested from the thigh was 7 cm (5 to 10 cm). Median operative time was 130 min (range 100 to 180 min) All patients were treated with split-thickness skin graft (STSG) for penile reconstruction. Two patients also underwent first-stage urethroplasty by Johanson's technique, while 1 patient underwent abdominoplasty. No perioperative and postoperative complications occurred. All patients were discharged on

the third postoperative day. The catheter was left in place for 5 days. Median follow-up of 23 months (range: 12-32 months). All 5 patients restored sexual function and good quality of life three months after surgery The 2 patients with urethral stricture gain a good urinary flow.

CONCLUSIONS: The main principles of male genital reconstruction are the excision of all the diseased skin and coverage of the defect. STSG is easy to harvest, and it is free from hairs. However, the drawbacks are the possibility of infection and necrosis. STSG represents a good solution for patients with buried penis and provides a durable definitive repair.

SMART (SC370-SC377)

Prostate cancer: surgical treatment 2

SC370
Surgical clips migration in urethra after robot-assisted radical prostatectomy: management of a rare complication
SC371
Correlation between short term urinary continence recovery and length of spared urethra after robotic radical prostatectomy: a multicenter, prospective study
SC372
Artificial intelligence guided 3D automatic augmented-reality biopsy: a new tool to improve the oncological safety of the nerve sparing phase during robotic prostatectomy
SC373
Survival after radical prostatectomy *vs.* radiation therapy in clinical node positive prostate cancer patients: a multicentric study
SC374
New telemedicine platform for telemonitoring and telerehabilitation in patients undergoing robot-assisted radical prostatectomy (RARP): first technical testing and patients and providers satisfaction
SC375
Technical surgical steps to follow during extirpative phase of robotic-radical prostatectomy to improve early urinary continence recovery: our way to skin the cat after more than 4000 robotic radical prostatectomies by single surgeon
SC376
Salvage robot-assisted radical prostatectomy post-HIFU: a tertiary care center experience
SC377
Complete biochemical response below 0.1 ng/mL predicts long-term therapy-free survival of patients treated with salvage lymph node dissection *via* PSMA-radioguided surgery

SC370

Surgical clips migration in urethra after robot-assisted radical prostatectomy: management of a rare complication

L. Lo Monaco, S. Tappero, L. Angelini, A. Di Stasio, B. Cavallone, V. Galica, D. Tiranti, P. Audino, M. Ferraro, G. Mantica, M. Borghesi, C. Terrone, A. Serao (Genoa)

BACKGROUND: Urethral migration of surgical clips placed on vascular bundles during robot-assisted radical prostatectomy (RARP) for prostate cancer is an uncommon surgical event. Potential complications consist of irritative urinary symptoms, leading to discomfort and anxiety. The current study aimed to address surgical and functional outcomes of endoscopic removal of surgical clips (Hem-o-Lok) displaced into the urethra. We relied on a European single-center database (2011-2020).

METHODS: All RARP patients that experienced postoperative surgical clips' migration in urethra were identified. Demographic and clinico-pathological characteristics were accrued. Specifically, age, Charlson Comorbidity Index (CCI), initial prostate specific antigen (iPSA), biopsy Gleason score (GS), pathologic T stage and GS, as well as required adjuvant treatments were recorded. Urinary continence recovery was defined as the usage of 0 to 1 safety-pad per day.

RESULTS: Among overall 494 RARP patients, 11 (2%) experienced surgical clip migration. Median age was 64 years (interquartile range [IQR]: 58-72), and median iPSA was 6.9 ng/mL (IQR: 4.1-9.1). Nine (82%) *vs.* two (18%) patients harbored pT2 *vs.* pT3a stage, respectively. One patient (10%) required salvage radiotherapy. Urinary continence recovery at 12 months from RARP was 91% (N.=10). Surgical clip migration was detected based on symptoms in nine (82%) patients. Symptoms consisted of urethral obstruction (N.=3, 27%) requiring catheterization, irritative urinary symptoms (N.=5, 45%), or both (N.=1, 9%). Diagnosis relied on ultrasound and cystoscopy in all cases. Subsequent endoscopic removal of displaced surgical clips was performed after a median interval from RARP of 24 months (range: 1-72). Two patients required concomitant bladder neck incision due to bladder neck contracture. All patients experienced symptoms resolution. No urinary leakages or infections were observed. At a median follow-up of 34 months from the endoscopic surgical clip removal, urinary continence recovery rate remained unchanged (91%).

CONCLUSIONS: Surgical clip migration in urethra represents a rare adverse event of RARP. Endoscopic removal is feasible, effective and not burdened by significant complications. With the due caution based on limited sample size, surgical clip migration in urethra and subsequent endoscopic removal do not seem to impact on urinary continence.

SC371

Correlation between short term urinary continence recovery and length of spared urethra after robotic radical prostatectomy: a multicenter, prospective study

A.L. Pastore, A. Martoccia, Y. Al Salhi, A. Fuschi, A. Carbone, P.P. Suraci, S. Scalzo, O.A. Rera, A. Antonioni, F.M. Valenzi, D. Graziani, M.B. Sequi, G. Martino, G. Candita, F. Gianfrancesco, C. De Nunzio, R. Lombardo, A. Cicione (Latina)

BACKGROUND: Urinary incontinence (UI) is considered one of the main complications of radical prostatectomy and can significantly affects patients' quality of life. Different characteristics of the urethra have been proved to be significant to obtain an early urinary continence following radical prostatectomy. The aim of the study was to correlate the length of the spared urethra in patients undergoing robotic radical prostatectomy (RALP) with the rates of short term (90 days postop) urinary continence.

METHODS: This multicenter prospective study enrolled 137 patients affected by adenocarcinoma of the prostate undergoing Nerve- sparing RALP. None of the patients had preoperative UI. Before surgery, the length of the urethra was calculated with the mpMRI, in the sagittal plane, as between the distal portion of the external urethral sphincter and the bladder neck. During the histological exam, the length of the removed urethra was measured in order to relate it to the urethral length previously calculated by the mpMRI. Three months after surgery patients were divided into two groups based on the presence (Group B, 69 pts) or absence (Group A, 68 pts) of UI evaluated through UDM.

RESULTS: At 3-month follow-up a statistically significant difference (P<0.0001) in mean recovery time of UI has been reported (Group A – 12.35 days SD: 3.09 *vs.* Group B – 93.86 days SD: 34.8). The ROC curve was statistically significant with an estimated cut-off value of 16.5% (P<0.0001) and a mean sensitivity of 87.5% and specificity of 91.8%. In both groups a statistically significant negative correlation was found between the percentage of spared urethra and the mean recovery time from UI (Group A – r=-0.655; P<0.0001; Group B – r=-0.340; P=0.017). Patients of Group A showed an average of 21.52% of spared urethra (SD=4.34) while group B showed an average value of 13.86% (SD=2.16) (P<0.0001). At one-year of follow-up, 126 pts (92.8%), 61 in Group A and 65 in Group B, reported urinary continence with no need for pads.

CONCLUSIONS: Our study highlighted how the percentage of spared urethra after performing RALP correlates with an early recovery of urinary continence. We can therefore conclude that the amount of urethra saved after RALP is one of the surgical variables that positively correlates with an earlier recovery of urinary continence.

SC372

Artificial intelligence guided 3D automatic augmented-reality biopsy: a new tool to improve the oncological safety of the nerve sparing phase during robotic prostatectomy

G. Volpi, M. Manfredi, A. Daniele, E. Checcucci, S. De Cillis, F. Piramide, A. Piana, M. Sica, P. Verri, D. Zamengo, A. Quarà, E. Cisero, G. Busacca, C. Gatti, F. Pini, A. Sterrantino, M. Ortenzi, G. Bignante, C. Fiori, F. Porpiglia (Candiolo, Turin)

BACKGROUND: Nowadays, new technologies are being adopted in order to maximize functional and oncological outcomes of urologic surgical procedures. Among them, 3D virtual models have already demonstrated their role. The aim of this study was to assess the accuracy of our new automatic augmented reality (AAR) system that allows to project the prostate and tumor virtual images at the level of the prostatic lodge and neurovascular bundle (NVB) preserved at the end of the extirpative phase of the intervention allowing to perform a 3D AAR guided biopsy, without the need of an assistant for the overlapping process.

METHODS: From December 2020, RARP candidates with suspicious bulging or extracapsular extension (ECE) at preoperative mpMRI were enrolled. Based on the radiological images, 3D virtual models were created for every single patient. After nerve- sparing (NS) prostatectomy, thanks to a specifically designed AAR software based on two convolutional neuronal networks, the catheter inserted into the prostatic lodge was recognized and the 3D virtual model of the prostate was automatically overlapped. Once the overlapping was made, a 3D AAR guided selective biopsy was performed at the level of the suspicious ECE, on the preserved NVB. Final pathological data were analyzed, and the patients were strati/ed according to pathological stage (pT). Furthermore, the rate of positive surgical margins (PSMr) and selective biopsy were evaluated.

RESULTS: Thirty-four patients were enrolled. Full or partial NS was performed in 30% and 70% of the cases, respectively. Regarding final pathology, 18/34 (52.9%) and 16/34 47.1%) patients had pT2 or pT3a disease, respectively. AR guided biopsies at the level of suspicious lesion projection was negative in all pT2 patients while it revealed the presence of cancer in 14 cases in pT3 cohort (14/16; 87.5%). PSMr in pT2 patients was 0%; whilst, in consideration of the extension of the resection with the 3D-guided excisional biopsy, the PSMr was 6.25% in pT3 group. No cases of biochemical recurrence were recorded at 1 year of follow-up.

CONCLUSIONS: Our findings suggest that the application of artificial intelligence to our AR platform allows an effective automatic AR RARP. The 3D virtual images, automatically anchored to the catheter, allow to correctly identify the location of ECE and to selectively extend the surgical margins in order to reduce the rate of positive surgical margins.

SC373
Survival after radical prostatectomy *vs.* radiation therapy in clinical node positive prostate cancer patients: a multicentric study

F. Chierigo, C. Scaffidi, A. Porcaro, D. Amparore, R. Bertolo, C.A. Bravi, G. Bozzini, C. Trombetta, E. Mearini, E. Montanari, P. Ditonno, A. Simonato, P. Bove, C. De Nunzio, A. Tubaro, R. Schiavina, E. Brunocilla, A. Antonelli, A. Galosi, A. Mottrie, F. Porpiglia, S. Barra, M. Borghesi, C. Terrone (Genoa)

BACKGROUND: The aim of this study was to compare BCR-free survival (BCR-FS), metastasis-free survival (MFS), and overall survival (OS) rates between radical prostatectomy (RP) *vs.* radiotherapy (EBRT) as primary radical treatment in clinical node positive (cN1) prostate cancer (PCa) patients.

METHODS: We relied on a multicentric database of 402 consecutive cN1 patients (according to either RECIST1.1 or PROMISE criteria) from 16 academic institutions, of whom 66 (16%) *vs.* 336 (84%) were treated with primary EBRT and RP, respectively. Logistic regression models assessed PSA persistence after RP *vs.* EBRT. Kaplan-Meier plots and Cox regression models tested the effect of RP *vs.* EBRT on BCR-FS, MFS, and OS. All analyses were adjusted for age, D'Amico risk group, subsequent treatment with adjuvant or salvage EBRT, and administration of androgen deprivation therapy (ADT).

RESULTS: Overall, RT patients were older (73 *vs.* 67 years) and presented with more adverse D'Amico criteria (high risk 88% *vs.* 69%, intermediate risk 12% *vs.* 25%, low risk 0% *vs.* 6%), as compared to their RP counterparts. After logistic regression analyses, we did not record differences in PSA persistence in RP *vs.* EBRT (OR=1.81, 95% CI: 0.81-4.17, P=0.15). Five-year BCR-FS, MFS, and OM were respectively 86 *vs.* 76% (P=0.15), 97% *vs.* 83% (P=0.051), and 87 *vs.* 97% (P<0.001) in EBRT *vs.* RP groups. These rates did not translate into statistically significant hazard ratios (HRs) in favor of one treatment for early oncological outcomes. Specifically, compared to EBRT, RP yielded an HR of 0.66 (95% CI: 0.18-2.45, P=0.5) for BCR- FS, and 1.07 (95% CI: 0.20-5.65, P=0.9) for MSF. However, OS rates translated into an HR of 0.08 (95% CI: 0.01-0.46, P=0.005) in favor of RP, after adjustment for age, D'Amico risk, subsequent treatment with adjuvant/salvage EBRT, and administration of ADT.

CONCLUSIONS: Our study suggests that RP and EBRT have similar early oncological outcomes, but RP might hold an OS advance in the treatment of cN1 PCa, even after adjustment for age, adverse clinical features, and subsequent adjuvant or salvage treatments.

SC374
New telemedicine platform for telemonitoring and telerehabilitation in patients undergoing robot-assisted radical prostatectomy (RARP): first technical testing and patients and providers satisfaction

S.T. De Cillis, M. Sica, D. Amparore, M. Burgio, E. Checcucci, D. Zamengo, A. Piana, C. Gatti, F. Piramide, F. Pini, G. Volpi, M. Ortenzi, A. Sterrantino, A.G. Mesterca, G. Bignante, N. Ziani, G. Trapella, M. Manfredi, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: It has been demonstrated how early postoperative monitoring and rehabilitation protocols provide better recovery of continence and erectile function in patient underwent RARP, but their adoption is limited by the lack of human resources and local services. The aim of this research was to investigate patient and providers satisfaction in the use of a new telemedicine (TM) platform designed for telemonitoring and telerehabilitation of patient undergoing RARP.

METHODS: We collaborated with software engineers to modify and implement the existing MAIA TM platform (ab medica, Cerro Maggiore, Milan, Italy) to obtain a suitable tool that could meets clinical needs in urology practice. The TM system was composed as follows: an online platform usable by medical providers that enables the acquisition, management, classification, and archiving of preoperative, intraoperative and postoperative data and allows defining a treatment plan and monitoring of the clinical response of the rehabilitation activities; secondly, an App for smartphone and tablet devices that is provided to the patient and enables receiving notifications for medication intake and/or rehabilitation exercises and uploading information for monitoring of clinical parameters (such as validated questionnaires or PAD tests). Patients undergoing RARP in our institution during September 2022 who had internet access *via* PC/tablet/smartphone were included in this first part of the study. Patients and providers self-reported their level of satisfaction on a visual analog scale ([VAS]; range 0-100) after 30 days of MAIA TM (ab medica). Patient satisfaction was additionally measured using a validated Telemedicine Satisfaction Questionnaire ([TSQ]; range 1-5). Technical issues and platform/app malfunctions were recorded.

RESULTS: Twenty-eight patients and 3 providers were enrolled in this first phase of the study. Patients and providers mean (SD) VAS satisfaction scores were 88.7 (17.2) and 82.2 (11.2), respectively. The mean (SD) TSQ score was 4.6 (0.4), all 28 patients reported they would use this new telemedicine platform again and would recommend it to other people. 10/28 (35.7%) patients reported App technical issues, namely 6 (21.4%) notification malfunctions and 4 (14.2%) online questionnaires filling failures. All these issues were easily solved by changing the smartphone's accessibility settings. Providers reported no technical malfunctions of the online MAIA™ platform (ab medica).

CONCLUSIONS: Our new MAIA TM platform (ab medica) specifically designed for telemonitoring and telerehabilitation of patients undergoing RARP appears to be user-friendly and shows a high level of satisfaction among both patients and providers. The prosecution of this study will be necessary to evaluate the long-term satisfaction and clinical effectiveness of this TM platform.

SC375
Technical surgical steps to follow during extirpative phase of robotic-radical prostatectomy to improve early urinary continence recovery: our way to skin the cat after more than 4000 robotic radical prostatectomies by single surgeon

F. Porpiglia, F. Porpiglia, S. De Cillis, G. Volpi, D. Amparore, F. Piramide, M. Sica, A. Piana, P. Verri, M. Burgio, J. Meziere, D. Zamengo, E. Cisero, G. Busacca, M. Colombo, F. Pini, C. Fiori, E. Checcucci (Orbassano, Turin)

BACKGROUND: In this study we described technical details during demolitive phase of robot-assisted radical prostatectomy (RARP), aimed to spare periprostatic anatomical structures related to continence recovery.

METHODS: From April 2022 to January 2023, patients with prostate cancer (cT1-3, cN0, cM0) underwent RARP with our new technique were enrolled in this study. Briefly the key steps of the demolitive phase are: 1) avoid the opening of the endopelvic fascia; 2) bladder neck sparing approach reaching the seminal vesicle plane laterally to the urethra before the incision of the urethra itself; 3) incision of the proximal urethra and isolation of the seminal vesicles; 4) incision of the Denonvillers' fascia and isolation of the postero-lateral face of the prostate reaching (when oncologically safe) the intra- or inter-fascial plane; after that the prostate pedicles are secured with Hem-o-Lok clips; 5) then moving to prostate apex, with a blunt dissection of the endopelvic fascia, laterally to the puboprostatic ligaments, the neurovascular fibers are separated from the prostate capsule according "retrograde" approach until meet the previously isolated prostate pedicles; and 6) lastly the Santorini plexus was incised and the prostate apex is managed sparing the peri-urethral tissue preserving as much as possible the length of the urethral stump. The reconstructive phase follows the principle of our previous described "total anatomic reconstruction" technique. Preoperative, intra-, postoperative and pathological variables were analyzed. Continence (0-1 safety pad) was evaluated at removal of the catheter, one week, 1 and 3 months after. Patients who did not use pads or just one safety pad were defined as continents.

RESULTS: Two hundred twenty-two patients were enrolled in this study. The median age at intervention was 66 years. Mean PSA at diagnosis was 9.88 (±10.59). 4.4%, 70.1% and 25.5% of the patients were respectively classified as low, intermediate and high risk according to D'Amico score. Mean operating time was 143 (±28.9) minutes, mean blood loss was 253.7 (±34.8) mL. PNLD was performed in 83.3% of the patients. The median catheterization was 4 days (IQR: 4-5). The overall complications rate was 6.7% and Clavien >2 complications rate was 2.3%. Transfusion, urinary retention and urine perianastomotic leakage rates were 2,7%, 2.2% and 1.8%, respectively. Positive surgical margins in pT2 pts were 7.8%. The overall continence rate was 73.4%, 76.5%, 84.2% and 93.2% at catheter removal, one week, 1 and 3 months, respectively.

CONCLUSIONS: The introduction of the proposed technical measures allows to spare the periprostatic structures designate for continence mechanisms, further improving the early continence recovery of the anterograde robotic prostatectomy. Furthermore, this technique resulted to be safe and feasible without increasing the risk of PSMs. Longer follow-up is needed to confirm these findings.

SC376
Salvage robot-assisted radical prostatectomy post-HIFU: a tertiary care center experience

A. Piana, S. De Cillis, S. De Luca, E. Checcucci, D. Amparore, F. Piramide, G. Volpi, M. Sica, D. Zamengo, E. Cisero, M. Colombo, C. Gatti, A. Sterrantino, A.G. Mesterca, F. Rosi, D. Garino, A.E.M. Venezia, C. Fiori, M. Manfredi, F. Porpiglia (Rocca di Neto, Crotone)

BACKGROUND: In the last years, among the urologist's armamentarium the focal therapies have gained a wide diffusion, especially in case of low/intermediate organ confined prostate cancer (PCa), following the direction of the precision surgery. Among them the High Intensity Focused Ultrasound (HIFU) has been approved for clinical use within prospective registry studies, although it remains experimental according to international guidelines. In the current Literature, the percentage of local recurrence after HIFU ranging from 30-40% in the first 5 years of follow-up. Despite no consensus on the optimal management of recurrent PCa after primary HIFU therapy, up to now salvage prostatectomy (sRP) is reserved for only very few patients because of technical challenges and frequent postoperative complications. The purpose of the study was to report the perioperative, functional, and oncological outcomes during the first-year follow-up after salvage robot-assisted radical prostatectomy (sRARP) in patient underwent primary HIFU.

METHODS: We retrospectively extracted from our prospectively RARP database all patients underwent sRARP for biochemical recurrence (BCR) after primary HIFU from January 2015 to June 2020. All the surgical interventions were performed by a single surgeon following our total anatomical reconstruction (TAR) technique. Demographics, perioperative, complications according to Clavien-Dindo, functional and oncological results were collected up to one-year follow-up.

RESULTS: Eleven patients underwent post-HIFU sRARP with TAR technique at our institution. All the surgical procedures were uneventful. Median catheterization time was 5 days (IQR: 4-7). All the complication recorded were classified as Clavien-Dindo Grade I. Continence rate at 1-, 3-, 6- and 12-month postintervention was 36.3%, 45.5%, 63.6% and

81.1%, respectively. On postoperative histopathology assessment positive surgical margin rate was 27.2%, in all of these cases was present an extracapsular extension of the disease (≥pT3). Medium PSA at 12 months follow-up was 0.2 ng/mL (SD 0,01), with no BCR recorded.

CONCLUSIONS: sRARP with TAR technique is a safe and feasible procedure in patient with BCR after primary HIFU. No major complications were recorded, with good oncological and functional results after one year follow-up.

SC377
Complete biochemical response below 0.1 ng/mL predicts long-term therapy-free survival of patients treated with salvage lymph node dissection via PSMA-radioguided surgery

F. Ambrosini, S. Knipper, F. Lischewski, D. Koehler, M. Eiber, F.W. van Leeuwen, H. de Barros, A. Berrens, P. van Leeuwen, H. van der Poel, F. Falkenbach, L. Budäus, T. Steuber, M. Graefen, J.E. Gschwend, P. Tennstedt, C. Terrone, T. Horn, M. M. Heck, T. Maurer (Genoa)

BACKGROUND: In a subset of patients with recurrent oligometastatic prostate cancer (PCa) salvage surgery with PSMA-targeted radioguidance (PSMA-RGS) seems to be of value. We evaluate if very low postoperative PSA (complete biochemical response <0.1 ng/mL) helps predict long-term oncological outcomes of salvage PSMA-RGS.

METHODS: Patients who consecutively underwent salvage PSMA-RGS for oligorecurrent PCa after radical prostatectomy at two different institutions between April 2014 and December 2022 were identified in the two prospectively collected institutional review board-approved databases. The biochemical response was assessed between 2 and 16 weeks after PSMA-RGS. PSA response was categorized as PSA≤0.1 ng/mL, PSA: 0.1-0.2 ng/mL, or PSA>0.2 ng/mL. We relied on Kaplan-Meier and multivariable Cox regression models to assess therapy-free survival (TFS) according to PSA response.

RESULTS: A total of 413 patients without concomitant treatment were collected. After RP, 62% of them received salvage or adjuvant radiation therapy. According to PSMA-PET performed for PCa recurrence, 42.2% had unilateral pelvic lesions, 3.3% had bilateral pelvic lesions, 8.8% had pelvic and presacral/pararectal or retrovesical/paravesical lesions, 13% showed only presacral/pararectal lesions, 15% had retrovesical/paravesical lesions, 7.7% showed retroperitoneal lesions, 7.4% had lesions in the retroperitoneum, 1% showed intraabdominal lesions, and 1.6% showed lesions with questionable PSMA uptake. At PSMA-RGS, the median age was 67 years (IQR: 62-71 years) with a median PSA value of 1.0 ng/mL (IQR: 0.5-1.9 ng/mL) prior to salvage surgery. Metastatic soft-tissue PCa lesions were removed in 373 (91%) patients. At 2-16 weeks post PSMA-RGS, 165, 47 and 138 patients reached a PSA<0.1 ng/mL, PSA: 0.1-0.2 ng/mL, and PSA>0.2 ng/mL, respectively. At two years, the TFS rate was 83%, 57%, and 44% in patients with a postoperative PSA<0.1 vs. 0.1-0.2 and ≥0.2 ng/mL (P<0.001). In multivariable analyses, a postoperative PSA between 0.1 and 0.2 ng/mL (Hazard Ratio [HR]: 2.0, 95% confidence interval [CI]: 1.1-3.6) and a PSA≥0.2 ng/mL (HR=2.9, CI: 1.8-4.5) were independent predictors of next treatment after PSMA-RGS. The main limitation is the lack of a control group.

CONCLUSIONS: Complete biochemical response with a PSA below 0.1 ng/mL seems to predict long-term therapy-free survival of patients treated with salvage lymph node dissection via PSMA-radio guided surgery. This may help in counseling patients postoperatively as well as the use of additional therapy.

SMART (SC378-SC391)

Prostate cancer: diagnosis 1

SC378
Probability of detecting clinically significant prostate cancer by MRI-identified lesions in a series of biopsy naïve-men

SC379
Correlation between single parameters of multiparametric ultrasound and prostate cancer

SC380
PI-RADS 3 lesions on MPMRI: are clinical risk factor and high-resolution micro-ultrasound helpful tools for detecting clinically significant prostate cancer? Update from a large single center experience

SC381
Association between MRI-detected tumor ADC and risk of 5-year biochemical recurrence after radical prostatectomy

SC382
MPMRI of the prostate in patients carrying a high clinical risk of prostate cancer diagnosis: is this imaging test necessary for diagnostic purposes in this subset of patients?

SC383
Comparison of the diagnostic performance between multiparametric MRI and microUS in the detection of clinically significance prostate cancer among patients with previous negative biopsy

SC384
Incidental prostate cancer in MRI era: is there a need for expansion in guidelines?

SC385
Impact of magnetic resonance imaging (MRI) scan and image acquisition protocol in detecting clinically significant prostate cancer at biopsy: results from the PROMOD Working Group

SC386
Diagnostic accuracy of multiparametric MRI and microultrasound targeted biopsy in biopsy naïve patients with a PI-RADS 5 lesion: a single-institutional study

SC387
Additional value of magnetic resonance imaging of the prostate in patients with a prostate-specific antigen >10 ng/mL and/or positive digito-rectal examination: a retrospective multicenter study

SC388
The relationship between MRI-derived apparent diffusion coefficient of periprostatic adipose tissue and prostate cancer aggressiveness in the preoperative setting: a single center preliminary report

SC389
MRI-invisible prostate cancer: a clinical, radiological, pathological and genomic analysis

SC390
Using artificial intelligence approach based to predict prostate target biopsy (TB) outcomes

SC391
Has the introduction of multiparametric magnetic resonance imaging of the prostate and targeted biopsies led to a risk of overgrading of high-risk prostate cancer? Results from a contemporary, large multi-institutional series

SC378
Probability of detecting clinically significant prostate cancer by MRI-identified lesions in a series of biopsy naïve-men

G. Anastasi, M. Di Falco, M. Rossanese, L. Macchione, G. Giannarini, V. Ficarra (Messina)

BACKGROUND: The aim of the present study was to evaluate the ability of MRI-identified lesions to detect clinically significant prostate cancer in a setting of not-screened population of patients who underwent cognitive targeted and systematic transperineal prostatic biopsies.

METHODS: We collected prospectively in a dedicated databases the clinical records of a series of biopsy naïve patients who underwent multiparametric prostatic MRI for suspicious prostate cancer between January 2019 and December 2021. Multiparametric MRI was performed using a 1.5-T scanner with a pelvic phased-array coil. MRI lesions classified as PI-RADS v2 ³3 were considered suspicious for prostate cancer. Patients with suspicious MRI findings received transperineal cognitive targeted biopsies (TBx) (1-3 cores) plus contemporary systematic prostatic biopsies (SBx). Clinically significant prostate cancers were defined as patients with ISUP GG ³2 (³GS 3+4). The Cohen's κ statistic was used to measure the concordance between TBx and SBx.

RESULTS: Overall, 686 patients with a median age of 65 years (IQR: 59-71) were included in the present study. The median value of total PSA was 6.2 ng/mL (IQR: 4.3-9.1). The median prostatic volume estimated during MRI was 55 cc (IQR: 40-80). Median PSAD was 0.14 (IQR: 0.08-0.21). According to mpMRI, PI-RADS 3 lesions were identified in 71 (10.3%) patients; PI-RADS 4 in 158 (23%) and PI-RADS 5 in 87 (12.7%). MRI findings significantly correlated with patient's age (P<0.001), total PSA (P<0.001), DRE (P<0.001) and PSAD (P<0.001). Prostate biopsies were performed in 102/370 (27.5%) PI-RADS 1-2, in 39/71 (54.9%) PI-RADS 3 and in all PI-RADS 4-5 cases. Overall, 202/386 (52.3%) prostatic biopsies resulted positive. Specifically, 75 (35.1%) were classified as GS 6 (indolent) and 127 (62.8%) as clinically significant (GG ³2). According to MRI findings, 284 (73.5%) patients received both cognitive targeted and systematic biopsies. CsPCa were identified in 119 (41.9%) patients. TBx resulted positive in 92 (32.3%). In details, the detection rate of csPCa was 1.5% for PI-RADS 3 lesions, 27.2% for PI-RADS 4 lesions and 55% for PI-RADS 5 (P<0.001). SBx detected an overall 108 (38%) csPCa. Eleven (9.2%) csPCa were detected only with TBx, 27 (22.6%) only with SBx and 81 (68%) with both techniques. The concordance between SBx and TBx resulted substantial (kappa 0.70)

CONCLUSIONS: Our data confirmed the correlation between mpMRI findings and the detection of csPCa. Cognitive TBx and SBx showed a substantial concordance in the detection of csPCa. However, our data highlighted the opportunity to combine cognitive TBx and SBx to avoid missing about 20% of csPCa.

SC379
Correlation between single parameters of multiparametric ultrasound and prostate cancer

E. Lepri, M. Del Zingaro, L. Guadagni, A. Paladini, G. Felici, E. Saqer, F. Pastore, M. Russo, S. Ciarletti, G. Cochetti, E. Mearini (Perugia)

BACKGROUND: Multiparametric MRI (mpMRI) is the recommended diagnostic tool for detection of prostate cancer (PCa). Multiparametric Ultrasound (mpUS) could be an alternative imaging technique to diagnose PCa and its use is currently under investigation. The aim of the study was to evaluate a possible correlation between mpUS parameters, Power Doppler (PD) and elastography (USE), with PCa. In addition, we explored their possible correlation with the clinical ISUP score.

METHODS: From November 2022 to February 2023, 60 patients underwent transperineal prostatic fusion biopsy were prospectively enrolled in our high-volume tertiary care institute. Inclusion criteria were patients with mpMRI diagnosis of PI-RADS score ≥3 and PSA ≥3 ng/mL. Each patient underwent mpUS of the prostate, performed by a mpMRI blind urologist, and transperineal prostatic fusion biopsy completed with systematic one under local anesthesia, performed by a second urologist. We codified elastography with a score based on tissue consistency ranging from 1 to 5 (1 for soft tissue, often associated with inflammatory process, 5 for stiff tissue often associated with adenoma or PCa). Power Doppler was codified with 5 vascular patterns: lack of vascularization pattern 1, regular vascularization pattern 2, peripheral vascularization pattern 3, vascular axis pattern 4 and hyper-vascularization pattern 5. For each lesion detected we also assigned a dichotomic score when at least one of the parameters resulted in a high score (4 or 5). We performed univariate and multivariate logistic regression to evaluate a potential association between each parameter with presence of PCa. Finally, we evaluated a potential association between each parameter and clinical ISUP score through linear regression.

RESULTS: Overall, 60 subjects of mean age of 70±1.75 years were enrolled. Total lesions identified by mpMRI were 102. At logistic regression analysis USE, ultrasound dichotomic score with one of two parameters, and ultrasound dichotomic score with both parameters did not correlate significantly with PCa (P=0.797, P=0.737, P=0.128, respectively). PD showed a statistically significant correlation with PCa (P=0.036). In addition, a PD score of 4 and 5 predicted the presence of PCa compared to score 1. We also performed multivariate logistic regression with backward elimination, highlighting that PD is the only parameter for PCa detection. Additionally, a statistically significant association between a PD score of 4-5 and ISUP score was also detected (P=0.003). In particular, ISUP score of 2, 3 and 4 were predicted by PD (P=0.013, P=0.042 and P=0.027).

CONCLUSIONS: Our findings showed that a PD score of 4-5 was predictive for presence of PCa as well as for intermediate and high grade of ISUP. In conclusion, the more aggressive forms of PCa seem to be easily detected by TRUS with PD.

SC380
PI-RADS 3 lesions on MPMRI: are clinical risk factor and high-resolution micro-ultrasound helpful tools for detecting clinically significant prostate cancer? Update from a large single center experience

M. Aljoulani, D. Maffei, V. Fasulo, P.P. Avolio, F. De Carne, M. Lazzeri, G. Guazzoni, N.M. Buffi, G. Lughezzani, A. Saita,

R. Hurle, N. Frego, S. Moretto, F. Dagnino, G. Chiarelli, P. Arena, P. Casale (Rozzano, Milan)

BACKGROUND: Multiparametric magnetic resonance imaging is an invaluable diagnostic tool in prostate biopsies (PBx) decision making. However, most Prostate Imaging-Reporting and Data System (PI-RADS) 3 lesions do not contain clinically significant prostate cancer (CsPCa; grade group ≥2). This study is an update of a previous study aimed to investigate clinical and high- resolution micro-ultrasound (microUS) derived risk factors that predict CsPCa in men with PI-RADS 3 lesions.

METHODS: A total of 160 patients who underwent microUS-guided PBx with the ExactVu system (Exact Imaging Inc., Markham, ON, Canada) for a PI-RADS 3 lesion were prospectively enrolled between October 2017 and October 2022. The prostate risk identification using microUS (PRI-MUS) protocol was used to identify suspicious areas; PBx included targeted and systematic sampling. The primary endpoint was the assessment of microUS diagnostic accuracy in detecting csPCa. Secondary endpoints included determining: the proportion of patients with a PI-RADS 3 lesion who may avoid PBx after microUS examination; predictors of csPCa in patients presenting with PI-RADS 3 lesions.

RESULTS: Median patient age was 62 (IQR: 60-72) years, median total PSA was 9 (IQR: 6.8-15) ng/mL, and median prostate volume was 51.6 (IQR: 35-70) mL. Overall, 78 (48.7%) patients were in the repeat biopsy setting. microUS detected prostate lesions with a PRI-MUS score of 3, 4 and 5 in respectively 24 (15.0%), 68 (42.5%) and 10 (6.20%) patients, while in 55 (34.3%) individuals micro-US did not identify any target. Overall, 28 (17.5%) patients harbored csPCa. Considering csPCa detection rate, microUS showed optimal sensitivity and negative predictive value (92.8% and 95.7%, respectively), while specificity and positive predictive value were 45.9% and 32.9%, respectively. Forty-seven (29.3%) patients with negative microUS could have avoided PBx with 2 (4.2%) missed csPCa. In multivariable logistic regression models, positive microUS (PRI-MUS>2), age, and PSA density ≥0.15 emerged as independent predictors of PCa. The accuracy of a model including PRI-MUS score, age, PSA density, family history and previous biopsies was 0.74 (95% CI: 0.673-0.854).

CONCLUSIONS: Our update findings confirm that microUS could represent a helpful tool capable of selecting patients harboring csPCa among subjects with PI-RADS 3 lesion avoiding a not negligible proportion of unnecessary PBx.

SC381
Association between MRI-detected tumor ADC and risk of 5-year biochemical recurrence after radical prostatectomy

M. Tozzi, G. Graps, O. Guglielmo, M. Tallini, G. Lucignani, M.L. Piccinelli, M. Fontana, S. Luzzago, F.A. Mistretta, A. Cioffi, D.V. Matei, M. Ferro, R. Bianchi, G. Petralia, S. Alessi, G. Musi, O. de Cobelli (Milan)

BACKGROUND: This study aimed to demonstrate the predictive utility of tumor apparent diffusion coefficient (ADC) values in assessing the risk of a 5-year BCR after radical prostatectomy (RP).

METHODS: A retrospective analysis was conducted on a cohort of 1207 PCa patients who underwent MRI before RP between 2012 and 2015. The outcome of interest was 5-year BCR, defined as two consecutive PSA values of >0.2 ng/mL. ADC values were categorized into three groups using empirical cut-offs: low (<850 μm²/s), intermediate (between 850 μm²/s and 1100 μm²/s), and high (>1100 μm²/s). Comparisons between groups (BCR and non-BCR) and categorical levels of ADC were performed using non-parametric statistical tests. Kaplan-Meier curves were plotted to depict survival functions, and Log-rank tests were used to test for differences among strata of determinant variables.

RESULTS: The median duration of follow-up in the cohort was 59 months, with 306 (25%) patients experiencing BCR. Patients who experienced BCR had significantly lower ADC values compared to those without BCR (874 *vs.* 1025 μm²/s, P<0.001). The 5-year BCR survival rates were 87.0%, 74.4%, and 52.3% for patients with tumor high, intermediate, and low ADC values, respectively (P<0.0001).

CONCLUSIONS: MRI-based tumor ADC values were found to be predictive of the risk of 5-year BCR after RP in PCa patients and may serve as a prognostic biomarker. External validation of these findings is warranted.

SC382
MPMRI of the prostate in patients carrying a high clinical risk of prostate cancer diagnosis: is this imaging test necessary for diagnostic purposes in this subset of patients?

A. Stabile, G. Gandaglia, F. Pellegrino, L. Afferi, J. Zhuang, H. Guo, P. Gontero, A. Minervini, G. Ploussard, E. Mazzone, M. Valerio, V. Cucchiara, N. Fossati, M. Moschini, A. Mattei, S. Serni, R. Rahota, J. Beauval, A. Marquis, A. Rakauskas, R. Van Den Bergh, T. Soeterik, F. Montorsi, A. Briganti (Milan)

BACKGROUND: mpMRI and subsequent targeted biopsy (TBx) significantly increases the detection of clinically significant prostate cancer (csPCa). However, its diagnostic benefit in men with a high clinical risk of PCa remains controversial. We hypothesized that not all patients with a clinical suspicion of PCa may benefit from mpMRI for diagnostic purposes. Specifically, the added value of TBx in patients with high risk of having CSPCa may be negligible.

METHODS: We identified 3,639 patients with clinical suspicion of PCa and suspicious mpMRI (PI-RADS≥3) that received a SBx + TBx at 10 referral centers between 2014-2022. We then compared the detection of csPCa between SBx and TBx, according to the individual patient risk of having csPCa in order to assess the added benefit of TBx over SBx. We used a multivariable logistic regression analysis (MVA) to predict the risk of csPCa at prostate biopsy relying on clinical and radiological characteristics such as age, PSA, digital rectal examination, and PI-RADS. We then used loess non-parametric analysis to graphically explore the probability of csPCa at TBx *vs.* SBx according to the pretest probability of csPCa diagnosis calculated at MVA, hence comparing the diagnostic benefit related to each biopsy technique in terms of csPCa detection.

RESULTS: 1491 (41%) patients had positive DRE and >86% had a PI-RADS 4-5 lesion at mpMRI. The median number of total and TBx cores taken was 14 and 4, respec-

tively. csPCa incidence was 80%. The detection of csPCa in TBx *vs.* SBx ranged from 15% *vs.* 30% (P<0.001) to 80% *vs.* 81% (P=0.3), for patients with very-low and very-high risk of having csPCa, respectively. The diagnostic benefit of adding TBx to SBx was highest in men with low risk of having csPCa (Δ=15%). Conversely, in men with a risk higher than 60%, csPCa detection in TBx *vs.* SBx were similar.

CONCLUSIONS: The added benefit of TBx to SBx in men with suspicion of PCa and concomitant positive mpMRI is highest in patients with low-intermediate risk of harboring csPCa. In patients with high clinical risk of having csPCa, adding TBx was not informative. The use of mpMRI in patients at high risk of csPCa is questionable for diagnostic purposes.

SC383
Comparison of the diagnostic performance between multiparametric MRI and microUS in the detection of clinically significance prostate cancer among patients with previous negative biopsy

F. Sordelli, N. Frego, V. Fasulo, D. Maffei, P.P. Avolio, P. Arena, G. Chiarelli, E. Beatrici, F. De Carne, A. Saita, R. Hurle, M. Lazzeri, N.M. Buffi, P. Casale, G. Lughezzani (Rozzano, Milan)

BACKGROUND: Men with persistent clinical suspicious of Prostate Cancer (PCa) and previous negative biopsy (Bx) represent a diagnostic dilemma for urologists. Multiparametric MRI (mpMRI) improved the detection rate of clinically significance PCa (csPCa) and is recommended for screening patients with previous negative Bx. Recently, microultrasound (mUS) has been proposed as a promising imaging tool able to identify lesions suspected for csPCa according to the PRI-MUS protocol. We sought to compare the diagnostic performance of mpMRI and mUS in the stratification of patients with a previous negative Bx according to the risk of harboring csPCa.

METHODS: We retrospectively identified patients with previous negative prostate Bx who performed both mpMRI and mUS before a second prostate Bx, between October 2017 and September 2021. Suspicious lesions were defined as PI-RADS ³3 and PRI-MUS ³3 for mpMRI and mUS, respectively. All patients with suspicious lesions at mpMRI and/or mUS underwent targeted Bx of any identified lesion. The procedures were then completed by at least 6 systematic Bx. The operators who performed the mUS assessment were blinded to the results of mpMRI. Clinically significant PCa was defined as Gleason Score ³7. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of mUS and mpMRI for the detection of csPCa were evaluated. Logistic regression analysis was used to identify predictors of csPCa.

RESULTS: Between October 2017 and September 2021, 1004 patients performed both mpMRI and mUS before prostate Bx. Of them, 230 (32%) had at least one previous negative prostate Bx. Median age was 66 years (IQR: 60-71) and median PSA was 8.8 ng/mL (IQR: 5.7-12). Suspicious lesions were found in 159/230 and 172/230 patients at mpMRI and mUS, respectively. Prostate cancer was diagnosed in 86/230 patients, of which 45 (19.6%) were csPCa. Among patients with csPCa, mpMRI showed suspicious lesions in 35/45 (77.8%) patients, while mUS in 42/45 (93.3%) patients. MicroUS provided higher sensitivity (93.3% *vs.* 77.8%) and NPV (72.7% *vs.* 50%) compared to mpMRI in predicting csPCa among men with previous negative Bx, while specificity and PPV were significantly lower for both the imaging exams. At multivariable logistic regression analysis, having a positive mUS was significantly associated with csPCa (OR=4.96, 95% CI: 1.01-24.9).

CONCLUSIONS: In our experience, mUS may represent a promising imaging tool showing higher sensitivity and NPV to detect patients with csPCa among those with a previous negative prostate Bx and a persistent clinical suspicion of PCa. Large-scale and multicentric studies are needed to provide further evidence supporting the use of mUS as a complementary tool to mpMRI in this specific setting.

SC384
Incidental prostate cancer in MRI era: is there a need for expansion in guidelines?

A. Minore, F. Esperto, R.M. Scarpa, L. Cacciatore, G. Raso, A. Testa, N. Deanesi, F. Tedesco, R. Papalia, R.M. Scarpa, F. Prata (Rome)

BACKGROUND: During the last two decades, PSA screening has decreased the rate of incidental prostate cancer (IPC) for TURP and enucleation of the prostate. Nowadays, the detection rate of IPC is ranged between 5 and 13% and no clear indications exist up to now on how to manage this condition. Aim of our study was to define our cohort prevalence of IPC.

METHODS: We retrospective enrolled patients (patients) who underwent TURP or open/laparoscopic prostatectomy for BPO (benign prostatic obstruction), in our high-volume tertiary university hospital between January 2020 to June 2022. Data about age, preoperative total and density PSA, prostate volume, previous prostate magnetic resonance imaging (MRI) and prostate biopsies were collected. Kruskal-Walli's Test was used for the evaluation of independent samples.

RESULTS: Three hundred ninety-three patients with negative DRE (digital rectal examination) underwent BPO surgery at our hospital. Incidental prostate cancer was found in 63 patients (16%). Mean preoperative±SD (standard deviation) age, PSA tot, PSA density, prostate volume and prostate tissue removed were respectively: 69.8±7.46 years; 3.72±3.54 ng/mL; 0.06±0.053; 59.88±23.29 cc; 25.12±17.59 g. Fourteen patients (22.2%) underwent prostate MRI before TURP. Out of these 7 were negative for suspected PCA (PIRADS score <3) and 7 were positive for MRI lesion PIRADS 3 or higher (all underwent a fusion biopsy with no evidence of PCA). Older age and higher total and density PSA level were statistically associated with higher ISUP score at pathological examination.

CONCLUSIONS: Incidental prostate cancer prevalence at our institution seems to be higher than data described in literature despite MRI usage in 22.2% of patients with IPC. Age, PSA tot and PSA density seem to predict higher ISUP score risk as expected. Studies are needed to identify strategies to lower IPC rates in the era of MRI and fusion biopsy and to offer proper staging and follow-up.

SC385
Impact of magnetic resonance imaging (MRI) scan and image acquisition protocol in detecting clinically significant prostate cancer at biopsy: results from the PROMOD Working Group

M. Finati, A. Fanelli, U. Falagario, A. Lantz, I. Jambor, L. Carmignani, E. Montanari, P. Bove, P. Gontero, A. Sciarra, P. Di Tonno, C. Trombetta, P. Bassi, G. Simone, V. Mirone, A. Antonelli, L. Schips, G.M. Busetto, C. Bettocchi, M. Ferro, P. Bostrom, T. Nordstrom, O. De Cobelli, L. Cormio, G. Carrieri (Foggia)

BACKGROUND: Prostate Imaging Reporting and Data System (PI-RADS) steering committee does not provide uniform consensus regarding the optimal magnet strength for magnetic resonance imaging (MRI) of the prostate, although low-level evidence suggests a higher diagnostic performance of 3 Tesla *vs.* 1.5 Tesla for clinically significant prostate cancer (csPCa) diagnosis. Moreover, while biparametric MRI (bpMRI) results in an elimination of adverse events, shortened examination time and reduced costs, its comparable accuracy when compared to multiparametric MRI (mpMRI) is still debated. Our study aimed to assess the impact of magnet strength and protocol acquisition (bpMRI *vs.* mpMRI) of prostate MRI in detecting csPCa.

METHODS: The PROMOD Working Group included a retrospective multicentric cohort of patients who underwent prostate MRI and subsequent systematic prostate biopsy (PBx) with MRI-target PBx in case of positive findings at MRI, defined as PIRADS≥3 lesion. Outcome of our analysis was csPCa detection rate, defined as GG≥2. MRI accuracy for diagnosis of csPCa was compared by sensitivity, specificity, negative (NPV) and positive (PPV) predictive values, according to type of magnet strength (3T *vs.* 1.5) and acquisition protocol (bpMRI *vs.* mpMRI). Multivariable logistic regression was performed to evaluate predictors of csPCa.

RESULTS: A total of 9294 patients were included. 4348/9294 (47%) of them underwent prostate MRI with 3T magnet, while the remaining 4946 (53%) with 1.5 Tesla. BpMRI and mpMRI acquisition were performed in 1298 (14%) and 7996 (86%) patients respectively. Overall, csPCa detection rate was 41% (3807/9294). PIRADS≥3 lesions were found in 87% of 3T patients *versus* 91% of 1.5 T and in 91% mpMRI *versus* 73% of bpMRI (all P<0.001). csPCa detection rate was 3153/7996 (39%) in mpMRI *versus* 654/1298 (50%) in bpMRI group, 44% (1917/4348) of 3T group and 38% (1883/4946) in 1.5 T (all P<0.001). Sensitivity, specificity, NPV and PPV of MRI (PIRADS≥3) were: 98%, 14%, 40% and 93% for 1.5 Tesla MRI and 96%, 19%, 87%, 84% in 3T group; 94%, 48%, 64% and 89% for bpMRI group and 97%,12%,40% and 88% for mpMRI. Sensitivity, specificity, NPV and PPV of MRI (PIRADS≥4) were: 87%, 48%, 49% and 93% for 1.5 Tesla MRI and 84%, 55%, 58%, 81% in 3T group; 88%, 72%, 76% and 86% for bpMRI group and 84%, 48%, 50% and 83% for mpMRI. At Multivariable analysis adjusted for age, PSA density, PIRADS score and previous PBx history (naïve *versus* previous negative), and type of acquisition (bpMRI *vs.* mpMRI), performing pMRI with 3T scan was independently associated with higher chances of csPCa.

CONCLUSIONS: While 3T MRI showed higher accuracy in detecting csPCa at subsequent MRI-target biopsy when compared with 1.5T scan, diagnostic performance of bpMRI was comparable with mpMRI. Our findings suggested how bpMRI use could be implemented in daily clinical practice in order to reduce waiting time for MRI prior to PBx.

SC386
Diagnostic accuracy of multiparametric MRI and microultrasound targeted biopsy in biopsy naïve patients with a PI-RADS 5 lesion: a single-institutional study

P.P. Avolio, D. Maffei, V. Fasuolo, C. Saitta, F. De Carne, R. Contieri, M. Paciotti, N. Frego, M. Lazzeri, P. Casale, N.M. Buffi, G. Lughezzani (Milan)

BACKGROUND: The aims of this study were to evaluate the diagnostic accuracy of multiparametric magnetic resonance imaging (MRI) and microultrasound (microUS) guided targeted biopsy (TBx) in detecting prostate cancer (PCa) and clinically significant (cs) PCa among men with Prostate Imaging Reporting and Data System (PI-RADS 5) lesions, and to compare this combined TBx (CTBx) with CTBx plus systemic biopsy (SBx).

METHODS: One hundred thirty-six biopsy-naïve patients with PI-RADS 5 lesion on multiparametric MRI undergoing CTBx plus SBx were prospectively enrolled between October 2017 and January 2023. The Prostate Risk Identification using microUS (PRI-MUS) protocol was used to identify suspicious areas at microUS examination. All patients received both TBx (based on either microUS or MRI findings) and SBx. The primary endpoint was to compare the detection rate of PCa and csPCa through CTBx and CTBx plus SBx approach in men with PI-RADS 5 lesion. Secondary endpoints were the following: to assess the diagnostic accuracy of microUS for detecting csPCa in this subset of individuals; to assess upgrading and downgrading of ISUP GG on radical prostatectomy (RP) specimens compared to CTBx and CTBx plus SBx; to assess how many PI-RADS 5 patients could avoid SBx and the proportion of missed csPCa; to assess the predictors of csPCa in PI-RADS 5 patients.

RESULTS: 108/136 (79.4%) and 92/136 (67.6%) patients were diagnosed as PCa and csPCa respectively. MicroUS identified lesions in 117/136 (86.0%) patients. Concordant lesions between mpMRI and microUS were found in 107/136 (78.7%) patients. CTBx achieved comparable detection rate to CTBx plus SBx in diagnosis of PCa and csPCa (PCa: 78.7% [107/136] *vs.* 79.4% [108/136]; csPCa: 67.6% [92/136] *vs.* 67.6% [92/136]; P>0.05) and outperformed SBx (PCa: 58.8% [80/136]; csPCa: 47.8% [65/136]; P<0.001). Overall, CTBx detected 99.1% (107/108) PCa and 100% (92/92) csPCa, while SBx missed 25.2% (27/107) PCa and 29.3% (27/92) csPCa. Of 27/136 (19.8%) csPCa cases missed by SBx, 23/136 (16.9%) csPCa cases were detected by both microUS and MRI-targeted biopsies. The remaining four cases of csPCa were diagnosed on microUS-targeted (N.=3; 2.21%) and MRI-targeted (N.=1; 0.73%) biopsies only. Using CTB would have avoided 41.1% (56\136) unnecessary SBx, without missing any csPCa. The rate of any upgrading or csPCa upgrading was significantly higher by SBx than by CTBx on RP specimens, (33/65 [50.8%] *vs.* 17/65 [26.1%] and 20/65 [30.8%] *vs.* 4/65 [6.15%] respectively, P<0.05). Considering csPCa detection rate, microUS showed high sensitivity and positive predictive value (94.6%, 87.9%, respectively), with lower specificity and

negative predictive (25.0% and 44.4%, respectively). At multivariable logistic regression models, positive microUS was identified as an independent predictor of csPCa (P=0.024), with an area under the curve of 0.79 (95% CI: 0.78-0.92).

CONCLUSIONS: A combined microUS/MRI-TBx approach could be the ideal imaging tool for characterizing primary disease in PI-RADS 5 patients, allowing SBx to be avoided.

SC387

Additional value of magnetic resonance imaging of the prostate in patients with a prostate-specific antigen >10 ng/mL and/or positive digito-rectal examination: a retrospective multicenter study

M. Finati, F. Guzzi, U. Falagario, A. Lantz, I. Jambor, L. Carmignani, E. Montanari, P. Bove, P. Gontero, A. Sciarra, P. Di Tonno, C. Trombetta, P. Bassi, G. Simone, V. Mirone, A. Antonelli, L. Schips, G.M. Busetto, C. Bettocchi, M. Ferro, P. Bostrom, T. Nordstrom, O. De Cobelli, L. Cormio, G. Carrieri (Foggia)

BACKGROUND: The European Association of Urology (EAU) guidelines for prostate cancer (PCa) strongly recommend the use of magnetic resonance imaging (MRI) as a screening tool for asymptomatic men with a PSA level between 3 and 10 ng/mL and a normal DRE (digital rectal examination). No consensus regarding the use of this screening tool outside this clinical setting has been assessed. This study aimed to evaluate the additional value of prostate MRI as a first-line diagnostic tool in patients with PSA>10 ng/mL and/or positive DRE who underwent prostate biopsy (PBx).

METHODS: The PROMOD study database was used to perform a retrospective multicentric analysis of patients who underwent prostate MRI and subsequent systematic PBx plus target PBx in case of positive findings at MRI, defined as PIRADS≥3 lesion. When PCa was found, data regarding overall Gleason Grade (GG) score was collected, as well as maximum GG found both at systematic and target cores. Outcome of our analysis was clinically significant (cs)PCA detection rate, defined as GG≥2. PCa and csPCa detection rate at systematic and target cores were assessed respectively and compared with chi-square test. Patients were primarily stratified according to DRE (suspicion *versus* negative), then classified into three categories, following serum level of PSA at PBx: PSA<10 ng/mL, between 10-20 ng/mL and >20 ng/mL.

RESULTS: A total of 6614 men were included. Suspicious DRE was found in 2412/6614 (36.5%). A PSA<10 ng/mL was found in 5108 patients (77.2%), while 1190 (18%) showed a serum level between 10-20 ng/mL and 316 (4.8%) >20 ng/mL. Overall, PCa and csPCa detection rate were 71% (4671/6614) and 51% (3340) respectively. Positive MRI (PIRADS≥3) and csPCa rate were higher in patients with suspicious DRE or PSA>10 ng/mL (all P<0.001). Considering patients with negative systematic PBx, csPCa was found in target cores of 191/729 (26%) of those with positive DRE, 126/470 (27%) for PSA between 10-20 ng/mL and 39/92 (42%) for PSA>20 ng/mL. When GG=1 PCa was found at systematic cores, csPCa was detected in 9% (37/405) of patients with positive DRE, 15% (25/168) for PSA 10-20 ng/mL and 13% (3/24) for PSA>20 ng/mL. When compared to systematic PBx, an overall upgrade to higher GG PCa at target cores were recorded in 7% (114/1683) of positive DRE patients, 10% (70/720) of patients with PSA 10-20 ng/mL and 9% (21/224) for PSA>20 ng/mL. The retrospective and multicentric nature of our cohort, including center with different PBx technique and MRI acquisition protocol, represents the major limits of this study.

CONCLUSIONS: MRI and subsequent MRI-guided biopsy increase the detection rate of csPCa and improve the accuracy of PCa staging at PBx in case of positive DRE and PSA>10ng/mL.

SC388

The relationship between MRI-derived apparent diffusion coefficient of periprostatic adipose tissue and prostate cancer aggressiveness in the preoperative setting: a single center preliminary report

A. Panunzio, A. Tafuri, F. Greco, A. Maglietta, F. De Carlo, F. Di Cosmo, E. Luperto, M. Rizzo, A. Cavaliere, R. De Mitri, F. Zacheo, M. Baviello, A. Cimino, M. Pisino, L. Giordano, C. Accettura, A.B. Porcaro, A. Antonelli, M.A. Cerruto, E. Ciurlia, S. Leo, L.G. Quarta, V. Pagliarulo (Lecce)

BACKGROUND: The use of multiparametric magnetic resonance imaging (mpMRI) of the prostate has been greatly increased in recent years leading to important improvements in clinically significant prostate cancer (PCa) diagnosis. In the mpMRI setting, apparent diffusion coefficient (ADC) is a measure of the extent of water molecules diffusion within tissues. Despite, there is no consensus regarding normal restriction values, lower ADC values are indicative of high organ cellularity. In this study, we aimed to test whether an association between the ADC of the periprostatic adipose tissue (PPAT), defined as the adipose bed surrounding the prostatic surface, and determinants of PCa aggressiveness existed.

METHODS: We retrospectively analyzed data of 219 consecutive patients undergoing prostate biopsy (PBx) for suspicion of PCa, between January 2020 and June 2022 at a single institution. Only patients who had mpMRI performed before PBx were included. A dedicated experienced radiologist, who was blinded from histology outcomes reviewed and recategorized all mpMRIs findings according to the Prostate Imaging-Reporting and Data System (PIRADS) v.2.1 and acquired PPAT-ADC values. Demographics and clinical features distribution among patients with PPAT-ADC up to *versus* above the median was studied using both parametric and non-parametric tests, according to variables. Linear and logistic regression analyses tested the association between PPAT-ADC values and standard determinants of PCa aggressiveness and the presence of intermediate-high risk PCa, respectively.

RESULTS: Overall, 132 patients were included, of whom 76 (58%) had a confirmed diagnosis of PCa. Median PPAT-ADC in the entire patient cohort was 876 (interquartile range: 654-1112) ×10-6 mm²/sec. Patients with PPAT-ADC up to median had higher rate of PIRADS 5 lesions at mpMRI (41% *versus* 23%, P=0.032), higher percentage of PBx positive cores (25% *versus* 6%, P=0.049), and more frequently harbored International Society of Urological Pathology (ISUP) grade group >1 PCa (50% *versus* 28%, P=0.048). At univariable linear regression analyses, prostate-specific antigen (PSA, β: -3.17), PSA density (PSAD, β: -131.12), PIRADS 5 (β: -180.54), and percentage of PBx positive cores (β: -570.54)

were associated with lower PPAT-ADC values (P<0.005 in all cases). At multivariable logistic regression analyses, PPAT-ADC up to the median was an independent predictor of the risk of detecting intermediate/high-risk PCa (Odds Ratio: 3.24; 95% confidence interval: 1.17-9.46; P=0.026), even after adjustment for age and Body Mass Index.

CONCLUSIONS: Lower PPAT-ADC values at mpMRI of the prostate were associated with both clinical and pathological determinants of PCa aggressiveness. If these preliminary results will be confirmed by larger-scale and higher-level studies, PPAT-ADC might represent a useful aid in the risk assessment and subsequent management of PCa patients.

SC389
MRI-invisible prostate cancer: a clinical, radiological, pathological and genomic analysis

A. Marquis, M. Oderda, L. Bertero, E. Vissio, M. Gatti, G. Calleris, D. D'Agate, G. Montefusco, F. Bracco, A. Dematteis, G. Marra, R. Faletti, P. Cassoni, P. Gontero (Turin)

BACKGROUND: Multiparametric (mp) MRI has become a key element in the diagnosis of prostate cancer (PCa). Nevertheless, it has been reported that up to 20% of PCa is invisible on mpMRI. It has been hypothesized that tumor MRI visibility is driven by specific genomic features, with high PI-RADS cancers preferentially harboring molecular hallmarks of aggressiveness. To date, however, no clear genomic profile has been detected for MRI-invisible PCa. The aim of this study was to better understand the molecular basis of MRI-visibility of tumors through a genomic analysis of MRI-invisible *vs.* -visible PCa.

METHODS: Thirty patients with negative mpMRI undergoing radical prostatectomy (RP) for PCa between 2015 and 2020 were identified from our institutional database. At radiological and pathological revisions, 11 men with false negative mpMRI and two with evidence of low-volume cancer were excluded. The final MRI-invisible cohort included 17 patients. A second MRI-visible cohort of 17 men with positive mpMRI and MRI-targeted biopsy undergoing RP in the same period was then identified. Patients in the two cohorts were matched 1:1 based on age, PSA, prostate volume, Gleason Score (GS) and pT stage. Histopathological data on perineural invasion, surgical margins, extracapsular extension, seminal vesicle involvement, HG-PIN, main PCa node diameter, foamy cells and glomeruloid/cribriform pattern were collected. Gene expression profile was assessed both for single genes and for whole genomic signatures through RNA analysis using the nCounter Tumor Signaling 360 Panel.

RESULTS: None of the examined cyto-architectural features were associated with MRI visibility. At single genes analysis, a large panel of genes involved in well-known oncogenic pathways and tumor microenvironment modulation was studied. Taken individually, none of these genes presented different levels of expression. However, amongst those with higher differential expression, genes involved in metastatic and invasive processes (upregulation of mRNA levels of COL6A2 and MYL9 and downregulation of MMP9) were observed. At the analysis of entire genetic signatures, MRI-invisible PCa showed an upregulation of the pathways related to cell adhesion and motility, extracellular matrix remodeling and metastatic process, but without reaching statistical significance.

CONCLUSIONS: No cyto-architectural features or genetic signatures have been found to predict the MRI-invisible status. However, MRI-invisible tumors appear to be associated with specific microenvironment hallmarks that might explain the MRI invisibility.

SC390
Using artificial intelligence approach based to predict prostate target biopsy (TB) outcomes

G. Quarto, F. Passaro, D. Franzese, A. Izzo, L. Castaldo, G. Grimaldi, R. Muscariello, G. Spena, A. Tufano, F. Calabrò, D.E. De Falco, S. Desicato, P. Del Prete, S. Perdonà (Naples)

BACKGROUND: In current precision prostate cancer (PCa) surgery era the identification of the best patients' candidate for prostate biopsy still remains an open issue. The aim of this study was to evaluate if the available prebiopsy characteristics are enough to predict prostate target biopsy (TB) outcomes. The study is conducted using artificial intelligence approach based on the available dataset.

METHODS: Prebiopsy characteristics in terms of PSA, vol, PSAD, and PIRADS were extracted from our prospectively maintained TB database from March2020 to December 2021. Our approach is based on 5 different machine learning algorithms (K Neighbors Classifier, Random Forest, Logistic Regression, Naive Bayes, ELM classifier), with the aim to predict TB outcomes.

RESULTS: A total of 115 patients were included. The subjects were divided in two groups, TEST (1/5 of the total, 29 items) and TRIAL (the remaining 86). Analyzing the total classified subjects, we obtained a specificity up to 88% (Random Forest) and sensitivity up to 93.8% (Random Forest). With single-layer Neural Network classification trained vial ELM, our model can correctly predict the biopsy outcomes in 84.9% of the TRIAL cases and in 70.0% of the TEST cases.

CONCLUSIONS: In this preliminar study we demonstrated that the possibility to look at standard prebiopsy variables with artificial intelligence algorithms can give indications of TB outcomes. Thus, the research opens the possibility to trial a different risk calculator.

SC391
Has the introduction of multiparametric magnetic resonance imaging of the prostate and targeted biopsies led to a risk of overgrading of high-risk prostate cancer? Results from a contemporary, large multi-institutional series

G. Sorce, G. Gandaglia, A. Stabile, V. Cucchiara, E. Mazzone, N. Fossati, M. Moschini, A. Mattei, L. Afferi, A. Minervini, R. Rahota, G. Ploussard, M. Valerio, J.B. Beavaul, A. Marquis, A. Rakauskas, G. Paolo, H. Guo, J. Zhuang, R. van den Bergh, T. Soeterik, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Although multiparametric magnetic resonance imaging of the prostate (MRI) and mpMRI-targeted biopsies (TBx) are associated with improved disease assessment, concerns have been raised regarding the increased risk of PCa overgrading at TBx due to extremely accurate biopsy core deployment in the Index Lesion. We thus hypothesized that targeted biopsies are associated with a non-negligible risk of overgrading due to oversampling of the IL.

METHODS: We identified 403 men with localized PCa and GGG 4-5 who received MRI and subsequent systematic biopsy (SBx) plus TBx and eventually underwent RP at ten tertiary referral centers (2014-2021). The outcome was downgrading at RP (defined as GGG 1-3 at RP) of patients with GGG 4-5 at TBx only *vs*. SBx only. Multivariable logistic regression models (MVA) were fitted. A local polynomial smoother weighted function was used to test the interaction between the rate of downgrading and clinical confounders.

RESULTS: Overall, 178 (44%) patients exhibited downgrading at RP. Specifically, 129 (32%) and 49 (12%) exhibited downgrading to GGG 3 and GGG 1-2, respectively. The rate of downgrading at RP of those men that had GGG 4-5 at SBx only *vs.* TBx only *vs*. TBx plus SBx was 25 (N.=102) *vs.* 30 (N.=120), *vs.* 13% (N.=54), respectively (P=0.013). At MVA PCa with GGG 4-5 found at TBx was at higher risk of downgrading as compared to PCa with GGG 4-5 found at SBx (OR=1.47). On the other hand, patients with higher GGG (OR=0.29) and larger IL (OR=0.96) were less likely to exhibit downgrading (all P<0.05). At interaction analyses, the rate of downgrading was significantly associated with the size of the IL. Specifically, the probability of downgrading at RP decreased with increasing size of the IL, being roughly half for those with an IL size higher than 20 mm.

CONCLUSIONS: The rate of PCa downgrading at RP is higher in patients with GGG 4-5 detected at TBx only, as compared to those with GGG 4-5 at SBx only and in both TBx and SBx. Patients with PCa with high GGG detected at TBx only should be carefully evaluated since they may harbor a more favorable disease and thus, they might benefit from a less intensive treatment approach.

SMART (SC392-SC399)

Urinary Lithiasis 1

SC392
Alfa-phytotherapy *vs.* tamsulosin in the treatment of ureteral stent related symptoms after ureterolithotripsy: a randomized clinical trial

SC393
Understanding the role of ureteral access sheath in preventing acute kidney injury in patients treated with ureteroscopy and Ho:YAG laser for urinary stone: results from a tertiary care referral center

SC394
Clinical and time-related predictors of sepsis in patients with obstructive uropathy due to ureteral stones in the emergency setting

SC395
Urinary tract infection predictors in patients undergoing retrograde intrarenal surgery for renal stones: does the instrument make the difference?

SC396
Characteristics and predictors of sepsis or acute pyelonephritis in combination with ureteral stone in the USA: a large population-based cohort analysis

SC397
Is it useful to drain every kidney access after percutaneous nephrolithotomy with multiple tracts? Findings from a cross-sectional study

SC398
CT relative findings in stone related-urosepsis prediction: a pilot study

SC399
Monocyte distribution width can help diagnose sepsis and monitor patients with obstructive urolithiasis in an emergency setting

SC392

Alfa-phytotherapy vs. tamsulosin in the treatment of ureteral stent related symptoms after uretero-lithotripsy: a randomized clinical trial

D. Fiasconaro, C. De Nunzio, A. Nacchia, C. Gravina, G. Gallo, L. Sarcinelli, F. Zammitti, N. Ghezzo, A. Guidotti, R. Lombardo, A. Franco, G. Tema, A. Cicione, A. Pastore, A. Sciarra, G. Di Pierro, G. Franco, A. Tubaro (Rome)

BACKGROUND: Ureteral double J stent are routinely applied for several urologic procedures although stent-related symptoms are common. In order to minimize these symptoms numerous attempts have been reported. The aim of our study is to compare an alfa-blocker phytotherapy (a combination of extracts of Solidago virga-aurea, *Phyllantus niruri*, *Epilobium angustifolium*, *Peumus boldus* and *Ononis spinosa*) *vs.* tamsulosin effect on double J stent-related symptoms.

METHODS: Between October 2021 and October 2022, 60 patients undergoing ureterolithotripsy for ureteral stoned with double J stent positioning were randomly divided into two (group 1, N.=30, group 2, N.=30). Each patient randomly received tamsulosin 0.4 mg (1 capsule per day before sleep, group 1) or phytodrug (1 capsule filled with extracts per day before sleep, group 2) for 1 month in an open label setting. Ureteral stent-related morbidity indices analyzed include urinary symptom, pain, general health, quality of work and sex scores. All of indices were measured by Ureteral Symptom Score Questionnaire (USSQ) at the first, seventh and twenty-first (double J stent removal) day after stent positioning (labeled as d1, d7, and d21, respectively).

RESULTS: Overall, the mean age was 57 years. Mean BMI was 24.8 kg/m^2 and mean overactive bladder symptom score (calculated at baseline) was 38. At baseline, there were no statistically significant differences in background characteristics between groups (P>0.05). Although both treatments resulted in an improvement from baseline in each USSQ parameter, no statistically significant differences were detected between the 2 groups in terms of improvements in urinary symptoms, pain, general health, work performance and sexual matters at 7 and 21 days (P>0.05).

CONCLUSIONS: According to our results, we suggest that this combination of extracts could be as effective as tamsulosine 0.4 mg to minimize stent-related urinary symptom and improve general health in patients with double J stent.

SC393

Understanding the role of ureteral access sheath in preventing acute kidney injury in patients treated with ureteroscopy and Ho:YAG laser for urinary stone: results from a tertiary care referral center

L. Candela, L. Villa, M. Fantin, A. D'Arma, E. Ventimiglia, F. Montorsi, A. Salonia (Milan)

BACKGROUND: The use of ureteral access sheath (UAS) improves the irrigation flow during ureteroscopy (URS), thus limiting the increase of intrarenal pressure and temperature. Elevated intrarenal pressure and temperature may cause renal parenchymal impairment. We aimed at evaluating the relationship between the UAS use and the occurrence of postoperative acute kidney injury (AKI) in stone patients treated with URS.

METHODS: Data from 584 patients treated with URS and Ho:YAG laser lithotripsy for ureteral/renal stone from February 2015 to October 2022 at a single academic referral center were analyzed. UAS (10/12 Fr) placement was attempted during intrarenal surgery. Post-operative AKI was defined as an increasing of serum creatinine level >0.3 mg/dL within postoperative day two according to the Kidney Disease Improving Global Outcomes (KDIGO) criteria. Univariable (UVA) and multivariable (MVA) logistic regression analyses tested the association of patients' characteristics (age at surgery, CCI score, renal function, stone diameter, hydronephrosis, stone location, prestenting) and operative data (use of UAS, operative time) with the rate of postoperative AKI.

RESULTS: Complete data including pre- and postoperative serum creatinine levels of 150 URS procedures were available. Median (IQR) age was 58 (48-68) years, and median (IQR) operative time was 60 (45-90) minutes. Eighty-four (68%) patients were males, and 20 (13%) patients had a CCI≥1. Median (IQR) preoperative serum creatinine level and estimated glomerular filtration rate (eGFR) were 1 (0.85-1.25) mg/dL and 74 (54-88) mL/min, respectively. Overall, 44 (29%) patients had preoperative chronic kidney disease stage ≥3 (*i.e.*, eGFR<60 mL/min). Stone was located in kidney, ureter or both in 46 (31%), 74 (49%) and 30 (20%) patients, respectively. UAS was used in 77 (51%) procedures. Overall, post URS AKI occurred in 12 (8%) patients; of those, 6 procedures were carried out with and 6 without UAS. At UVA and MVA performing URS without UAS was not associated with an increased risk of AKI (OR=1.97; 95% CI: 0.43-8.97; P=0.38). Interestingly, age at surgery and operative time resulted independent predictors of postoperative AKI (OR=1.07; 95% CI: 1.00-1.13; P=0.03 and OR=1.02; 95% CI: 1.00-1.03;P=0.02, respectively).

CONCLUSIONS: AKI is a not neglectable postoperative complication in patients treated with URS. The use of UAS does not influence the onset of post URS AKI. However, older age and longer URS procedure are associated with a higher risk of developing postoperative AKI. Current findings should be considered for the perioperative management of stone patients treated with URS.

SC394

Clinical and time-related predictors of sepsis in patients with obstructive uropathy due to ureteral stones in the emergency setting

E. Lievore, A. Marmiroli, A. Nogara, G. Lucignani, M. Turetti, C. Silvani, M. Nizzardo, S.P. Zanetti, F. Longo, E. De Lorenzis, G. Albo, E. Montanari, L. Boeri (Milan)

BACKGROUND: Evaluation of obstructive uropathy due to ureteral stones is not well defined and clear clinical predictors of sepsis in this situation are lacking. Our aim is to identify clinical and time-related predictors of sepsis after decompression of the upper urinary tract, such as delay time from symptom onset to hospital presentation (StH) and from hospital presentation to surgical decompression (HtD).

METHODS: We collected 196 consecutive patients evaluated at the Emergency Department between January 2016 and August 2021 and submitted to stent or nephrostomy tube decompression for obstructive uropathy from ureteral

stones. Complete clinical, laboratory and radiological data were analyzed. Comorbidities were scored with the Charlson Comorbidity Index (CCI). Computerized tomography (CT) was performed before surgery. We evaluated St and HD timing and stone characteristics. A postoperative increase in ≥2 SOFA points together with positive blood or urine cultures defined sepsis. Predictors of sepsis were evaluated using descriptive statistics and logistic regression models.

RESULTS: Eighty-six (43.9%) patients were female, median (IQ) age was 55 (44-67) years and 88 patients (44.9%) had CCI≥1. Median stone diameter was 6.2 (4.4-8.0) mm. Distal ureteral stones were present in 74 (37.8%) patients and a nephrostomy tube was placed in 58 (20.8%) patients. In the whole cohort, 33 (16.8%) patients developed sepsis, of which 75.8% were female (P=0.001). Median St and HD were 24 (6-48) and 17 (10-30) hours, respectively. Higher preoperative max body temperature (P<0.001), white blood cells (WBC) count (P<0.01) and C-reactive protein (CRP) values (P<0.001) were found in septic patients than in non-septic ones. Septic patients had also higher (7.2 *vs.* 6 mm, P=0.02) stone diameters. St and HtD did not differ according to sepsis status. Septic patients required longer time for WBC normalization and CP halving than those who did not develop sepsis (all P<0.02). Female gender (OR=3.6; P=0.02), max body temperature ≥38 °C (OR=15.5; P<0.001) and higher CRP (OR=1.1; P=0.01) at presentation were predictors of sepsis status at multivariable logistic regression analysis after accounting for age, CCI, stone diameter and HiD.

CONCLUSIONS: Risk of sepsis after urinary diversion in patients with obstructive uropathy does not appear to be associated with delay from symptom onset to hospital presentation or to surgical decompression. Conversely, clinical and laboratory parameters such as female gender, higher body temperature and CP are associated with higher risk of sepsis after urinary diversion. These data could indicate that urinary diversion may be delayed and/or primary ureteroscopy may be considered in selected patients.

SC395
Urinary tract infection predictors in patients undergoing retrograde intrarenal surgery for renal stones: does the instrument make the difference?

F. Prata, A. Salerno, L. Cacciatore, S. Basile, A. Ragusa, A. Iannuzzi, F. Tedesco, A. Civitella, P. Tuzzolo, P. Callè, G. Raso, M. Pino, M. Ricci, R.M. Scarpa, R. Papalia (Rome)

BACKGROUND: Retrograde intrarenal surgery (RIRS) with flexible ureterorenoscope is one of the main approaches used for renal stone removal, however it is associated with a non-negligible rate of postoperative urinary tract infection (UTI) with potential complications. For this reason, single use ureterorenoscope are gaining popularity among stone centers worldwide. The aim of this study was to evaluate the postoperative infection rate in patients undergoing RIRS with single-use flexible ureterorenoscope in comparison to multi-use ureterorenoscope, and to identify predictors of postoperative UTI.

METHODS: Between March 2022 and March 2023, one hundred thirteen consecutive patients affected by renal stones underwent RIRS at our Institution. Peri-operative data were collected. Evaluation included age, gender, Body Mass Index (BMI), stone size, stone location, type of ureterorenoscope, Hounsfield units (HU), preoperative hydronephrosis, laboratory analysis, and operative time. All surgeries were performed by a single surgeon and ureteral stenting was not done prior surgery. The predictors of UTI after RIRS were assessed by univariate and multivariate logistic regression analysis. A two-sided P<0.05 was considered statistically significant.

RESULTS: Of the cohort considered, 77 (68.7%) surgeries were performed with multi-use ureterorenoscope while 35 (31.3%) with single use, whereas one patient was excluded from the analysis due to the intraoperative malfunctioning of the ureterorenoscope (N.=1). Median age and BMI were 58 years (IQR: 50-66) and 26.12 kg/m^2 (IQR: 23.74-29.39), respectively. The majority of patients showed left renal stones (58%), 39% of them had right renal stones, and only 3% presented bilateral lithiasis. Median stone size and HU were 12 mm (IQR: 9.5-17.5) and 1350 (IQR: 950-1640), respectively. The majority of procedures were carried out with the use of Holmium laser (69.9%) while 30.1% underwent lithotripsy through Thulio® with RealPulse technology (Dornier MedTech GmbH, Weßling, Germany). Median operative time was 57 mins (IQR: 35-85). Twenty-five patients (22.3%) presented postoperative UTI. At univariate logistic regression analysis, stone diameter (OR=1.15; 95% CI: 1.05-1.25; P=0.001), number of stones (OR=2.24; 95% CI: 1.25-4.01; P=0.006), type of ureterorenoscope (multi-use *vs.* single use) (OR=1.28; 95% CI: 0.55- 0.97; P=0.01), and operative time (OR=1.13; 95% CI: 1.08-1.18; P<0.001) were predictors of postoperative UTI. Multivariable logistic regression showed that operative time (OR=1.3; 95% CI: 0.55-0.99; P=0.03) and type of ureterorenoscope (multi-use *vs.* single use) (OR=1.14; 95% CI: 1.08-1.2; P<0.001) resulted to be the only independent predictors of postoperative UTI.

CONCLUSIONS: In the setting of retrograde endoscopic treatment for renal stones, multi-use ureterorenoscope and longer operative time appear to be related with development of postoperative UTI. Careful preoperative evaluation and patients' selection are key factors to prevent undesirable postoperative UTIs.

SC396
Characteristics and predictors of sepsis or acute pyelonephritis in combination with ureteral stone in the USA: a large population-based cohort analysis

P. Dipinto, V. Asero, C.M. Scornajenghi, E. De Berardinis, A. Sciarra, S. Basran, M.L. Eisenebrg, B.I. Chung, F. Del Giudice (Rome)

BACKGROUND: Approximately 78% of urinary sepsis cases are caused by obstructive uropathy: 43% by urinary stones, 25% by an enlarged prostate, and 18% by urinary tract cancer. If sepsis or APN is caused by ureteral obstruction, intensive treatment with surgical decompression, such as percutaneous nephrostomy or retrograde double J stenting, is necessary. Ureteric stones can be treated with medical expulsive therapy, shockwave lithotripsy, and endoscopic surgery, but if sepsis or APN is accompanied, the treatments are different and more urgent. We aimed to analyze the risk factors and to recognize the characteristics of patients with sepsis or APN caused by ureteral calculi using a large private insurance claims-based dataset.

METHODS: We included patients with sepsis or APN caused by ureteral calculi who received treatment in the United States from January 2003 to December 2017 using the Optum® deidentified Clinformatics® Datamart Claims Database (Optum, Eden Prairie, MN, USA). Logistic regression modeling was applied to assess the risk factors of sepsis. To avoid the possible confounding effect by age, propensity score matching method was used to match one sepsis patient with two non-sepsis patients. Conditional logistic regression was applied for the age-matched data.

RESULTS: Of 467,502 urinary stone patients, age-matched multivariate analyses revealed that a history of urinary tract infection (OR=11.31, 95% CI: 10.68-11.99, P<0.0001) and female gender (OR=2.73, 95% CI: 2.62-2.84, P<0.0001) were significantly related to an increased risk of sepsis or APN. Conversely, a previous past medical history of urolithiasis (OR=0.91, 95% CI: 0.87-0.95, P<0.0001) and cancer (OR=0.91, 95% CI: 0.87-0.95, P<0.0001) were associated with a decreased risk of sepsis or APN. With regards to comorbidities, when more than one comorbidity was present, there was an additive effect with higher OR point estimates, rising to 11.31 (10.68-11.99) when three or more comorbidities were present.

CONCLUSIONS: A history of urinary tract infection and female gender are the highest individual risk factors for development of sepsis or APN in patients with ureteral calculi. The presence of concomitant comorbidities also is significant, especially when there are multiple; moreover, understanding all these factors should be the basis of risk stratification in the treatment of these high-risk patients.

SC397
Is it useful to drain every kidney access after percutaneous nephrolithotomy with multiple tracts? Findings from a cross-sectional study

A. Marmiroli, A. Nogara, G. Lucignani, M. Turetti, C. Silvani, M. Nizzardo, E. Lievore, S.P. Zanetti, F. Longo, E. De Lorenzis, G. Albo, E. Montanari, L. Boeri (Milan)

BACKGROUND: Percutaneous nephrolithotomy (PCNL) with multiple accesses tracts is usually considered the surgical technique for complex kidney stones. To ensure proper drainage and hemostasis of the tract following PCNL, the nephrostomy tube is the standard exit approach. The need for draining each tract following PCNL with numerous kidney accesses is not well understood. The aim of our study was to compare outcomes of PCNL for complex renal stones performed with multiple drained tracts with procedures performed with multiple accesses but only one tract drained.

METHODS: Data from 398 patients who had PCNL at a single tertiary-referral academic between January 2016 and September 2022 were examined. Among the 398 procedures, 33 (8.3%) PCNL were performed with multiple accesses and only one tract drained (group 1) and 37 (9.3%) PCNL with multiple drained tracts (group 2). Stones characteristics, operative data and patient's demographics were collected. Stone-free status was outlined as the absence of any remaining stones. Modified Clavien-Dindo Classification was used to record and grade complications. The association between predictors and procedural outcomes was tested with descriptive statistics and linear regression models.

RESULTS: Overall, the stone volume and median (IQR) age were 5.1 (2.6-14.0 cm^3 and 51 (45-61) years, respectively. Mini PCNL was performed in 51 (72.9%) cases. After surgery, 28 (40.0%) patients had postoperative complications (any Clavien) and 31 (44.3%) were stone free. Groups were similar in terms of stone volume, clinical characteristics, hemoglobin drop and operative time. The frequency of complications (42.4% *vs.* 38.9%) and stone free rate (37.5% *vs.* 41.4%) were similar among group 1 and 2. Hospitalization time was longer for group 2 than 1 (7 *vs.* 6 days, P=0.03). According to multivariable linear regression analysis accounted for stone volume, procedures with multiple drained tracts (β: 2.4, P=0.03) and the incidence of postoperative complications (β: 2.7, P=0.02) were independently associated with hospitalization time.

CONCLUSIONS: According to our findings, using a single nephrostomy tube as an exit strategy rather than draining each tract during PCNL for complicated renal stones did not impact procedural outcomes. Procedures using a single access drain resulted in a shorter hospitalization time. In clinical practice, draining only the most useful tract for potential second-look procedures should be taken in consideration.

SC398
CT relative findings in stone related-urosepsis prediction: a pilot study

C. Labate, A. Panunzio, F. Zacheo, E. Luperto, A. Cavaliere, F. Di Cosmo, F. De Carlo, M. Rizzo, S. Marinacci, F. Greco, P. Ditonno, A. Tafuri, V. Pagliarulo (Lecce)

BACKGROUND: Urosepsis is an acute event often caused by urolithiasis, with potential serious effects on patient survival. Hydronephrosis and pyuria may be associated with faster systemic bacteria dissemination, while laboratory changes often appear as a late manifestation. The CT evaluation is recommended by guidelines for a safer and faster diagnosis. The aim of this study was to identify the CT related findings which may predict the onset of sepsis in patients with ureteral stones.

METHODS: This is a retrospective study. Only patients with first ER access due to renal colic pain, treated with ureteral stenting, were included in the study. Demographic, clinical, laboratory and radiological data were collected. Preoperative radiological kidney pelvis density (HU) was measured in three different ROI (region of interest) and the mean value was calculated. Univariate analysis was used to evaluate the association between pelvis density, intraoperative pyuria detection after ureteral stent placement and pre- and postoperative laboratory and clinical data.

RESULTS: Between January 2022 and December 2022, 84 patients were included (group A: intraoperative pyuria after ureteral stenting; group B: no intraoperative pyuria after ureteral stenting). Intraoperative pyuria after ureteral stent positioning was detected in 44 (52%) patients. No statistically significative differences in age, gender and BMI were reported. Our statistical analysis showed significative differences (P=0.013) in preoperative mean renal pelvis radiological density (HU), where higher renal pelvis density, reported as continuous variable, revealed to be associated with more frequent intraoperative pyuria detection (5.50 HU in group B *vs*. 8.25 HU in group A; OR=1.07, 95% CI: 1.00-1.16, P=0.047). Similarly, also preoperative fever was more frequent in case of intraoperative pyuria reporting (10% *vs.* 23%, P=0,009; OR=3.53, 95% CI: 1.37-9.84, P=0.011). Diabetes

mellitus was a risk factor for pyuria, as it was reported in 23% of patients with intraoperative purulent discharge *vs.* 5% group B (P=0.20). No statistically significant differences between the two groups were reported for each lab test (white blood cell count, procalcitonine, C-reactive protein and serum-creatinine), for each time point comparison, except for 24-hour PCT, P=0.034. Only the presence of preop fever revealed to be associated with postoperative fever onset (yes *vs.* no OR=18.00, 95% CI: 4.36-123.51; P<0.001), but not the intraoperative pyuria detection during double j positioning (yes *vs.* no OR=2.58, 95% CI: 0.78-10.11; P=0.14) or renal pelvis density (OR=1.01, 95% CI: 0.92-1.09; P=0.9). Patients who experienced postoperative fever required longer hospitalization (OR=1.65, 95% CI: 1.16-2.47, P=0.008) and catheterization (OR=1.47, 95% CI: 1.07-2.12, P=0.024).

CONCLUSIONS: Given that laboratory changes may appear as a late urosepsis manifestation, preoperative renal pelvis density HU, may be a useful tool for sepsis onset prediction and in patient management.

SC399
Monocyte distribution width can help diagnose sepsis and monitor patients with obstructive urolithiasis in an emergency setting

D. Baiamonte, I. Lampasona, S. Altomare, P. Mannone, N. Pavan, G. Tulone, R. Giaimo, L. Agnello, B. Lo Sasso, R.V. Giglio, C.M. Gambino, M. Ciaccio, A. Simonato (Palermo)

BACKGROUND: Sepsis of the urinary tract secondary to stones is a urological emergency that requires immediate diagnosis and treatment. Monocyte distribution width (MDW) is a new emergent sepsis marker that evaluates the morphological changes of activated monocytes, and it is part of a complete blood cell count (CBC). MDW showed promising results in the emergency rooms and ICUs in diagnosing sepsis, and it seems to not be influenced from other factors such as surgical stress. The aim of our study was to evaluate whether MDW is able to identify septic patients who seek emergency treatment for urolithiasis and to monitor their responses to therapies.

METHODS: Clinical data of patients with kidney or ureteral stones undergoing urgent nephrostomy or stent placement (mono J vs. double J) from April 2021 to October 2022 were evaluated. Complete blood count (CBC), MDW and C-Reactive Protein (CRP) were evaluated and divided into preoperative, postoperative and at discharge time tests. A value ≥23 of MDW was considered indicative of sepsis, according to the literature. To calculate MDW, CBC samples were analyzed with the DxH 900 Analyzer (Beckman Coulter Inc., Brea, CA, USA). Sepsis was defined as SIRS and simultaneous infection, in accordance with the Sepsis 2 criteria. Chi square test for nominal variables and the t student test for continuous variables were used.

RESULTS: One hundred seven patients were included in this study. 42 patients (32.3%) had sepsis according to Sepsis2 criteria. Older age (P=0.005), fever upon entry (P=0.01), cloudy urine (P=0.02) and positive urine cultures (P=0.002) were more frequent in patient with sepsis. There was no difference in total monocytes number between the two groups (no sepsis 1.08 10^3/μL±1.36 vs. sepsis 0.82 10^3/μL±0.49; P=0.26). There was a statistically significant difference in preoperative MDW values between patients with sepsis and those without (sepsis MDW 31±9.58 vs. no sepsis MDW 22.3±5.82; P=0.001). An MDW value ≥23 was statistically associated with sepsis (P=0.001). Considering kinetics in septic patients, MDW decreased significantly postoperatively (preoperative MDW 31±9.58 vs. postoperative MDW 25.3±6.3; P=0.01) and tended to normalize at discharge time (preoperative MDW 31±9.58 vs. discharge time MDW 22.2±5.6; P=0.001).

CONCLUSIONS: Monocyte Distribution Width (MDW) could be used to diagnose sepsis in patients with urinary stones in an emergency setting. MDW was found to be able to discriminate septic patients from non-septic ones and to give indications about the patients' responses after surgical urinary derivation and concomitant therapies. Considering that MDW is part of a complete blood count, it is easily measurable and available as well as cheap compared to other sepsis markers (e.g., CRP or procalcitonin).

SMART (SC400-SC401)

Trauma and urethral surgery

SC400
Fournier gangrene: evaluation of preoperative CT findings and interobserver reliability through NSTI score

SC401
Robot-assisted ureteral reconstruction for iatrogenic injuries of the ureter

SC400
Fournier gangrene: evaluation of preoperative CT findings and interobserver reliability through NSTI score

G. Schiraldi, A. Pavan, F. Gadda, M.C. Andrisani, G. Carrafiello (Milan)

BACKGROUND: The aim of this study was to introduce a new evaluation for the investigation of Fournier's gangrene targeted to search for certain findings that would emerge on the CT abdomen and pelvis to achieve early diagnosis of the disease and the best treatment for the patient.

METHODS: This is a monocentric retrospective study wherein we selected 11 male patients with a mean age of 63±15 years with an anatomopathological diagnosis of Fournier's gangrene derived from tissue sampling in the surgical field and who had performed a preoperative CT scan. We subsequently involved two radiologists with long-term experience to evaluate the CT images by utilizing the NSTI score taking into consideration of 5 parameters at imaging: fascial air, muscle or fascial edema, fluid tracking, lymphadenopathy, and subcutaneous edema. Cohen's *k* coefficient was calculated for interobserver reliability.

RESULTS: For both examiners, due to the NSTI score, all patients had a score >6 and thus were compatible with a diagnosis of Fournier's gangrene. The results reproduced from this analysis reported the perfect interobserver agreement (k=1) for the parameters of fascial air, muscle or fascial edema, and subcutaneous edema. For lymphadenopathy, there was modest concordance between the two evaluators (k=0.31). Finally, the two radiologists had only moderate concordance for fluid tracking (k=0.47).

CONCLUSIONS: Our study demonstrated good reproducibility of the NSTI system for early radiologic diagnosis of Fournier's gangrene and for scheduling the best surgical approach for the patient. The limitations of our study were that all patients examined were males and that no defined parameters were used for lymph node assessment.

SC401
Robot-assisted ureteral reconstruction for iatrogenic injuries of the ureter

S. Viganò, M. Rossanese, L. Macchione, G. Mucciardi, V. Ficarra (Messina)

BACKGROUND: Iatrogenic ureteral injuries are devastating complications potentially resulting in irreversible impairment of renal function and/or infectious sequelae. The objective of the present study was to report the perioperative outcomes, and treatment failure rate of a recent series of patients who underwent robot-assisted ureteral reconstruction for iatrogenic injuries of the ureter.

METHODS: We prospectively collected in a dedicated databases all the patients requiring a surgical treatment for iatrogenic ureteral lesions at our academic centers between January 2018 to December 2022. For the objective of the present study, we extracted from the database only cases who underwent a laparoscopic robot-assisted approach. All cases were performed by a single expert surgeon. In details, different surgical reconstructive procedures, such as ureteral reimplantation with or without bladder psoas hitch; Boari bladder flap, ureteroureterostomy, and pyeloureteroplasty, have been adopted according to the level of the ureteral lesion. Outcome measures were rate of postoperative complications, and rate of treatment failure, defined as upper urinary tract obstruction requiring permanent urinary drainage.

RESULTS: An overall of 24 patients received a robot-assisted ureteral reconstruction. Patients who underwent robotic surgery had a mean age of 58 years. Fourteen (58.3%) patients were females and 10 (41.7%) males. The mean BMI value was 25.6. Injuries were consequent to endourological procedures in 14 (58.3%) cases, gynecological procedures in 6 (25%); robot-assisted radical prostatectomy in 3 (12.5%%) and colonic surgery in 1 (4.1%). The lesions were in 16 (66.6%) cases at level of the pelvic ureter; in 4 (16.7%) at level of iliac ureter and in 4 (16.7%) cases at level of the lumbar ureter. Ureteric reimplantation with or without psoas hitch was performed in 12 (50%) cases; Boari flap in 7 (29.2%), uretero-uretero anastomosis in 4 (16.7%) cases and pyeloureterostomy in 1 (4.1%). The median (IQR) OR was 245 min (215-270), and no intraoperative complications were reported. The median EBL was 0 (0-50) mL. The median time to catheter removal was 7 (6-9) days. The median in-hospital stay (days) was 8 (8-10). Minor postoperative complications were observed in 2 (8.3%) cases and only 1 (4.1%) major complication was observed (grade 3 complication, patient requiring mono J placement). At a minimum follow-up of 6 months, no treatment failure was observed.

CONCLUSIONS: Robot-assisted approach can be safely used in the treatment of iatrogenic ureteral injuries. Therefore, this approach represents a valid minimally invasive option above all in those patients in which the ureteral lesion was determinate during endourological or laparoscopic procedures.

SMART (SC402-SC411)

Prostate cancer: diagnosis 2

SC402
Prospective evaluation of the diagnostic accuracy of different PSMA-PET/CT tracers for primary staging in prostate cancer: a single institutional analysis
SC403
Early results of Prospet-Bx trial on prospective comparison of PSMA PET/CT *vs.* MPMRI in patients with previously negative prostate biopsy
SC404
PSMA expression in high-risk prostate cancer: head-to-head comparison of preoperative PSMA-PET features and immunohistochemistry analysis of bioptic cores and whole mount specimen
SC405
Comparison of the diagnostic accuracy of PSMA-PET/CT scan and Briganti nomogram to predict lymph node invasion in prostate cancer: a single institutional analysis
SC406
Correlation between PSMA-PET/CT data and pathological tumor staging and grading of prostate cancer
SC407
SUV variation on PSMA PET/CT correlates with biochemical response in patients with prostate cancer undergoing high-intensity focused ultrasound (HIFU) focal therapy
SC408
The role of stadiative PSMA-PET/CT scan prior to radical prostatectomy: a single center experience
SC409
The association between PSA density and the detection of clinically significant prostate cancer across all PIRADS scores in men with positive MPMRI: when PSA density can help avoiding prostate biopsy?
SC410
PSMA radio-guided surgery to detect nodal metastases in prostate cancer patients undergoing robot-assisted radical prostatectomy and extended pelvic lymph node dissection: updated results of planned interim analyses of a prospective phase 2 study
SC411
The prognostic impact of preoperative PSMA-PET on early oncological outcomes in prostate cancer patients treated with radical prostatectomy: results of a multicenter analysis

SC402
Prospective evaluation of the diagnostic accuracy of different PSMA-PET/CT tracers for primary staging in prostate cancer: a single institutional analysis

P. Arena, V. Fasulo, G. Chiarelli, N. Frego, F. De Carne, D. Maffei, J. Jandric, F. Gelardi, G. Garofano, C. Saitta, S. Mancon, F. Sordelli, E. Beatrici, R. Hurle, A. Saita, M. Lazzeri, G. Guazzoni, N. Buffi, G. Lughezzani, P. Casale (Pieve Emanuele, Milan)

BACKGROUND: PSMA PET/CT has emerged as a useful tool for primary and recurrent prostate cancer (PCa). The rational of the technique is the use of agents able to detect PSMA, overexpressed in PCa cells. Radiopharmaceuticals adopted are 68Ga-PSMA-11 (68Ga) or 18F-PSMA-1007 (18F). Despite the widespread use of PSMA PET/CT, the impact of lack of standardization and use of different tracers on its diagnostic accuracy is still unknown. The aim was to evaluate the accuracy of the two agents for nodal staging and to compare the diagnostic performance.

METHODS: We reviewed prospectively collected data of patients (patients) that referred to our tertiary-hospital from October 2020 to January 2023. We included patients who underwent 68Ga or 18F PSMA PET/CT in a primary staging setting that underwent robot assisted radical prostatectomy (RP) with lymph node dissection (LND). We excluded PSMA PET/CT performed elsewhere and patients who did not receive LND. For each examination, the maximum standard uptake value (SUV) of both primary tumor and nodes (LN) as well as the SUV node to Background Ratio was reported. We adopted 2 different cut off of node to background ratio (≥/<2 *vs.* >/≤15.5) to evaluate the performance of both tracers. The first one was empirically decided, the second was based on Liu methods for optimal cut-point.

RESULTS: Overall, 156 patients were included; mean age was 67 (60-71) and mean PSA 7.6 (6- 14.29) ng/mL. Based on EAU risk group 80 (51.28%) patients had low-intermediate risk, and 76 (48.71%) high-risk PCa; they all had an estimated risk of LN invasion ≥5% or 7% according to the Briganti 2012 or 2019 nomograms. Eighty-three (53.21%) patients underwent 68Ga and 73 (46.79%) 18F PSMA PET/CT. Twenty-five (16.03%) patients were pN1. PSMA PET/CT showed suspicious LNs in 21 patients, 8 (38.09%) with 68Ga and 11 (52.38%) with 18F. Nine of those 21 patients had positive LNs at the pathological report. Considering a SUV Cut Off Ratio ≥2 the diagnostic performance of 68Ga and 18F PSMA PET/CT respectively was: sensitivity (SE) 37.5 (15.2-64.6) and 33.3 (7.49- 70.1); specificity (SP) 98.5 (92-100) and 100 (94.4-100). The accuracy was slightly higher for 68Ga PSMA PET/CT: 0.68 (0.55-0.90) *vs.* 0.66 (0.50-0.83). Increasing the cut off to >15.5 SE was 31.3 (11.0-58.7) and 11.1 (0.28-48.2) while SP was 100 (94.5-100) and 100 (94.4-100) for both tracers. Finally, the accuracy was slightly higher for 68Ga 0.65 (0.53-0.77) *vs.* 18F 0.55 (0.44-0.66) PSMA PET/CT.

CONCLUSIONS: 18F PSMA PET/CT showed a lower SN and relatively higher SP for nodal staging compared to 68Ga PSMA PET/CT, irrespective of the SUV ratio used. Further studies are warranted to provide a better risk stratification in RP candidates.

SC403
Early results of Prospet-Bx trial on prospective comparison of PSMA PET/CT *vs.* MPMRI in patients with previously negative prostate biopsy

D. Maffei, V. Fasulo, L. Disconzi, P.P. Avolio, N. Frego, R. Hurle, A.R. Saita, P.G. Colombo, K. Marzo, L. Leonardi, L. Balzarini, A. Chiti, G.F. Guazzoni, M. Lazzeri, G. Lughezzani, P. Casale, N.M. Buffi, E. Lopci (Milan)

BACKGROUND: We present the preliminary data obtained from a prospective registered trial (NCT05297162) designed to compare in parallel (68Ga) PSMA PET/CT with mpMRI-targeted prostate biopsy in men with high suspicion of prostate cancer (PCa) after at least one previous negative biopsy.

METHODS: Patients who completed the study investigations from April 2022 were considered for analysis. Inclusion criteria were: 1) PSA level >4.0 ng/mL; 2) free-to-total PSA ratio<20%; 3) progressive rise of PSA levels in two consecutive blood samples despite antibiotics; 4) >1 previous negative biopsy (including ASAP and HG-PIN); and 5) negative digital rectal examination. All eligible patients underwent (68Ga) PSMA PET/CT and mpMRI scans within one month from each other. Targeted TRUS-fusion and systematic biopsy was performed on all lesions detected with PET and mpMRI.

RESULTS: 18/24 enrolled patients have completed the diagnostic pathway. Median age was 64 years (range: 50-80) and median PSA 11.4 ng/mL (range: 7.8-25). The majority (17/18) of patients had previously undergone one negative biopsy only, while one had undergone two. Median SUV_{max} and SUV_{ratio} to background of the targeted areas on biopsy were 4.2 (range: 2.2-42) and 1.6 (range: 1-14), respectively. A cut-off of SUV_{max}>5.4 and SUV_{ratio}>2.2 on PSMA PET/CT identified 6 patients (33.0%). MpMRI identified one (5.6%) patient with index lesion PI-RADS 3, three with PI-RADS 4 (16.7%) and 5 with PI-RADS 5 (27.8%) Index lesion. Pathology confirmed PCa diagnosis in 5 patients: two with Gleason Score (GS) 3+3 disease, 2 with Gleason 3+4 and one with GS 4+5. All clinically significant PCa (csPca; GS≥3+4) had a SUV_{max}>5.4, SUV_{ratio}>2.2 and PIRADS score 5. The SUV_{max}>5.4 and SUV_{ratio}>2.2 cut-offs yielded two false positives and two false negatives (both GS3+3 disease); PI-RADS ≥4 cut-offs yielded three false positives. Combination of both modalities resulted in an 80% detection rate for overall PCa and 100% for csPCa. The combination of two negative modalities would have spared 8 unnecessary repeat biopsies (44.4%) without missing any csPca.

CONCLUSIONS: Preliminary trial results show that the combination of [68Ga] PSMA PET/CT with mpMRI in patients candidate to rebiopsy, can increase the detection rate of clinically significant prostate cancer up to 100% while sparing 44% of unnecessary biopsies.

SC404
PSMA expression in high-risk prostate cancer: head-to-head comparison of preoperative PSMA-PET features and immunohistochemistry analysis of bioptic cores and whole mount specimen

M. Presutti, M. Droghetti, L. Bianchi, L. Vetrone, R. Mei, F. Giunchi, A. Farolfi, P. Castellucci, A. Degiovanni, A. D'Errico, M. Fiorentino, R. Schiavina, S. Fanti, E. Brunocilla (Bologna)

BACKGROUND: PSMA-PET has led to a change in the management of prostate cancer (PCa) patients, showing a

superiority in sensitivity and specificity to detect PCa compared to conventional imaging and other molecular imaging techniques. Among the different factors that may contribute to PSMA-PET positivity, the role of PCa immunohistochemical (IHC) features is still poorly addressed, and especially the potential utility of biopsy core staining and its correspondence with final pathological specimen. The primary outcome of this study was to assess the concordance between IHC features for PSMA expression of MRI Index lesion at target biopsy cores and the primary tumor at whole-mount final pathological examination. The secondary outcome of the study was to evaluate the correlation between IHC features of PCa at biopsy cores and PSMA-PET parameters.

METHODS: We included patients who underwent 68Ga PSMA-PET for high-risk PCa at our institution from January 2020 to December 2022 during the preoperative work up for radical prostatectomy (RP). PSMA-PET disease characteristics of the primary tumor such as SUV_{max}, relative tumor volume (RTV) and total lesion activity (TLA) were collected. MRI target biopsy cores and RP specimen were further analyzed with IHC tests. PSMA immunohistochemistry features consist of visual score (the intensity of the stain for PSMA expression was visually quantified through a four-tiered system [0 to 3]) and visual pattern (PSMA staining patterns, namely membranous and/or cytoplasmatic). Mann-Whitney's *U* Test was used to assess the correlation between median values of PET parameters (SUV_{max}, RTV, TLA) and IHC features (visual score and pattern) of both biopsy and final specimen. Cohen's *k* coefficient was used to assess the correlation and the concordance between biopsies and final pathology's IHC features. An alpha value of 5% was set to be the threshold to determine statistical significance.

RESULTS: Overall, 43 patients were available for our analyses with a median (IQR) age of 66 years (62-72). Median iPSA was 9.4 ng/mL. Two (4.7%) patients had a negative PSMA-PET for primary tumor. Median SUV_{max} was 15 (8.5-21.7). Median RTV and TLA were 4 (2.7-10-8) and 34.5 (14-50), respectively. Twenty-eight patients (65.1%) had a visual score 3 on biopsy. Membranous pattern was found in 74.4% of patients on biopsy cores. On final specimen, a visual score 3 was found in 76.8% of patients, and membranous pattern was found in 76.7%. Cohen's kappa coefficient between biopsy and final specimen visual score was 0.39, while for visual pattern was 0.38.

CONCLUSIONS: The IHC features for PSMA expression of MRI target biopsy cores showed poor correlation with final pathology specimen, therefore its utility to select patients who may have PSMA expression at PSMA-PET scan is suboptimal. However, the presence of membranous PSMA expression on biopsy specimens is related with higher disease activity on PET scan compared to cytoplasmatic expression.

SC405
Comparison of the diagnostic accuracy of PSMA-PET/CT scan and Briganti nomogram to predict lymph node invasion in prostate cancer: a single institutional analysis

V. Fasulo, P. Arena, G. Chiarelli, N. Frego, D. Maffei, F. De Carne, J. Jandric, F. Gelardi, F. Dagnino, C. Saitta, G. Garofano, E. Beatrici, F. Sordelli, S. Mancon, R. Hurle, A. Saita, M. Lazzeri, G. Guazzoni, N. Buffi, G. Lughezzani, P. Casale (Pieve Emanuele, Milan)

BACKGROUND: Lymph node involvement (LNI) is an important prognostic factor in prostate cancer (PCa) patients. According to guidelines, computer tomography (CT) and magnetic resonance imaging (MRI) may be used as preoperative imaging tools. However, considering the limitations of these tools, the Briganti nomogram, currently represents the gold standard for identifying those patients where a lymphadenectomy (LND) is indicated. Recently, PSMA PET/CT has emerged as a potentially accurate staging tool for PCa. We aimed to compare the accuracy of PSMA PET/CT *vs*. the Briganti nomogram within a single-institutional series.

METHODS: We reviewed data of patients referred to our tertiary-care center from October 2020 to January 2023. All patients included underwent PSMA PET/CT in a primary staging setting and they all were subjected to robot assisted radical prostatectomy (RARP) with LND because of a Briganti nomogram score higher than 5%. We excluded PSMA PET/CT done elsewhere as well as individuals who did not received LND. Nuclear doctors calculated standard uptake value $(SUV)_{max}$ nodes and Node to Background Ratio. Two different cut off values of node to Background Ratio (*i.e.*, ≥/<2 *vs.* >/≤15.5) were used to evaluate the diagnostic N staging performance of PSMA PET/CT. Logistic regression models were fitted to evaluate the predictors of LNI. The accuracy of PSMA PET/CT and Briganti nomogram was subsequently compared.

RESULTS: Overall, 156 patients were included; mean age was 67 (60-72) and 28 (17.95%) patients had a family history of PCa and mean PSA was 7.6 (6-14.29) ng/mL. PSMA-PET/CT medical reports showed positive nodes in 21 patients, with 9 (42.86%) having positive nodes at definitive pathological examination. N staging PSMA PET/CT accuracy, considering SUV Cut Off Ratio ≥/<2 and >/≤15.5, respectively was the following: sensitivity (SE) 36% (18-57.5) and 24% (9.36-45.1), specificity (SP) 99.2% (95.8-100) and 100% (97.2-100) Conversely, the Briganti nomogram accuracy was SE 21.7% (7.46-43.7) and SP 82.2% (74.5-88.31). At LRM the area Area Under the Curve (AUC) of Briganti nomogram was 0.51 (OR=1.2), AUC of PSMA PET/CT Ratio ≥/<2 plus biopsy ISUP was 0.76 (OR=66), while AUC of PSMA PET/CT Ratio >/≤15.5 was not shown due to collinearity.

CONCLUSIONS: PSMA PET/CT appears to be a promising tool to improve our ability to estimate the risk of LNI in PCa patients. Further large-scale studies should further explore its role in this specific setting, potentially promoting the use of this imaging tool alongside with the clinical parameters included in current nomograms.

SC406
Correlation between PSMA-PET/CT data and pathological tumor staging and grading of prostate cancer

P. Arena, G. Chiarelli, V. Fasulo, N. Frego, D. Maffei, F. De Carne, S. Moretto, M. Aljoulani, M. Lazzeri, N. Buffi, G. Lughezzani, P. Casale (Pieve Emanuele, Milan)

BACKGROUND: PSMA PET/CT has become the gold standard in clinical practice for whole-body re-staging of intermediate to high-risk prostate cancer (PCa). Its application in primary diagnosis has also been suggested. The aim of our study was to investigate PSMA-PET/CT performance in predicting local staging and pathological grading prior to

radical surgery, with the aim of tailoring the surgical approach according to disease characteristics.

METHODS: We retrospectively reviewed prospectively collected data of patients referred to our tertiary-care center from October 2020 to August 2022. All of them performed primary staging PSMA PET/CT and the primary treatment was robot assisted radical prostatectomy (RARP) with or without lymph node dissection (LND). The standard uptake value max of primary tumor (SUV_{max}) and Tumor to Background Ratio (SUV Ratio) were reported. We evaluated the relationship between SUV_{max} and SUV_{ratio} with pathological tumor (pT) staging and International Society for Urological Pathology (ISUP) grade. The Cochran-Armitage Test for trend was used to assess the relationship between SUV values and PCa stage and grade.

RESULTS: Overall, 179 patients were included; mean age was 66 (IQR: 60-71) and 38 (21.23%) patients had PCa family history. Mean PSA was 7.07 (5.44-11.95) ng/mL. According to European Association of Urology risk groups, 109 (61%) patients were low/intermediate risk and 70 (39%) were high risk. LND was performed in 134 (74.86%) patients. Mean SUV_{max} and SUV_{ratio} significantly increased from 5.3 (4.2-10.8) and 12 (7-20) in pT2a to 9.9 (6.9-18.5) and 20 (12-53) in pT3b patients, respectively (all $P<0.001$); mean SUV_{max} and SUV_{ratio} increased from 5.9 (5.3-67) and 9 (4-14) in ISUP 1 PCa to 11.9 (5.5-19.3) and 33 (17-53) in ISUP 5 PCa, respectively (all $P<0.001$). Similarly mean SUV_{max} and SUV_{ratio} increased from 6.82 (4.29-11.94) and 14 (10-30) in organ confined disease to 14.28 (7.1-22.88) and 29 (14-58) in non-organ confined disease, respectively (all $P<0.001$).

CONCLUSIONS: According to our results, both pT stage and ISUP grade appear to be significantly associated both with tumor stage and grade. In consequence, PSMA PET/CT could be useful for the pretreatment risk stratification of PCa individuals and may be adopted in the treatment decision-making process of these individuals.

SC407
SUV variation on PSMA PET/CT correlates with biochemical response in patients with prostate cancer undergoing high-intensity focused ultrasound (HIFU) focal therapy

E. Lopci, V. Fasulo, D. Maffei, E. Adjaye, S. Moretto, A. Saita, P. Colombo, R. Hurle, A. Chiti, L. Balzarini, N. Buffi, M. Lazzeri, G. Lughezzani, P. Casale (Rozzano, Milan)

BACKGROUND: Focal therapy (FT) for localized prostate cancer (PCa) offers minimally invasive localized ablative treatment while minimizing treatment-related toxicity compared to standard radical options. Recent advances in PCa imaging with PSMA PET/CT offer new opportunities to detect PCa foci and monitor response to treatment. The current study is designed to evaluate the role of PSMA PET/CT for response assessment in PCa patients candidate to High-Intensity Focused Ultrasound (HIFU) focal therapy.

METHODS: The present analyses was conducted in patients enrolled in an ongoing, prospective, single-center cohort study of patients treated with HIFU FT for localized PCa. Inclusion criteria were PSA<20ng/mL, radiological stage ≤T2bN0M0, ISUP grade 1-3, PSMA PET/CT at baseline and at response evaluation. Follow-up included: PSA at 3, 6 and 12 months; PSMA PET/CT between 6-12 months post treatment. Biochemical response and PET response were statistically correlated: SUV_{max} and SUV_{ratio} to background of the target lesions were used as semi-quantitative parameters for PSMA PET/CT, together with their variations before and after HIFU FT (*i.e.*, ΔSUV_{max} and ΔSUV_{ratio}).

RESULTS: Overall, 23 patients met inclusion criteria for the analysis. Median age was 67 years (IQR: 63-72), initial PSA (iPSA) was 5.9 ng/mL (IQR: 5.2-8.7) and prostate volume was 40 mL (IQR: 35.8-50.8). ISUP score was 1 in 16 (70%) patients and 2 in the remaining 7 (30%). Median SUV_{max} and SUV_{ratio} before treatment resulted 3.4 (IQR: 2.6-6.3) and 1.4 (IQR: 1.1-1.8), respectively. At 3 months post-HIFU, 35% of the patients obtained a PSA response ≥50%; whereas at 6 months and 12 months, PSA responses were 35% and 36%, respectively. Median SUV_{max} and SUV_{ratio} post-treatment resulted 2.5 (IQR: 1.7-3.4) and 0.9 (IQR: 0.7-1.0), respectively, proving a statistically significant reduction compared to baseline values ($P=0.048$ and $P=0.0051$, respectively). Median ΔSUV_{max} was -22% and ΔSUV_{ratio} resulted 30%. There was a statistically significant correlation of ΔSUV_{max} and PSA response at 12 months post-HIFU ($P=0.021$).

CONCLUSIONS: PSMA-PET may be a useful tool for monitoring response in PCa patients undergoing HIFU FT. Moreover, the SUV variation can predict biochemical response at 12 months post-treatment completion.

SC408
The role of stadiative PSMA-PET/CT scan prior to radical prostatectomy: a single center experience

E. Checcucci, E. Cisero, E. Alladio, G. Volpi, P. Verri, D. Amparore, S. De Cillis, F. Piramide, A. Piana, C. Fiori, F. Porpiglia (Candiolo, Turin)

BACKGROUND: Conventional imaging based on contrast enhanced CT and bone scan are still the recommended investigations for the staging of patients with intermediate/high risk prostate cancer (PC). However, their sensitivity and specificity are suboptimal in the detection of non-localized disease. The role of PSMA-PET has already been widely proven in the setting of recurrent prostate cancer, but evidence are lacking concerning its execution for primary staging. The aim of our study was to assess the additive role of PSMA-PET for preoperative staging in patients with intermediate/high risk PC.

METHODS: Patient with intermediate/high risk biopsy proven PCa diagnosed between September 2021 to March 2023 were retrospectively recruited. All patients included underwent CT-scan, bone-scan and subsequent 18F-PSMA-PET/CT scan before undergoing robotic radical prostatectomy (RARP) with extended pelvic lymph-node (LN) dissection (ePLND) at one referral center. After surgery, in case of M+ disease at preoperative imaging, hormone deprivation therapy with LH-RH analogous for 2 years and metastasis direct radiation therapy were planned. Specificity and sensitivity of PSMA PET-CT for bone and LN metastasis' detection were evaluated using contingency tables.

RESULTS: One hundred seven patients were included. Mean PSA was 16.29 (SD=19.25) and median biopsy ISUP grade was 4 (IQR: 2). Six and 8 patients had suspicious cN+ or cM+ disease at preoperative standard imaging; whilst 27

and 17 patients at preoperative PSMA-PET/CT scan respectively. pN+ disease was identified in 11 (10.3%) patients after ePLND. PSMA PET-CT had a 5% greater accuracy than that of conventional imaging (78.75% *vs.* 73.75%, P<0.05, equal to 0.001793). Mean follow-up was 6 months and BCR occurred in 12 patients. A receiver operating characteristic (ROC) curve showing the sensitivity and the specificity of the approaches has been calculated, showing better performance of PSMA PET-CT.

CONCLUSIONS: In primary staging of intermediate- and high-risk prostate cancer, 18FPSMA-PET/CT has a better accuracy in diagnosis of metastatic disease.

SC409

The association between PSA density and the detection of clinically significant prostate cancer across all PIRADS scores in men with positive MPMRI: when PSA density can help avoiding prostate biopsy?

F. Barletta, F. Pellegrino, G. Gandaglia, A. Stabile, V. Cucchiara, M. Bandini, E. Mazzone, G. Rosiello, G. Sorce, A. Pellegrino, M. Longoni, P. Scilipoti, L. Quarta, P. Zaurito, N. Fossati, E. Zaffuto, F. Dehò, F. De Cobelli, G. Brembilla, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Multiparametric MRI (MRI) has a high diagnostic accuracy for clinically significant PCa (csPCa). However, a significant proportion of patients with positive MRI still have negative biopsy. We hypothesized that PSA density (PSAd) may help to identify patients with positive MRI that might avoid biopsy. We investigated the entire range of PSAd to identify an adequate PSAd cutoff for this purpose.

METHODS: We included 1678 patients with positive MRI (PIRADS score ≥3) undergoing MRI-targeted plus systematic random prostate biopsies at our center between 2016 and 2022. The outcome of the study was the detection of csPCa (Gleason score ≥7) at prostate biopsies. Multivariable model (MVA) was used to assess the association between PSAd and the risk of csPCa after accounting for confounders. We then plotted the risk of csPCa according to PSAd values and mpMRI results, using the LOWESS function.

RESULTS: Overall, 737 (44%) patients had csPCa at prostate biopsy. Patients with csPCa had lower prostate volume (40 cc *vs.* 51 cc), higher median PSA (7.1 ng/mL *vs.* 6.4ng/mL), and median PSAd (0.18 *vs.* 0.12; all P<0.05). Overall, the csPCa detection in patients with PIRADS 3, 4, and 5 was 22% (N.=127), 51% (N.=389), and 65% (N.=221), respectively. At MVA PSAd was strongly associated with the risk of csPCa at biopsy (OR=1.1, P=0.01) after accounting for potential confounders (PIRADS score, age, total number of cores, and number of targeted cores). Patients with PIRADS≥4 had a risk of csPCa higher than 20% regardless of their PSAd values. Conversely, for patients with PIRADS 3 lesion and PSAd<0.10, the csPCa detection was lower than 10%. Using this cutoff in patients with PIRADS 3 lesion at mpMRI, 101 (18%) biopsies could be avoided while missing only 8 csPCa (8%).

CONCLUSIONS: Our analyses demonstrated that PSAd can be used to identify patients with suspicious prostate MRI that might avoid prostate biopsy given a low risk of csPCa. Patients with PIRADS 3 lesion and PSAd<0.10 can safely avoid biopsies. Conversely, the use of PSAd in patients with a visible PI-RADS 4-5 did not show any diagnostic benefit in identifying those men with lower risk of harbouring csPCa.

SC410

PSMA radio-guided surgery to detect nodal metastases in prostate cancer patients undergoing robot-assisted radical prostatectomy and extended pelvic lymph node dissection: updated results of planned interim analyses of a prospective phase 2 study

L. Quarta, G. Gandaglia, E. Mazzone, A. Pellegrino, V. Cucchiara, F. Barletta, S. Scuderi, D. Robesti, R. Leni, A.M. Samanes Gajate, M. Picchio, G. Brembilla, F. De Cobelli, M.N. Van Oosterom, F.W. Van Leeuwen, F. Pellegrino, L. Nocera, G. Cirulli, M. De Angelis, M. Longoni, P. Scilipoti, L. Gianolli, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Extended pelvic nodal dissection (ePLND) represents the gold standard for nodal staging in prostate cancer (PCa). Prostate-specific membrane antigen radio-guided surgery (PSMA-RGS) could identify lymph node invasion (LNI) during robot-assisted radical prostatectomy (RARP). We aimed to report the updated results of interim analyses of a phase 2, prospective, single center study (NCT04832958) aimed at describing the feasibility and accuracy of PSMA-RGS during RARP.

METHODS: Twenty-one eligible patients with intermediate- or high-risk cN0cM0 prostate cancer at conventional imaging with a risk of LNI>5% at a single center were enrolled. Among those, 18 patients underwent PSMA-RGS between June 2021 and September 2022. All patients received a 68Ga-PSMA PET preoperatively. 99mTc-PSMA I&S was synthesized and administered intravenously the day before surgery (median activity: 735 MBq) followed by SPECT/CT. A drop-in gamma probe was used for *in-vivo* and *ex-vivo* measurements during PSMA-RGS. All positive lesions (count rate ≥2 compared to background) were excised and an ePLND was performed. The ePLND included obturator, internal, external and common iliac nodal regions. Side effects, perioperative outcomes, and accuracy of PSMA-RGS for LNI at final pathology were evaluated.

RESULTS: Overall, 6 (33%), 8 (50%) and 4 (17%) patients had intermediate-risk, high-risk, and locally advanced PCa. Seven (38%) patients had nodal uptake at PSMA PET/MRI. No adverse events were recorded after 99mTc-PSMA administration. Median operative time, blood loss and length of stay were 218 min, 100 mL and 4 says, respectively. No intraoperative complications were recorded. One patient experienced a 30-day complication (Clavien-Dindo 2). A total of 116 pelvic nodal specimens were resected, which included 446 nodes (median 22 per patient). Overall, 5 (27%) patients had LNI (median 3 positive LN per patient). At a per-region analysis combining both *in-vivo* and *ex-vivo* measurements, PSMA-RGS had sensitivity, specificity, positive (PPV) and negative predictive value (NPV) of 70%, 45%, 86% and 94%, respectively. At per-patient level, the same figures for PSMA-RGS were 100%, 61%, 50% and 100% respectively.

CONCLUSIONS: Our updated results confirm that 99mTc-PSMA-RGS during RARP is a safe and feasible procedure characterized by an excellent sensitivity and NPV but suboptimal PPV in a per-patient level analysis using a target-to-background count rate ≥2.

SC411

The prognostic impact of preoperative PSMA-PET on early oncological outcomes in prostate cancer patients treated with radical prostatectomy: results of a multicenter analysis

S. Scuderi, G. Gandaglia, E. Mazzone, E. Brunocilla, F. Dal Moro, A. Sartorello, L. Ibanez, J. Moreno-Sierra, A. Mattei, L. Afferi, S. Shariat, W. Fendler, M. Picchio, G. Marra, F. Zattoni, G. Reitano, P. Rajwa, J. Gomez-Rivas, C. Kesch, F. Porpiglia, D. Amparore, E. Checcucci, F. Montorsi, A. Briganti (Milan)

BACKGROUND: PSMA-PET in prostate cancer (PCa) staging is associated with higher accuracy for nodal and metastatic detection than conventional imaging. Clinical guidelines still do not recommend PSMA-PET before radical prostatectomy (RP). We hypothesized that the implementation of PSMA PET in the preoperative staging pathway is associated with better patient risk stratification and early cancer control.

METHODS: We relied on 3978 N0M0 PCa patients treated with RP ± extended pelvic nodal dissection between 2010-2022. 3518 men staged with conventional imaging were identified in a single institution dataset (group 1). Additional 278 patients with available details both on PSMA PET and CT scans were identified from a multi-institutional cohort of men staged with PSMA-PET (group 2). Early recurrence was defined as PSA persistence (first postoperative PSA≥0.1 ng/mL) or PSA≥0.2 ng/mL within 1 year after RP. Multivariable logistic regressions (MLR) tested the impact of the preoperative imaging on early recurrence. MLR models tested for predictor status of PET-PSMA and CT-scan after adjusting for PSA, biopsy grade group and non-organ-confined (NOC) disease at mpMRI. Accuracy of MLR models containing PET-PSMA (model 1) and CT-scan (model 2) were assessed with the ROC-derived AUC. Decision-curve analyses (DCA) assessed the net benefit associated with the use of the two models.

RESULTS: Two hundred eighty-two patients experienced early recurrence. Patients in group 2 had higher preoperative PSA values (8.5 vs. 6.4 ng/mL) and higher rates of biopsy grade group (GG)>3 (57% vs. 11%, all P<0.01) compared to group 1. Early BCR rates were similar between the two groups (12% vs. 10% for group 2 and group 1, respectively, P=0.3). At MLR, being staged with PSMA-PET was associated with a lower risk of early recurrence (OR=0.61, P=0.01) after accounting for PSA, clinical stage, and biopsy ISUP GG. Focusing on men with available PSMA-PET and CT, the presence of positive PET-PSMA (OR=4.34, P=0.004) but not CT-scan predicted early recurrence. The discrimination was higher for model 1 including PSMA-PET compared to model 2 (73 vs. 67%). The adoption of model 1 including PSMA-PET was associated with a higher net benefit as compared to model 2.

CONCLUSIONS: Non-metastatic PCa patients staged with PSMA PET scan are at lower risk of early recurrence when compared to those staged with conventional imaging alone. PSMA PET scan helps clinicians to improve preoperative risk stratification and to the identification of men who might benefit most from treatments.

SMART (SC412-SC424)

Kidney cancer 7

SC412
Characterization of benign histology of cT1 renal masses treated with robot-assisted partial nephrectomy and its impact on perioperative and functional outcomes

SC413
Assessing the impact of obesity on survival outcomes of off-clamp robotic partial nephrectomy: analysis from a tertiary referral center

SC414
Are we improving rates of pentafecta achievement after robot-assisted partial nephrectomy? A single high-volume institution experience

SC415
Transition from acute kidney injury to acute kidney disease after robot-assisted partial nephrectomy: results from a single tertiary referral center

SC416
Metastasectomy in oligometastatic RCC brings a survival benefit in immunotherapy era: results from the REMARCC-IO Registry

SC417
Minimally invasive partial *versus* radical nephrectomy in obese patients: perioperative and midterm functional outcomes from a large perspective contemporary series (RECORd2 project)

SC418
Simplifying retroperitoneal robotic single-port surgery: a novel Supine Anterior Retroperitoneal Access (SARA)

SC419
Minimally invasive cytoreductive nephrectomy for metastatic renal cell carcinoma in the immunotherapy era: results from the REMARC-IO database

SC420
Nightmare in minimally invasive radical nephrectomy

SC421
Single center experience in 3D models-guided robot-assisted partial nephrectomy: is CT scan becoming obsolete?

SC422
Outcomes of on-clamp *vs.* off-clamp robot-assisted partial nephrectomy for large highly complex renal tumors: a multicenter study

SC423
3D-model reconstruction in the diagnosis and surgical treatment of complex renal masses: are they useful? Results of a prospective single center study

SC424
Functional outcomes of different renal clamping techniques during robot-assisted partial nephrectomy at 5 European robotic centers

SC412
Characterization of benign histology of cT1 renal masses treated with robot-assisted partial nephrectomy and its impact on perioperative and functional outcomes

F. Portè, C. Palumbo, M. Nicolazzini, A. Abdulvagabov, S. Cavalli, P. De Angelis, M. Zacchero, M. Billia, A. Volpe (Novara)

BACKGROUND: Partial nephrectomy (PN) is the gold standard treatment for localized renal masses, but preoperative confirmation of malignancy with percutaneous biopsy is not routinely performed. This inevitably leads to a proportion of patients undergoing surgery for a benign mass. We retrospectively reviewed our robot assisted PN (RAPN) series to assess the impact of benign histology on perioperative and functional outcomes.

METHODS: All patients with cT1N0M0 renal mass treated with RAPN at our center were included. Descriptive statistics were performed to assess differences in baseline characteristics, perioperative and functional outcomes between patients with benign *vs.* malignant histology. Multivariate logistic regression models (LRM) were performed to assess predictors of postoperative complications and *de-novo* CKD stage III or higher at both 12 months and last follow-up.

RESULTS: Out of 336 patients who underwent RAPN 62 patients (18.5%) had benign histology, of which 41 oncocytomas and 14 angiomyolipomas. No significant differences in baseline characteristics were observed, with the exception of tumor diameter at diagnosis (29 *vs.* 35 mm for benign and malignant tumors respectively, P=0.009). Overall, 73 (21.7%) patients had postoperative complications, of which 13 (3.6%) Clavien-Dindo grade 3 or higher, without significant differences between the two groups. After a median follow-up of 37 months, 65 patients developed *de-novo* CKD stage III or higher (51 patients within the first year), without significant differences between the two groups. At multivariate LRMs models, presence of benign histology was not an independent predictor of complications or de-novo CKD at both 12 months and last follow-up.

CONCLUSIONS: Almost 1 out of 5 renal masses treated with RAPN at our institution have been shown to be benign at final pathology. This should be discussed when counseling patients for surgical management of small renal masses. Nonetheless, the impact of benign histology on complications and postoperative kidney function is negligible due to the excellent outcomes ensured by RAPN.

SC413
Assessing the impact of obesity on survival outcomes of off-clamp robotic partial nephrectomy: analysis from a tertiary referral center

G. Simone, R. Mastroianni, G. Tuderti, M. Costantini, U. Anceschi, L. Misuraca, A. Bove, A. Brassetti, S. Guaglianone, M. Gallucci, M. Ferriero (Rome)

BACKGROUND: Increasing evidence suggested the role of obesity in renal cell carcinoma. We investigated the impact of obesity on survival outcomes of robotic partial nephrectomy (RPN) performed in a tertiary referral center.

METHODS: Our prospectively maintained "renal cancer "database was queried for RPN. BMI was tested as a continuous variable with a binomial logistic regression to find the best cut-off for categorization. Obesity class 2-3 is defined according to WHO classification as Body Mass Index (BMI) higher than 35 kg/m^2. The potential impact of obesity on recurrence free survival (RFS), cancer specific survival (CSS) and overall survival (OS) probabilities were assessed with the Kaplan Meier method. Age, gender, ASA Score, BMI, CT2 stage, RENAL and PADUA Score were included in univariable and multivariable Cox regression analyses to identify predictors of RFS, CSS and OS.

RESULTS: Out of 856 cases, obesity rate was 20.1% while 44 patients (5.1%) were affected by obesity class 2-3. Overall, high-grade complication rate was 2.5%. RFS probabilities were significantly lower in severe obese patients (5-yr: 78.1% *vs.* 87%, log rank P=0.027), while CSS and OS probabilities were comparable between groups (100% *vs.* 99.2%, log rank P=0.84 and 100% *vs.* 97.1%, log rang P=0.49, respectively). At univariable and multivariable regression analysis age (HR=1.02, 95% CI: 1-1.04, P=0.025) and BMI≥35 (HR=2.24, 95% CI: 1.07-4.67, P=0.032) were independent predictors of RFS. At univariable Cox regression analysis, the only predictors of any cause mortality were age (HR=1.13, 95% CI: 1.03-1.23, P=0.007) and ASA Score ≥2 (HR=7.33, 95% CI: 1.34-40, P=0.022).

CONCLUSIONS: Patients with obesity class 2-3 displayed an increased risk of developing disease recurrence after RPN with a comparable risk of all-cause mortality. The potential protective effect of weight loss on disease recurrence should be further investigated. On the other hand, a strict follow-up for obese patients should be considered to promptly identify disease recurrence.

SC414
Are we improving rates of pentafecta achievement after robot-assisted partial nephrectomy? A single high-volume institution experience

S. Rebuffo, L. Nocera, C. Bravi, A. Piro, M. Paciotti, M.L. Peraire, E. Balestrazzi, F. Piramide, R. De Groote, G. De Naeyer, A. Mottrie, G. Sorce, M. Ticonosco, N. Frego, C. Collà Ruvolo, L. Sarchi, A. Mottaran (Ghent)

BACKGROUND: Robotic-assisted partial nephrectomy (RAPN) is widely adopted to treat renal lesions. Still, RAPN may lead to positive surgical margins (PSM), postoperative complications and impairment of renal function, all features that are included in the pentafecta as proxy of surgical success. We examined rates of pentafecta achievement after RAPN in more than a decade experience at a high-volume institution.

METHODS: We analyzed data of 435 patients with a single renal mass treated with RAPN at OLV Hospital (Aalst, Belgium) between 2009 and 2021. The endpoint was achievement of all pentafecta outcomes: 1) absence of PSM; 2) warm ischemia time (WIT)<20 minutes; 3) pre-/post-surgery increase in creatinine <20%; 4) absence of new-onset chronic kidney disease (CKD) at 1-year follow-up; and 5) no Clavien-Dindo ≥3 complications. Pentafecta outcomes temporal trend was examined using estimated annual percentage change (EAPC).

RESULTS: Median (interquartile range [IQR]) age and Body Mass Index were 64 (55, 73) years and 27 (24, 29) kg/m^2, respectively. Median preoperative creatinine was 0.9 (IQR: 0.8, 1.1) mg/dL. Median tumor size was 3.1 (2.1, 4.5) cm, median PADUA Score 8 (7, 10) and median WIT 13 (6, 19) minutes. Few patients (4%) experienced Clavien-Dindo ≥3 complications. Median (IQR) postoperative and 1-year creatinine were both 1.0 (0.8, 1.2) mg/dL, only a minority

of patients experienced a creatinine increase ≥20% during hospital stay (17%) and new-onset CKD at 1-year follow-up (5%). Only 32 patients (7%) exhibited PSM. Pentafecta was achieved in 290 patients (61%). These patients harbored smaller (2.8 *vs.* 3.5 cm), less complex tumors (PADUA score 8 *vs.* 9), and lower EBL (150 *vs.* 245 mL) as compared to those who did not achieve the pentafecta (all P<0.01). No difference was recorded in other characteristics. Pentafecta outcomes achievement rate grew from 53% in 2009 to 85% in 2021 (EAPC +3.77%; P=0.03).

CONCLUSIONS: Rate of pentafecta achievement increased over time between 2009-2021, leading to optimal oncological and functional outcomes. This trend may reflect the increasing adoption of less invasive surgical refinements during RAPN, such as clampless and sutureless techniques.

SC415
Transition from acute kidney injury to acute kidney disease after robot-assisted partial nephrectomy: results from a single tertiary referral center

V. Salamone, L. Lambertini, F. Valastro, F. Di Maida, A. Cadenar, A.A. Grosso, M. Bacchiani, A. Sandulli, S. Coco, S. Giudici, A. Mari, A. Minervini (Florence)

BACKGROUND: The role of acute kidney disease (AKD) in the transition process from acute kidney injury (AKI) to chronic kidney disease (CKD) is still controversial, particularly in the partial nephrectomy (PN) patients setting. Aim of this study was to assess the role of AKD after robot assisted PN (RAPN) in patients with preserved preoperative renal function, focusing on clinical and surgical predictors of the AKI to AKD transition.

METHODS: Clinical and surgical data from 981 consecutive patients with cT1-2N0M0 renal masses treated with RAPN in a single tertiary referral center between January 2017 and March 2021 were prospectively collected and retrospectively reviewed. Only patients with a preoperative estimated glomerular filtration rate >60 mL/min/1.73m^2 were included in the final analysis. The presence of AKI, AKD and CKD was defined according to the Kidney Disease Improving Global Outcomes (KDIGO) criteria. AKD was defined as increase in serum creatinine by ≥0.3 mg/dL (≥26.5 micromol/L) or increase in serum creatinine to ≥1.5 times baseline between the 2nd and the 90th postoperative days. Uni- and multivariable analyses were adopted to identify risk factors promoting the AKI to AKD transition.

RESULTS: Overall, 864 patients were evaluated, median age was 64 (IQR: 54-71) years and median BMI was 25.7 (IQR: 23-5-28.3) kg/m^2 while median baseline serum creatinine level was 0.9 (IQR: 0.7-1.1) mg/dL. Overall, 748 (86.6%) patients were treated with an on-clamp approach while 116 (13.4%) cases underwent to clampless procedure. Median warm ischemia time was 15 (IQR: 11-18) minutes and median estimated blood loss was 100 (IQR: 70-200) mL. Postoperative AKI occurred in 189 (21.9%) patients, while a transition from AKI to AKD was recorded in 43 (5%) cases. In case of AKD, subsequent transition to CKD was recorded in nearly 25% of cases at a median follow-up of 38 (24-45) months. Multivariate analysis confirmed age >55 (HR=1.45, 1.09-1.99, P=0.03), Charlson Comorbidity Index (CCI)>3 (HR=1.98, 95% CI: 1.48-2.32; P=0.01), early postoperative acute tubular necrosis (HR=1.14, 1.03-1.34, P<0.001), and warm ischemia time >25 minutes (HR=1.44, 1.10-1.56, P=0.001) as independent risk factors of postoperative AKI to AKD transition.

CONCLUSIONS: The AKI to AKD transition after RAPN represents a relatively under investigated event negatively affecting the long-term functional recovery. In this setting, the development of a postoperative risk stratification model might play a pivotal role in maximizing functional outcomes.

SC416
Metastasectomy in oligometastatic RCC brings a survival benefit in immunotherapy era: results from the REMARCC-IO Registry

G. Litterio, G. Primiceri, R. Campi, A. Tafuri, R. Autorino, A. Minervini, M. Kriegmair, G. Rebez, S. Erdem, N. Paksoy, F. Claps, N. Pavan, E. Roussel, M. Albersen, A. Antonelli, M. Meagher, E. Linares Espinos, V. Hevia, M. Musquera, M. D'Anna, M. Marchioni, M. Mir, L. Schips (Chieti)

BACKGROUND: Since the advent of CARMENA trial results in the setting of metastatic renal cell carcinoma (mRCC), the role of cytoreductive nephrectomy (CN) has been questioned. We examined the impact of complete metastasectomy in patients with oligometastatic RCC in the immunotherapy era.

METHODS: This was a multicenter retrospective analysis of cases included in a multicenter international registry (Registry of Metastatic RCC [REMARCC-IO]) of mRCC patients treated with CN in the period 2010-2020. The effect of metastasectomy was analyzed *via* Kaplan-Meier plots and Cox's regression analyses. Outcomes of interest were overall complications, high grade complications (Clavien-Dindo grade >3) and overall mortality (OM).

RESULTS: Overall, 155 patients were included in our analyses, of them 13.2% underwent metastasectomy. Patients classified as favorable (22.2 *vs.* 13.7%), intermediate (72.2 *vs.* 66.9%) and poor (5.6 *vs.* 19.4%) prognosis were similar in those who underwent metastasectomy *vs.* those who did not (P=0.282) according to Heng's criteria. Patients treated with open surgery less frequently metastasectomy (7.0 *vs.* 25%; P<0.001). Metastasectomy individuals showed a remarkably higher 3-year OS rates (75.0±6.8% *vs.* 34.5±12.5%, P<0.001). These differences remained statistically significant after accounting for pT and pN stage (HR=0.30, 95% CI: 0.10-0.86, P=0.021) but not after adjustment according to Heng's Criteria (HR=0.38; 95% CI: 0.13-1.09, P=0.057), but such absence of statistically significance could be related to our relatively small sample size.

CONCLUSIONS: Our findings suggest that a metastasectomy in oligometastatic RCC in the immunotherapy era remains a treatment option with some survival advantage. Further prospective studies are required for validation.

SC417
Minimally invasive partial *versus* radical nephrectomy in obese patients: perioperative and mid-term functional outcomes from a large perspective contemporary series (RECORd2 project)

L. Lambertini, S. Giudici, M. Bacchiani, F. Valastro, S. Vincenzo, A. Sandulli, E. Massaro, S. Coco, D. Paganelli, F. Di Maida, G. Vittori, A. Minervini, A. Mari (Florence)

BACKGROUND: Obesity deeply influences the surgical management as well as the postoperative recovery of patients across several disciplines. Given the association between obesity and the increased incidence of localized RCC, the definition of the optimal surgical approach still represents an unmet need. In this scenario, Laparoscopic (LPN) and robot assisted partial nephrectomy (RAPN) has shown safe and effective approaches in the normal-weight population. However, the potential benefits and harms of minimally invasive PN in terms of perioperative and long-term outcomes compared with minimally invasive RN in case of obese patients are still undetermined. Herein, the present manuscript aimed to explore the perioperative and long-term functional outcomes of transperitoneal LPN and RAPN compared to laparoscopic RN in obese patients.

METHODS: We prospectively evaluated all patients undergone transperitoneal LRN, LPN and RPN for localized RCC between 01/2013 and 12/2016 at 26 urological Italian Centers collecting the pre-, intra-, and postoperative data (RECORd2 project). A threshold Body Mass Index (BMI)≥30 was used to select obese patients. Only patients with preoperative eGFR≥60 mL/min were included in the analysis. Patients were then stratified and compared according to the surgical approach (LRN, LPN and RPN).

RESULTS: Overall, 477 obese patients were included in the final analyses, of which 212 (44.4%) were treated with LRN, 120 (25.2%) with LPN while 145 (30.4%) patients undergone RAPN. No differences were found in terms of preoperative features between the groups, median (IQR) eGFR values were 80.1 (76.1-88.9), 76.8 (62.9-90.4) and 76.7 (69.8-91.1) mL/min/m^2 for LRN, LPN and RAPN cohort, respectively. As concerns intraoperative features, complications were comparable among the three groups (P=0.12) meanwhile open conversion rate was significantly higher in the LRN and LPN group as compared to the RAPN group (1.9% *vs.* 1.7% *vs.* 0%, P=0.03). In terms of early functional outcomes, LRN was associated with higher early postoperative AKI occurrence (40.6% *vs.* 15.3% *vs.* 7.6%, P=0.001). No significant differences were found in terms of eGFR loss at a 6- months follow-up between groups while LRN showed statistically relevant kidney function decline at 12-24 and 48 h months follow-up evaluation (P=0.01). After uni- and multivariate analysis were fitted, LRN was confirmed as independent predictor of eGFR loss ≥25% (OR=1.42 [IQR: 1.15-1.54], P=0.01) while LPN and RAPN were not associated with higher rate of intra-postoperative complications CD≥3a.

CONCLUSIONS: In a large multicenter prospectively maintained Italian dataset, LPN and RAPN in the obese population setting were found to provide favorable perioperative outcomes with functional benefits emerging over LRN after a 6-month follow-up. Renal function preservation should be prioritized particularly in case of metabolic impairment.

SC418
Simplifying retroperitoneal robotic single-port surgery: a novel Supine Anterior Retroperitoneal Access (SARA)

A.A. Pellegrino, G. Chen, L. Morgantini, R. Sauer Calvo, S. Crivellaro (Chicago)

BACKGROUND: Multiport robotic surgery is limited in retroperitoneal (RP) surgery by its bulky frame, which in narrow spaces causes instrument clashing and poor triangulation. Moreover, patients are often in lateral decubitus, which has been linked to complications. The da Vinci (Intuitive Surgical, Inc., Sunnyvale, CA, USA) single-port (SP) may solve these issues, owing to improved dexterity in narrow areas. We present a novel supine anterior RP access (SARA).

METHODS: SARA Approach: In a supine position, a 3cm incision is made at the McBurney point. Abdominal muscles dissected bluntly. Finger dissection is used to develop the RP space. The SP Access Port kit is inserted. A 5 mm port may be placed in a "sidecar" fashion. After docking, first step is to dissect RP tissue to reveal Lat. Dorsi, quadratus lumborum and Psoas muscle. This allows identification of the overlying ureter and subsequently the inferior pole, renal pelvis and hilum. Patients operated between October 2022 and January 2023 were studied. All surgeries were done by the same surgeon and included renal (regardless of location) and urothelial cancers and UPJO. Data collected included demographics, operative time, WIT, surgical margin, complications, hospital stay, 30-day Clavien-Dindo and postoperative narcotic use. Renal tumors were classified with the RENAL score. Ethical Committee approval was obtained.

RESULTS: Eighteen patients were eligible for the SARA approach. 12 patients underwent partial nephrectomy (PN), 2 patients Pyeloplasty, 2 patients Radical Nephroureterectomy and 2 patients radical nephrectomy. In patients which underwent PN, mean age was 57 yrs (IQR: 30-73). Average BMI was 32 (IQR: 17-58). 25% had ≥ stage 3 CKD. Mean CCI was 3 (IQR: 0-7) and 75% were ASA 3. Median RENAL score was 5 (IQR: 4-7). All patients underwent on-clamp ischemia, with mean WIT of 25min (IQR: 16-48). The mean tumor size was 35mm (IQR: 16-50). Peri-operative bleeding was 105 mL (IQR: 20-400). Mean operative time was 160 min (IQR: 110-200). Total OR time was 200 min (IQR: 150-255). Positive surgical margins were found in 1 patient. Overall, 1/18 patient was readmitted, for nausea and managed conservatively. 15/18 (83%) patients were discharged the same day, with the remainder discharged the next. At 7 days postop, no patients reported narcotic use.

CONCLUSIONS: The SARA approach for RP surgery is simple to set-up, feasible and safe. Larger volume studies are needed to consolidate this approach as a staple for retroperitoneal surgery using the SP.

SC419
Minimally invasive cytoreductive nephrectomy for metastatic renal cell carcinoma in the immunotherapy era: results from the REMARC-IO database

G. Primiceri, M. Marchioni, R. Campi, A. Tafuri, A. Riccardo, M. Andrea, M. Kriegmair, S. Erdem, N. Paksoy, F. Claps, N. Pavan, E. Roussel, M. Albersen, A. Antonelli, I. Darweesh, E. Linares, V. Hevia, M. Musquera, M. D'anna, D.P. Antonio, M.C. Mir, L. Schips (Chieti)

BACKGROUND: Since the advent of CARMENA Trial results in the setting of metastatic renal cell carcinoma (mRCC), the role of cytoreductive nephrectomy (CN) has been questioned in patients at highest risk, but CN remains a standard of care in patients at good prognosis. Moreover, such results might not apply to patients treated with immunotherapy. We examined the impact of surgical approach (open

vs. minimally invasive surgery-MIS) on survival outcomes of mRCC patients undergoing CN on the immunotherapy era, by using a multicenter registry.

METHODS: This was a multicenter retrospective analysis of cases included in a multicenter international registry (Registry of Metastatic RCC-Immunotherapy [REMARCC-IO]) of mRCC patients treated with CN and immunotherapy as first or subsequent systemic treatment line, in the period 2010-2020. The impact of surgical approach (open *vs.* MIS) was analyzed *via* Kaplan-Meier plots and Cox's regression analyses. Outcomes of interest were overall complications, high grade complications (Clavien-Dindo Grade >3) and overall mortality (OM).

RESULTS: Overall, 155 patients were included in our analyses, of them 40 (25.8%) underwent MIS. Patients classified, according to Heng's criteria, as favorable (14.4 *vs.* 15.8%), intermediate (65.4 *vs.* 73.7%) and poor (20.2 *vs.* 10.5%) prognosis were similar in the open *vs.* MIS groups (P=0.407). Patients treated with open surgery underwent more frequently to thrombectomy (28.7 *vs.* 7.5%, P=0.006) but had less frequently metastasectomy (7.0 *vs.* 25%; P<0.001). Moreover, open surgery was more frequently performed in pT3-4 patients (86.1 *vs.* 62.5%; P<0.001) and in presence of nodal metastases (27.0 *vs.* 10.0%, P=0.003). However, MIS patients had less frequently postoperative complications (25.0% *vs.* 45.2%, P=0.004) and similar rates of high-grade complications (1.1 *vs.* 3.5%, P=0.235). These results were confirmed in multivariable regression models taking into account Heng risk classification, pN and pT-stage, the use of thrombectomy, metastasectomy or adjacent organ removal (OR for complications in open *vs.* MIS=2.67 [95% CI: 1.05-7.27]; P=0.045). As a consequence, MIS was associated with shorter length of stay (median 5 *vs.* 8 days, P<0.001). In addition, MIS approach individuals showed a remarkably higher 2-year OS rates (65.9±12.5% *vs.* 61.5±6.2%, P<0.001). However, these differences did not remain statistically significant after accounting for Heng's risk group, type of surgery and pT and pN stage (HR=1.58, 95% CI: 0.65-3.80, P=0.310).

CONCLUSIONS: Our findings suggest that a MIS approach in mRCC patients undergoing CN in the immunotherapy era is safe and it does not compromise patient's outcomes. Minimally invasive surgery can be offered on a selective-case basis.

SC420
Nightmare in minimally invasive radical nephrectomy

M. Martiriggiano, S. Tappero, L. Lo Monaco, G. Marchi, G. Drocchi, E. Vecchio, F. Ambrosini, F. Chierigo, D. Panarello, G. Mantica, M. Borghesi, C. Terrone (Genoa)

BACKGROUND: Robot-assisted radical nephrectomy (RARN) is a common major urological procedure, potentially associated to life-threatening intra-operative adverse events. The current study reports a case of accidental clipping of the superior mesenteric artery (SMA) during the isolation and dissection of the renal vascular pedicle during a left RARN.

METHODS: The current video, produced in 2023, illustrates the case of a 45-year-old woman, ECOG 0, BMI 19, with a personal history of multiple sclerosis and breast cancer (Charlson Comorbidity Index 2), submitted to left RARN for a rapidly growing Bosniak IV left renal complex cyst (from 24 to 55 mm over a one-year period). The preoperative CT scan showed a single left renal artery unusually located cranially to the ipsilateral renal vein. During the left renal vascular pedicle isolation, the supposed left renal artery was found cranially to the vein and closed with a Hem-o-Lok surgical clip. The left renal vein was then isolated, closed, and cut. After this step, unfortunately, the real left renal artery was identified cranially and behind the left renal vein. The surgeons understood that the first isolated and clipped artery did not correspond to the left renal artery. Contrariwise, it was the SMA. Lacking the laparoscopic surgical clip-removing device, the clip was cut with laparoscopic scissors and removed. The integrity of the SMA was checked and the left RARN was completed. No additional interventions on the SMA or the intestine were required.

RESULTS: The SMA did not result damaged, and the overall SMA closure time was 40 minutes. The total operative time was 160 minutes. The postoperative period was uneventful, the time to flatus was three days, and the patient was discharged in the fifth postoperative day. Final pathology revealed an undifferentiated malignant renal tumor (pure epitheliod peacoma, stage pT1b). At nine months from surgery, the patient is alive, recurrence-free, and gastroenteric sequelae-free.

CONCLUSIONS: Accidental surgical clipping of the SMA can lead to devastating consequences for the patient, including the exitus. This is especially true for those cases in which the error is not rapidly recognized, and the SMA not only clamped but also cut, causing massive bowel ischemia. The current video proves that the SMA can sometimes be confused with the left renal artery. Therefore, utmost attention must be paid to carefully correct renal vascular pedicle isolation. Moreover, the current video shows that prompt recognition of the error can avoid the worst consequences and that the cautious removal of applied surgical clips is feasible.

SC421
Single center experience in 3D models-guided robot-assisted partial nephrectomy: is CT scan becoming obsolete?

L. Nocera, M. PAciotti, F. Piramide, C.A. Bravi, A. Piro, M. Peraire Lores, E. Balestrazzi, C. Collà Ruvolo, G. Sorce, S. Rebuffo, M. Ticonosco, N. Frego, M. Belmonte, R. De Groote, P. De Backer, G. De Naeyer, A. Mottrie (Aalst)

BACKGROUND: Since their inception 3D virtual models have helped clinician in surgical indication and preoperative planning, as well as in intraoperative guidance. The added value of 3D models was particularly true in "tailored" surgical procedures, such as robot-assisted partial nephrectomy (RAPN) given the wide spectrum of possible tumor locations and the presence of anatomical variants. We aimed to examine the impact of 3D virtual models on surgical outcomes in a tertiary referral center.

METHODS: We relied on 474 patients identified in our prospectively maintained renal cancer database, and treated with RAPN between 2009 and 2022. All patients were treated by highly experienced surgeons. Patients harboring multiple masses were excluded. The endpoints of the analyses were: 1) presence of positive surgical margins (PSM); 2) warm ischemia time (WIT); and 3) length of stay (LOS). Multivariable regressions examined the impact of the use of 3D virtual model on PSM, WIT and LOS. For all models, the adjustment for casemix included: age, sex, tumor size, tumor side, clinical T stage, PADUA Score and estimated blood loss (EBL).

RESULTS: Overall, median age was 64 years (interquartile range [IQR]: 55, 73). Median (IQR) tumor size and PADUA score were 3.1 (2.1, 4.5) cm and 8 (7, 10), whereas tumor side was more frequently right (54%). Median WIT was 13 minutes (IQR: 6, 19). OR console time and blood loss were 120 minutes (IQR: 90, 150) and 200 mL (IQR: 100-300), respectively. Median LOS was 3 days (IQR: 3, 5) and 7% of patients had PSM on final pathology. A 3D model was reconstructed for 84 (18%) patients. Patients with reconstructed 3D virtual models had more complex tumors (median PADUA Score 9 *vs.* 8, P<0.05). No other statistically significant differences were recorded, although patients with available 3D models were older (66 *vs.* 64 years), less frequently male (63% *vs.* 71%), and exhibited longer WIT (14 *vs.* 13 minutes), shorter LOS (3 *vs.* 4 days) and lower PSM rate (3.6% *vs.* 7.4%) (all P>0.05). On multivariable logistic regression models, 3D virtual model usage was an independent predictor of lower PSM rate (Odds Ratio [OR]=0.27; 95% confidence interval [CI]: 0.14, 0.40; P<0.05). Similarly, on multivariable Poisson regressions, 3D virtual model usage was an independent predictor of shorter WIT (OR=0.78; 95% CI: 0.68, 0.87; P<0.05) and shorter LOS (OR=0.82; 95% CI: 0.75. 0.90; P<0.01).

CONCLUSIONS: Our findings suggest a potentially crucial role of 3D virtual reconstructions for candidates to RAPN for both surgical planning and intraoperative guidance. Indeed, the use of 3D virtual models led to an improvement of potentially both oncological (reduction in PSM) and functional outcomes (reduction in WIT). Further studies are required to confirm these findings at long-term follow-up.

SC422
Outcomes of on-clamp *vs.* off-clamp robot-assisted partial nephrectomy for large highly complex renal tumors: a multicenter study

A. Brassetti, G. Tuderti, A. Mari, U. Anceschi, A.M. Bove, M. Ferriero, R. Mastroianni, S. D'Annunzio, L. Misuraca, F. Proietti, S. Flammia, C. Leonardo, A. Minervini, G. Simone (Rome)

BACKGROUND: The aim of this study was to determine the impact of the off-clamp approach on outcomes of robotic partial nephrectomy (RPN) to treat large and highly complex renal tumors.

METHODS: The prospectively maintained databases of the 2 participating institutions were searched for patients undergone RPN for highly complex (RENAL 9) cT2N0M0 renal tumors from January 2012 onwards. The study population was split according to clamping technique. Categorical variables were compared by means of the χ^2 test; the Mann-Whitney *U* Ttest was utilized for continuous ones. Predictors of significant renal function deterioration (sRFD; defined as >30% postoperative eGFR reduction) were identified by means of the univariable logistic regression model.

RESULTS: Overall, 103 patients were included in the analysis, 42 of which underwent an on-clamp RPN (onRPN). The rates of obesity and hypertension were significantly higher in this group and median warm ischemia time (WIT) was 28 (19/37). The Trifecta rate was significantly higher in the off-clamp cohort (77% *vs.* 50%; P=0.004), essentially because of the difference in sRFD (11% *vs.* 34%; P=0.003). At logistic regression analysis, the clamping approach was the only independent predictor of sRFD at discharge (OR=0.23; 95% CI: 0.85-0.64; P=0.005).

CONCLUSIONS: in experienced hands, off-clamp RPN is a viable option also to treat large and surgically complex renal tumors. Especially in this setting, avoiding the long WIT usually required during an on-clamp approach may significantly reduce the risk of postoperative renal function deterioration.

SC423
3D-model reconstruction in the diagnosis and surgical treatment of complex renal masses: are they useful? Results of a prospective single center study

F. Lavagno, C. Mangione, F. Soria, R. Faletti, M. Calandri, M. Gatti, M. Rosazza, M. Allasia, G. Marra, P. Gontero (Turin)

BACKGROUND: Technological improvement is moving the boundaries of nephron sparing surgery (NSS) towards more complex cases and increased clinical stages. In this context 3D-model reconstructions (3DMR) may help in guiding the surgeon, potentially improving surgical outcomes, and may also increase the ability of the radiologist in detecting locally advanced cases. Our aim was to evaluate the impact of 3DMR on the diagnostic evaluation and treatment of complex renal masses.

METHODS: Consecutive patients with newly diagnosed PADUA score ≥8 renal masses on CT imaging had 3DMR and subsequently underwent surgery. To assess diagnostic accuracy three radiologists blinded to clinical data evaluated the usefulness of 3DMR. To assess the impact of 3DMR on NSS surgical outcomes a comparison with a cohort of patients not undergoing 3DMR using inverse probability of treatment weighting (IPTW) analysis was performed to minimize selection bias. Primary outcomes were the evaluation of diagnostic accuracy of 3DRM plus CT scan compared to CT-scan alone and 3D-models alone in differentiating between ≤T2 and ≥T3 lesions where final pathology was used as reference standard; the impact of 3DMR on use of clamping (clampless *versus* selective clamping *versus* complete clamp) in patients undergoing nephron sparing surgery. Secondary outcomes included the evaluation of diagnostic ability of correctly identifying the number of arteries and PADUA Score concordance between CT-scan and 3DMR and the surgeon esteemed usefulness of 3DMR and impact on other surgical related-outcomes.

RESULTS: We included 76 patients. Median PADUA score and lesion maximum diameter were 9 (IQR: 8-10) and 3.7cm (IQR: 2.8-5) respectively. Diagnostic accuracy for pT3 disease of 3DMR, CT-scan and 3DMR plus CT-scan together were evaluated. No major differences were described. Similarly, no major differences in number of identified arteries and PADUA score were noted between the three groups (P>0.5). For what it concerns the Nephron Sparing surgery cohort, in forty-six cases 3DMR were deemed useful or very useful by the operator (score 3 or 4-71%).

CONCLUSIONS: In the context of newly diagnosed complex renal masses, 3DMR may have a non-significant impact in the preoperative radiological assessment in the differentiation amongst confined and locally advanced disease. Despite not providing major advantages in terms of surgical outcomes, in patients undergoing NSS 3DMR is considered useful by the surgeon and may favor less invasive clamping techniques.

SC424
Functional outcomes of different renal clamping techniques during robot-assisted partial nephrectomy at 5 European robotic centers

F. Piramide, M. Paciotti, C.A. Bravi, A. Piro, M. Peraire Lores, E. Balestrazzi, C. Collà Ruvolo, G. Sorce, S. Rebuffo, M. Ticonosco, N. Frego, M. Belmonte, D. Amparore, S. Puliatti, R. De Groote, R. Schiavina, C. Fiori, G. De Naeyer, C. Terrone, S. Micali, E. Brunocilla, F. Porpiglia, A. Mottrie (Aalst)

BACKGROUND: In the last years several different techniques for the management of renal pedicle during partial nephrectomy (PN) has been developed and described with the aim to reduce the postoperative impairment of renal function. Nevertheless, it has been rarely reported which are the clamping strategies routinely performed at high volume centers and their long-term functional results. Aim of the present study is to describe and report functional results of the current renal clamping techniques used at 5 European robotic centers.

METHODS: Five European high-volume robotic centers were involved in this study. Data of consecutive patients underwent robot assisted PN (RAPN) from January 2012 to January 2023 were retrieved from prospectively maintained institutional databases. All patients were treated by highly experienced robotic surgeons. Demographic, perioperative and functional (serum creatinine [SCr] and estimated glomerular filtration rate-eGFR, collected before surgery, at discharge, and during follow-up visits) data were collected and analyzed. Continuous and categorical variables were reported as median and interquartile range (IQR) or frequencies as appropriate. Paired samples t-test was used to compare the baseline and postoperative functional data. Moreover, any decline of chronic kidney disease class (CKD) was recorded, and cumulative incidence analysis (CIA) was built to compare global clamping and the other clamping strategies in terms of CKD class decline.

RESULTS: 1479 patients were finally included in this study. Overall, median age, BMI and Charlon's comorbidity index were 64 (IQR: 55-72) years, 26 (IQR: 23.5-29) and 2 (IQR: 1-3), respectively. Median tumor size and PADUA Score were 35 (IQR: 24-47) mm and 8 (IQR: 7-10). Median SCr and eGFR were 0.90 (IQR: 0.79-1.09) and 84.7 (IQR: 67.65-95.57), respectively. Median operative time was 160 (IQR: 120-206) minutes. Overall, global clamping was used in the 45.3% of cases, off-clamp and selective clamping were performed in the 20.7% and 13.3% whilst early unclamping was adopted in the 20.6% of cases. Overall, major postoperative complication and positive surgical margins (PSM) rates were 16.9%, 3.0% and 6.2% respectively. Median follow-up was 13 (IQR: 4-27) months. Postoperative (1.03, IQR: 0.86-1.30) and last SCr (1.00, IQR: 0.85-1.21) as well as postoperative (72.5, IQR: 54.45-85.08) and last eGFR (76.3, IQR: 60.4-89.18) levels were found to be significantly lower than baseline (all $P<0.001$). Concerning the decline of CKD class, CIA showed no difference between global clamping and the other clamping strategies in CKD class decline risk ($P=0.70$).

CONCLUSIONS: Although global clamping still represents the most used strategy during RAPN, off-clamp and early unclamping techniques are increasingly chosen in case of low and high complex masses, respectively. Nevertheless, in experienced hands global clamping still represents a valid strategy with no differences in renal function decline respect the other techniques.

SMART (SC425-SC435)

Prostate cancer: surgical treatment 3

SC425
Prevalence of bilateral loco-regional spread in unilateral pelvic PSMA PET-positive recurrent prostate cancer
SC426
Detrusor apron sparing "hood" technique: preliminary experience at a tertiary referral center
SC427
3D augmented reality robotic-surgery guided by artificial intelligence: human assistance is still crucial to overcome technical limits
SC428
Robot-assisted bladder diverticulectomy and radical prostatectomy: a combined technique
SC429
Association between age at surgery and urinary continence recovery after Retzius-sparing robot-assisted radical prostatectomy
SC430
Mid-term outcomes after robot-assisted laparoscopic prostatectomy with bladder neck sparing in a large prospective cohort of patients
SC431
The impact of adjuvant radiotherapy on urinary continence recovery after Retzius sparing robot-assisted radical prostatectomy
SC432
Is the base location of primary lesion at MRI a predictor of clinically significant positive surgical margin in bladder neck sparing RARP? insight from a large series
SC433
Accuracy of intraoperative frozen section in assessing surgical margins status during robot-assisted radical prostatectomy: a single-center retrospective analysis
SC434
Cancer specific mortality after radical prostatectomy versus radiation therapy in high-risk prostate cancer patients: a multitrial cohort analysis
SC435
Ten-year impact of task force recommendations against PSA screening: effect on functional and oncological outcomes after robotic-assisted radical prostatectomy

SC425
Prevalence of bilateral loco-regional spread in unilateral pelvic PSMA PET-positive recurrent prostate cancer

F. Ambrosini, F. Falkenbach, D. Koehler, F. Lischewski, M. Graefen, M. Eiber, C. Terrone, M. Heck, S. Knipper, T. Maurer (Genoa)

BACKGROUND: The spread of more accurate PSMA-based PET imaging and thus the early detection of PCa oligo-recurrence has led to a growing interest in locally targeted treatment including salvage pelvic lymph node dissection (SLND). The best surgical template for SLND in patients with unilateral PCa recurrence is currently unknown. We retrospectively evaluated the risk of missing contralateral lesions in patients exhibiting unilateral PCa recurrence in pelvic lymph nodes (LNs) who were treated with bilateral PSMA-radioguided (RGS) SLND.

METHODS: Patients who consecutively underwent bilateral PSMA-radioguided SLND for one-side PCa recurrence in pelvic LNs detected with PSMA-PET at two different institutions between April 2014 and January 2023 were collected. We compared the PSMA PET findings with the location of PCa lymph node metastases (LNM) in the final pathology report. We relied on univariable and multivariable logistic regression models to predict missed disease on the contralateral side. Covariables for adjustment consisted of PSA level at sLND, number of PSMA PET positive lesions before PSMA-RGS, Gleason grade group at RP, LN dissection performed during RP, number of LNs removed during sLND, adjuvant radiation therapy after RP, pT stage at RP, pN stage at RP. Lastly, the rate of complete biochemical response (cBR) defined as a PSA level <0.2 ng/mL at 2-16 weeks after PSMA-radioguided SLND was assessed.

RESULTS: Overall, 60 consecutive patients were collected. All patients included in the analysis underwent RP as primary treatment. The median time between RP and PSMA-RGS was 25 months (IQR: 10-54) and the median age at salvage surgery was 64 years (IQR: 60-67). At PSMA-RGS, the median PSA level was 0.71 ng/mL (IQR: 0.38-2.28). The PSMA-PET pre-SLND showed one, two, three, four, or more than four lesions in 35 (58.3%), 12 (20%), 9 (15%), and 4 (6.7%) patients, respectively. Of these, 49 (81.7%) patients had unilateral positive pelvic lesions, 2 (3.3%) had unilateral positive nodes at the level of the common iliac arteries, and 9 (15%) had unilateral positive nodes in both pelvic and at the level of common iliac artery. Final pathology revealed unilateral LN involvement in 43 (71.7%) patients and a negative report in 3 (5%) cases. The rate of missed contralateral positive lesions was 23.3% (14 cases out of 60). A cBR was reported in 25 (41.7%) patients. In the univariable logistic regression models, all tested factors failed to achieve predictor status for missing contralateral lesions. Although not significant, a positive trend was found for the PSA level before PSMA-RGS (odd ratio: 1.02, 95% confidence interval: 1.00-1.04; P=0.084).

CONCLUSIONS: Defining the best surgical template for PSMA-radioguided SLND in patients with one-sided positive lymphogenic PCa recurrence at PSMA PET is challenging. The results of the prospective, randomized ProSTone trial will shed new light on the best recommendation for these selected patients.

SC426
Detrusor apron sparing "hood" technique: preliminary experience at a tertiary referral center

F. Gaboardi, A. Martini, L. Nocera, G. Passaretti, A. Russo (Milan)

BACKGROUND: The Detrusor apron sparing "hood" technique for robotic-assisted radical prostatectomy (DASH-RARP) has been proposed as a modification of the traditional anterior approach for radical prostatectomy to reduce postoperative urinary incontinence while maintaining an acceptable surgical margin rate. Here, we describe the preliminary experience with DASH-RARP at our tertiary referral center. The video was produced in October 2022.

METHODS: Patients with localized prostate cancer treated with the DASH-RARP technique at our tertiary center between June 2021 and October 2022 were prospectively enrolled and followed-up for a median (interquartile range [IQR]) time of 7 (3-13) moths following surgery. Pelvic lymph node dissection was performed according to the estimated lymph node involvement risk by nomograms. Frozen sections were performed in all patients to minimize surgical margin rate. Patients with anterior tumor location based on biopsy or multiparametric magnetic resonance imaging were excluded. Patient demographics, Body Mass Index (BMI), baseline prostate-specific antigen (PSA), clinical and pathological stage, and Gleason grading group were retrospectively extracted for all patients. Rates of positive surgical margins, post-surgery urinary retention and social continence, at catheter removal as well as at 3-month follow-up, were collected.

RESULTS: A total of 54 patients were included. Median age was 67 years (62-73), most patients were overweight (39 of 54, 72%), median (IQR) Body Mass Index (BMI) being 25.6 (22.5-27.1) kg/m^2. Median (IQR) baseline PSA was 7.2 (4.5-9.3) ng/mL and Gleason grading group was I in 8 (14.8%) patients, II in 16 (29.6%) patients, III in 19 (35.2%) patients, IV in 7 (13.0%) patients and V in 4 (7.4%) patients. Stage at final pathology was T2 in 37 (68.5%) patients, T3a in 12 (22.2%), T3b/T4 in 2 (3.7%) patients and pN1 in 3 (5.6%) patients. None of the patients had positive surgical margins at final pathology. Conversely, 6 (11.1%) patients experienced surgical margins at frozen sections. Urinary retention requiring catheterization occurred in 15% of patients (8 of 54). Social continence rate (defined as the use of 1 security pad) at the 1st week following catheter removal was 31.5% (17 out of 54 patients) and gradually improved to 70.4% (38 of 54 patients) at 3 months after surgery.

CONCLUSIONS: Our preliminary experience encourages the use of DASH-RARP in the setting of localized prostate cancer due to low rates of long-term urinary incontinence without significantly affecting the positive surgical margin rates.

SC427
3D augmented reality robotic-surgery guided by artificial intelligence: human assistance is still crucial to overcome technical limits

G. Volpi, P. Piazzolla, E. Checcucci, D. Amparore, A. Piana, F. Piramide, S. De Cillis, P. Verri, G.A. Mesterca, A. Bellin, C. Fiori, F. Porpiglia (Candiolo, Turin)

BACKGROUND: The use of 3-dimensional (3D) virtual models in an augmented reality (AR) setting has already

demonstrated an outstanding potential in urology, particularly for surgeon's guidance in "tailored" surgical approaches. In this scenario, artificial intelligence is considered a very promising and fascinating tool able to harmonize and maximize the performances of this technology, obtaining an automatic surgical guidance during robot-assisted partial nephrectomy (RAPN) and radical prostatectomy (RARP). However, some issues in the complete automation of this process still exist, and a human correction is sometimes required.

METHODS: The initial software we developed for 3D models' overlapping relied entirely on human abilities: using a 3D mouse, an assistant was able to follow the movements of the organ and correctly overlap the 3D virtual model over the real anatomy. However, this solution was not cost-effective. The next step was the introduction of automatization in the overlap process. Segmentation techniques proved to be effective to determine position values. By finding all the extrapolated frame pixels belonging to the target organ we were able to determine its x, y and z scale values. To determine the rotation, we resorted to some heuristic strategies that allowed us to determine at least one or two axes of rotation of the organ. Since a precise segmentation is fundamental for position and rotation prediction, we optimized this process training a Convolutional Neural Network (CNN) for this task, the core of our latest automatic overlap system implementation.

RESULTS: After several in-vivo test, the CNN-based system proved to be reliable in overlap precision, as computed using the IoU, Intersection over Unit, standard performance metric for these tasks. After several in-vivo test, the CNN-based system proved to be reliable in overlap precision, as computed using the IoU, Intersection over Unit, standard performance metric for these tasks. However, during RARP, sometimes the size of the real catheter and the diameter detected inside the image don't match. This requires human intervention for size correction. During RAPN, the system can be fooled by the soft consistency of the parenchyma. In these cases, deformation induced by surgical tools are misinterpreted as rotations or translations. This requires a minimal manual intervention to correct the issue.

CONCLUSIONS: AI has furtherly improved the automation of overlapping process during AR procedures. However, some situations might create issues regarding the correct prediction of organs' position during the interventions. In these cases, human intervention proved to be the best short-term solution.

SC428
Robot-assisted bladder diverticulectomy and radical prostatectomy: a combined technique

M. Martiriggiano, S. Tappero, L. Lo Monaco, G. Marchi, E. Vecchio, G. Drocchi, F. Ambrosini, C. Francesco, D. Panarello, G. Mantica, M. Borghesi, C. Terrone (Genoa)

BACKGROUND: Acquired bladder diverticula (BD) are usually due to bladder outlet obstruction (BOO) secondary to prostatic enlargement. In this peculiar scenario, Robot-assisted radical prostatectomy (RARP) for prostate cancer (PCa) is not contraindicated, although it might represent a challenging procedure, even in experienced hands. The current video aims to describe a case of RARP preceded by robot-assisted bladder diverticulectomy (RABD).

METHODS: The current video, produced in 2023, addressed the case of a 67-year-old man, ECOG 0, previously submitted to appendectomy, with no major comorbidities (Charlson Comorbidity Index 2), in pharmacological treatment for BOO. Prostate biopsy was indicated based on a PSA of 10.2 ng/mL, a suspicious area of 13 mm in the left prostatic lobe at magnetic resonance and revealed a PCa Gleason grade group 3. A concomitant large BD (12 cm) was detected in the left lateral wall of the bladder. The preoperatory staging was negative. The patients had a urinary chronic retention managed with self- catheterization. Before surgery, an open-tipped 12-Ch Foley catheter was placed in the BD under cystoscopic guidance, and a second 12-Ch Tiemann catheter was placed in the bladder. Intra-operatory ultrasound checked the correct positioning of the catheters. The surgery consisted of bladder diverticulectomy followed by radical prostatectomy and pelvic bilateral lymph node dissection and was performed with da Vinci Xi surgical platform (Intuitive Surgical, Inc., Sunnyvale, CA, USA). The first surgical step consisted of anterior bladder detachment, complete extravesical isolation of diverticulum with careful identification of the left ureter and complete resection of the BD, followed by a running single-layer cystorraphy, with Vycril 2/0 (Ethicon Inc., Raritan, NJ, USA). A standard antegrade RARP was performed, with bilateral inter-fascial nerve-sparing. Watertightness of both urethro-vesical anastomosis and cistorraphy was ascertained.

RESULTS: Operative time was 225 minutes, estimated blood losses were 150 cc, and no intra-operatory complications occurred. The postoperatory period was uneventful, and the patient was discharged on the third postoperatory day. On the 15th postoperatory day, a cystogram confirmed the absence of leakages and the catheter was removed. Time to continence recovery (0 to 1 pad per day) was 20 days. The time to first intercourse, with 5-phosphodiesterase inhibitors, was 45 days. Final pathology revealed PCa Gleason grade group 2, pT3a-pN0 (0/15 nodes)-R0. Post-operatory PSA was undetectable. The patient no longer needed self-catheterization and was able to empty the bladder with 70 cc post-void residual urine volume.

CONCLUSIONS: Large bladder diverticula are unusual findings that may enhance the difficulty of RARP and its related morbidity. However, combined robot-assisted bladder diverticulectomy and radical prostatectomy represent a feasible procedure.

SC429
Association between age at surgery and urinary continence recovery after Retzius-sparing robot-assisted radical prostatectomy

P. Dell'Oglio, S. Tappero, O. Maltzman, E. Vecchio, M. Martiriggiano, G. Granelli, A. Olivero, S. Secco, A.M. Bocciardi, A. Galfano (Milan)

BACKGROUND: The role of age at surgery on urinary continence (UC) recovery after Retzius-sparing (RS) robot-assisted radical prostatectomy is object of debate.

METHODS: 1417 patients underwent RS at a single high-volume European center between 2010 and 2021. Immediate UC recovery was defined as the use of zero or one safety pad per day at catheter removal. UC recovery was also evaluated at 12-month follow-up. Surgical procedures were performed by nine experienced robotic surgeons. Multivariable logistic and Cox regression analyses were used to assess the association between age at surgery and, respectively, immedia-

te and 12-month UC recovery, after accounting for year of surgery, Charlson comorbidity index, previous benign prostatic hyperplasia surgery, prostate volume, D'Amico Risk Classification, nerve sparing approach, surgical experience (SE). The predictive accuracy of each model was quantified using the receiver operating characteristic-derived area under the curve. SE was defined as the total number of RS performed by each surgeon before the patient operation. LOWESS function graphically displayed the relationship between age at surgery and immediate and 12-month UC recovery, after accounting for all confounders.

RESULTS: Median age at surgery was 65 (range: 45-80). Median follow-up was 25 months. Rates of immediate and 12-month UC recovery were 69 and 91%, respectively. After adjusting for case mix, age at surgery was an independent predictor of immediate (OR=0.97, P=0.03; C-Index: 70%) and 12-month UC recovery (HR=0.98, P=0.03; C-Index: 75%). A progressive decrease of the probability of immediate and 12-month UC recovery with the increasing of age was observed. The immediate UC recovery rates for a 45-, 60- and 80-year-old patient were, respectively, 86%, 76%, and 45% (absolute difference between 45 and 80-year-old patients: 41%). 12-month UC recovery rates for a 45-, 60- and 80-year-old patient were, respectively, 93%, 87%, and 73% (absolute difference between 45 and 80-year-old patients: 20%).

CONCLUSIONS: Age at surgery significantly affects immediate and 12-month UC recovery after RS. These findings should be taken into account in order to improve patient counseling in all patients' candidate to RS approach.

SC430
Mid-term outcomes after robot-assisted laparoscopic prostatectomy with bladder neck sparing in a large prospective cohort of patients

A. Alberti, R. Nicoletti, E. Dibilio, G.R. Resta, I. Mattei, C. Caneschi, A. Cifarelli, M.L. Gallo, A. Rivetti, A. Pecoraro, A. Manera, F. Sessa, D. Facchiano, P. Spatafora, R. Campi, M. Gacci, S. Serni, A. Sebastianelli (Florence)

BACKGROUND: To improve continence rates after robot-assisted laparoscopic prostatectomy (RALP), several reconstruction techniques have been proposed, however their impact is still controversial. The aim of our study was to present the mid-term functional and oncological results in a large cohort of patients treated with RALP with bladder-neck sparing and maximal urethral length preservation at our institution.

METHODS: After Ethical Committee approval, data from all consecutive patients undergoing RALP with bladder-neck sparing and maximal urethral length preservation technique between January 2017 and December 2022 were prospectively collected. Oncological outcomes consisted of significative positive surgical margins (PSM) (focal invasion ≥2 mm) and biochemical recurrence (BCR)-free rate. χ^2 test was used to compare differences among patients with index lesion located at the prostate base and all locations (P≤0.05). Urinary incontinence (UI) was defined, according to the EPIC criteria, as the need for more than 1 pad per day at follow-up. Univariable and multivariable logistic regression analysis assessed the potential independent predictors of continence. Erectile function was evaluated *via* self-reported questionnaires. Complications were assessed using Clavien-Dindo (CD) Classification.

RESULTS: Overall, 1179 patients were included, of which 181 (15.3%) were lost to follow-up. Median age was 68 years old (IQR: 63-72) and preoperative median PSA was 6.8 ng/mL (IQR: 4.9-9.8). Median follow-up was 31 months (IQR: 17-43). A nerve sparing (NS) RALP was performed in 758 patients (64.3%). The overall significative PSM was 12% (6.5% for stage pT2, 13% for pT3a and 22.9% for ≥pT3b). Among patients with index lesion at the prostate base, according to preoperative mpMRI and MRI-fusion biopsy, 12.6% had significative PSM (P=0.836). At last follow-up 91 (9.1%) patients had experienced BCR after a median of 17 months (IQR: 11-31) from surgery. Of those, only 5 had preoperative index lesion at the prostate base (4.2%) (P=0.162). At 30-days from surgery, 826 (82.8%) patients were fully continent or wore one safety pad. At 12-months a decreasing rate of UI (≥1 pad/*die*) was recorded (13.2% *vs.* 17.2%). At multivariable analysis, only a non-NS RALP (OR=1.57 [95% CI:1.03-2.59], P=0.035) was a significant predictor of early postoperative UI. At last follow-up, 345 (45.5%) patients who received a NS procedure had erections sufficient for intercourse, with or without pharmacological therapy. Postoperative early complications (within 30 days from surgery) were observed in 166 (14.1%) patients (54 CD 1, 84 CD 2 and 28 CD≥3); later compliances occurred in 79 (6.7%) patients (16 CD 1, 13 CD 2, 50 CD≥3).

CONCLUSIONS: RALP with bladder-neck sparing achieved favorable outcomes in terms of functional recovery, while preserving oncological radicality, even for tumors manly located at the prostate base. Longer follow-up and larger prospective studies are necessary to confirm these promising results.

SC431
The impact of adjuvant radiotherapy on urinary continence recovery after Retzius sparing robot-assisted radical prostatectomy

A. Olivero, O. Maltzman, S. Tappero, S. Secco, E. Strada, G. Petralia, D. Di Trapani, G. Napoli, M. Barbieri, F. Chierigo, P. Dell'Oglio, A.M. Bocciardi, A. Galfano (Milan)

BACKGROUND: Retzius sparing robot-assisted radical prostatectomy (RS-RARP) allows the preservation of the structures of the Retzius space that are crucial in the continence mechanism. This study aimed to evaluate the impact of adjuvant radiotherapy (aRT) on urinary continence (UC) recovery after RS-RARP.

METHODS: The current study is a retrospective analysis of PCa patients submitted to RS-RARP with or without pelvic lymph node dissection (PLND) at a single high-volume European institution between January 2012 and December 2020. The inclusion criteria for the study were pT2 stage with positive surgical margins or pT3/pN1 stage with or without positive surgical margins. We divided the patient into two groups, patients who received aRT and patients who went to observation. Administration of aRT was based on the indication given by each treating physician and followed an extensive discussion with patients about treatment options and expectations. Adjuvant RT was delivered within 1-6 months after surgery. Between 2012 and 2014, all patients underwent three-dimensional conformal radiation therapy (3D-CRT). Since 2015 intensity-modulated RT (IMRT) with image-guided RT or volumetric arc radiation therapy (VMAT) with image-guided RT has been used. Urinary continence recovery was defined as using no pads at the last follow-up. Patients

were evaluated at 1, 3, 6, and 12 months postoperatively and every six months after that.

RESULTS: A total of 1684 patients underwent RS-RARP during the period of the study. According to the inclusion criteria, 531 patients were included in the analysis: 124 patients underwent aRT, while 407 continued standard follow-up protocol after the surgery. These two groups were not balanced in oncological and surgical features, with worse prognosis features in the aRT group. We reported a rate UC-recovery at the last follow-up of 82% overall, 82% in the RS-RARP alone group *versus* 81% in the aRT group; this result did not show statistical significance (P=0.071), as shown by Kaplan-Meier analyses. Cox Regression analyses show an effect on UC-recovery at 12 months after surgery for aRT both in UV, but this has not been confirmed in the MV models (HR=0.80; 95% CI: 0.64-0.92; P=0.036 and HR=0.81; 95% CI: 0.52-1.25; P=0.3, respectively). No other variables were associated with UC recovery in the MV model. In the subset of aRT patients, only the Nerve sparing technique was associated with UC recovery (HR=1.86; 95% CI: 1.06-3.24; P=0.03 and HR=2.5; 95% CI: 1.11-5.64; P=0.027, partial and full nerve sparing, respectively).

CONCLUSIONS: Our study is the first to investigate adjuvant radiotherapy's effect after Retzius-sparing radical prostatectomy on urinary continence. Unlike other surgical approaches, we did not find statistically significant differences in urinary continence recovery after treatment in this setting. In the adjuvant radiotherapy cohort, the NS approach predicts UC recovery.

SC432
Is the base location of primary lesion at MRI a predictor of clinically significant positive surgical margin in bladder neck sparing RARP? insight from a large series

E. Dibilio, R. Nicoletti, A. Alberti, G.R. Resta, A. Mariotti, D. Paganelli, A. D'Amico, S. Giancane, F. Sessa, A. Rivetti, P. Spatafora, A. Pecoraro, I. Mattei, S. Serni, R. Campi (Florence)

BACKGROUND: While preservation of the bladder neck (BNP) during robot-assisted radical prostatectomy (RARP) is proposed to improve urinary continence without any adverse effect on oncological outcomes, concern remains regarding margins status for cancers located at the prostate base. Our study aimed to investigate the rates of clinically significant positive surgical margins (PSM) in a large cohort of patient treated with RARP with bladder neck sparing technique at a referral Academic Centre and its potential correlation with tumor location at preoperative Magnetic Resonance Imaging (MRI).

METHODS: After Ethical Committee approval, we prospectively collected data of patients who underwent RARP with bladder neck preservation between March 2017 and December 2021. All surgical procedures were performed by expert surgeons (>200 RARP). Among these we selected patients who performed a prostate magnetic resonance imaging (MRI) prior to surgery. We evaluated the position of the Major positive lesions at MRI as "base" *vs.* "all other locations." According to Sammon *et al.*, we considered clinically significant a PSM>2 mm. Multivariable logistic regression analysis assessed the potential predictors of clinically significant PSM.

RESULTS: Overall, 605 patients were included. Eighty-nine of them had the primary lesion at MRI located at the prostate base. A clinically significant PSM was found in 65 patients (10.7%). Among these, 7 patients (10.7%) had prostatic base lesions. The base localization of the major MRI positive lesion was not a predictor of clinically significant PSM (P=0.516, OR=0.737, 95% CI: 0.293-1.853). In the other hand, MRI major diameter lesion <15 mm (P=0,051 OR=0,521 CI 0,217-1,003) and a preoperative PSA<10 ng/mL (P=0.002, OR=0.367, 95% CI: 0.192-0.701) were identified as protective factors for clinically significant PSM.

CONCLUSIONS: RARP with bladder neck sparing technique is a safe and functionally favorable procedure in experienced hands; our study confirms its oncological safety in term of clinically significant PSM. In our experience, the localization at prostatic Base of primary lesion on MRI does not seem to be associated with a higher risk of clinically significant PSM. However, larger studies are needed to refine the role of the location of Primary lesion at MRI in the surgical planning.

SC433
Accuracy of intraoperative frozen section in assessing surgical margins status during robot-assisted radical prostatectomy: a single-center retrospective analysis

E. Beatrici, C. Roberta, A. Ercolani, P. Arena, G. Chiarelli, F. De Carne, S. Mancon, A. Saita, G. Guazzoni, P. Casale, M. Lazzeri, N.M. Buffi, G. Lughezzani (Milan)

BACKGROUND: We aimed to evaluate the effect of intraoperative frozen section (FS) in assessing margins status in order to preserve neurovascular bundles (NVBs) during robot-assisted radical prostatectomy (RARP).

METHODS: We retrospectively analyzed data from men with localized prostate cancer who underwent robot-assisted radical prostatectomy (RARP) between January 2015 and October 2022. For each case, the surgeon made the decision regarding the technique used to preserve the neurovascular bundle based on a comprehensive assessment of preoperative and intraoperative factors. Intraoperative FS analyses were conducted on prostatic margins marked by the surgeon with India ink, and further tissue removal was performed if positive surgical margins were found. Descriptive statistics were used to summarize the data, and Pearson's χ^2 test to assess associations between categorical variables. Univariable and multivariable logistic regression models were fitted to evaluate the association between positive surgical margins at final pathology and margin status at FS, adjusting for relevant men and disease preoperative characteristics.

RESULTS: A total of 1,457 men were included in the study. The median (IQR) age at intervention was 65.4 (60.2-69.9) years. At biopsy, the median PSA was 6.7 (5.1-9.4) ng/mL, and 64.6% of prostate cancer cases were classified as International Society of Urological Pathology (ISUP) grade group 1-2. In intraoperative frozen section (FS) analyses, 25.9% of men had positive surgical margins, while 74.1% had negative surgical margins. Among men with positive margins at FS, only 27.0% were confirmed to have positive surgical margins at the final pathology. In contrast, among men with negative margins at FS, 88.8% also had negative margins at the final pathology. Positive surgical margins at final pathology in locations not detected by FS were observed in a

minority of cases (15.1%). Our analysis showed that positive surgical margins at FS were strongly associated with increased odds of positive surgical margins at final pathology, both in univariable (OR=2.93; 95% CI: 2.17-3.95) and multivariable models (aOR=2.76; 95% CI: 2.02-3.78). Additionally, the multivariable model indicated that higher PSA levels at biopsy (>20 ng/mL) (aOR=5.30; 95% CI: 3.04-9.23) and ISUP grade group 5 at biopsy (aOR=2.21; 95% CI: 1.01-4.82) were also associated with increased odds of positive margins at final pathology.

CONCLUSIONS: While FS analysis demonstrated high specificity when negative, caution is warranted when interpreting the strong association between positive surgical margins at FS and final pathology, given that a considerable proportion of positive FS margins did not correspond to positive final margins. Tailoring patient selection based on preoperative condition and prostate cancer features could further refine the identification of cohorts that would benefit the most from FS analysis, ultimately improving the accuracy of margin status assessment during RARP.

SC434
Cancer specific mortality after radical prostatectomy *versus* radiation therapy in high-risk prostate cancer patients: a multitrial cohort analysis

M. Righetto, V. Fulcoli, D. Modonutti, A. Andrisano, A. Guttilla, G. Costa (Padua)

BACKGROUND: According to the National Comprehensive Cancer Network (NCCN) definition, high-risk prostate cancers (HR-PCa) are defined as those with at least 1 of the following features: Gleason Grade Group IV/V or PSA>20 ng/mL or ≥cT3. HR-PCa patients are eligible for either radical prostatectomy (RP) or radiotherapy (RT) with curative intent. Large-scale, population- based analyses testing which treatment may lead to an improvement in cancer-specific mortality (CSM) are lacking, and the currently available results are from retrospective databases, such as the Surveillance, Epidemiology, and End Results (SEER). We conducted a survival analysis based on a large data pool from 4 randomized clinical trials (RCTs) and our prospective institutional database.

METHODS: HR-PCa patients were enrolled from the control arms of 4 RCTs (NCT00002633, NCT00004054, NCT00288080, NCT00004124) and from our institutional database. Clinical node positive patients, patients who received adjuvant RT or neoadjuvant androgen deprivation therapy, and not evaluable/not acceptable RT protocols were excluded from the analysis. Firstly, we performed a 1:1 propensity score weighting (inverse probability of treatment weighting; according to age, race, PSA, cT, comorbidities, concomitant therapies, and Gleason Score) between HR-PCa patient treated with RP or RT. Secondly, cumulative incidence plots for the estimated 5-year CSM were performed. Finally, multivariable Fine-Gray competing risk regression model tested for CSM differences between RP and RT patients, after adjustment for stage, race, comorbidities and PSA value. The statistical analysis was performed with R software (version 4.1.2, The R Foundation, Vienna, Austria). All tests were 2-sided with a level of significance set at P<0.05.

RESULTS: 1755 HR-PCa patients were identified. 1059 (60%) underwent RP, and 696 (40%) RT. RP patients were younger (median age 63 [interquartile range, IQR: 54-70]) *vs.* 74 [IQR: 68-77] years), with lower PSA values (mean 12.9 [standard deviation, SD=11.7] *vs.* 22.1 [SD=23.3] ng/mL), higher clinical T stage, higher Gleason Score and lower comorbidities. Median survival was 117 months in the RP group and 102 months in the RT group. Adjusted 5-year CSM rates were 1.4% (95% CI: 0.6-2.9) for the RP group *vs.* 4.2% (95% CI: 2.9-6) for the RT group (P<0.01). The multivariable Fine-Gray competing-risk Hazard Ratio was 0.36 (95% CI: 0.18-0.72, P=0.004) favoring RP.

CONCLUSIONS: Currently, there is no definitive evidence in favor of RP rather than RT in HR-PCa patients. Moreover, there are no available high-quality RCTs comparing RP *vs.* RT in this population. We controlled confounders and biases of retrospective registry data, by using the control-arms of RCTs. Our study suggests an advantage in CSM for NCCN HR-PCa patients undergoing RP compared to those receiving primary RT.

SC435
Ten-year impact of task force recommendations against PSA screening: effect on functional and oncological outcomes after robotic-assisted radical prostatectomy

M.C. Moschovas, A. Jaber, S. Saikali, S. Bhat, M. Sandri, T. Rogers, A. Gamal, D. Loy, E. Patel, S. Assumma, T. Calcagnile, M.C. Sighinolfi, B. Rocco, V. Patel (Celebration)

BACKGROUND: For experienced surgeons, prostate cancer outcomes are ultimately affected by the pathology of the disease they treat. Over the last decade and a half, we have experienced a dramatic alteration in the pathology that we are addressing. During this time, the most significant shift in prostate cancer management was observed following the May 2012 decision by the United States Preventive Service Task Force (USPSTF) that recommended against PSA screening for all men. This has affected the types of prostate cancers we are treating and can potentially influence treatment outcomes. We aimed to analyze the functional and oncologic trends in prostate cancer outcomes in the largest single surgeon, single practice series.

METHODS: We retrospectively reviewed our prospective IRB-approved prostate cancer registry for 11,396 patients that underwent robotic-assisted laparoscopic prostatectomy (RALP) between 2008 and 2021. Each patient had at least a 12-month follow-up. The cohort was divided into two groups based on the date of RALP: Group 1, before USPSTF recommendations took effect (01/2008-12/2012); and Group 2 no fewer than six months following the implementation of USPSTF recommendations (01/2013-12/2021). Group 1 had 4760 patients, and Group 2 had 6636 patients, with a median follow-up of 109 and 38 months, respectively. We assessed the functional and oncologic outcomes of the two groups.

RESULTS: We detected time-trend changes after 2012. There was a migration to younger ages, less than 60, and an increase in the median preoperative PSA (5 to 6 ng/mL). There was an 18% increase in the higher grade and stage of the disease, Gleason ≥3+4 (19% increase), and ≥pT3 (18% increase). This translated to a 6% increase in positive surgical margins with an initial rapid increase that was tempered with a surgical adjustment in the amount of nerve sparing

(NS). There was a 24% reduction in full nerve sparing in response to the worsening pathology. Outcomes were also affected by the modification in NS. Comparing groups 1 and 2, there was a significant decline in postoperative outcomes in Group 2, including: a 12-month continence reduction of 9%, reduction in potency by 27%, and reduction trifecta by 22%. The breakpoint in functional outcomes appears to be mid-2012.

CONCLUSIONS: In our experience, we have witnessed a significant change in the types of patients we are seeing and the outcomes we are able to deliver. We are treating younger patients with higher-grade diseases, and the increasing number of high-risk patients has led to worse functional and oncologic outcomes. The initial rapid rise in PSM was leveled by the move towards more partial nerve sparing. The USPSTF recommendation has affected the oncology and outcomes of prostate cancer in an increasingly younger patient population who could benefit from PSA screening at the appropriate time.

SMART (SC436-SC442)

Urinary calculosis 2

SC436
The ILY® robotic system: paving the way for robotics' use in endoscopy
SC437
Immediate *versus* deferred treatment of ureteral stones: what are we waiting for?
SC438
DJ substitution with a pigtail suture stent after ureteroscopy reduces stent related symptoms
SC439
Ureteroscopy in the elderly: clinical outcomes and prognostic value of Modified Frailty Index
SC440
Active ureteral stone treatment in an emergency setting: experience in a single center
SC441
Intraoperative radiation exposure during ureterorenoscopy: urologist *vs.* technician, do we have a winner?
SC442
Double-J stenting complications: a tertiary center overview

SC436
The ILY® robotic system: paving the way for robotics' use in endoscopy

M. Cossu, A. Quarà, M. Poggio, S. De Cillis, D. Amparore, E. Checcucci, A. Piana, F. Piramide, G. Volpi, P. Verri, M. Sica, M. Burgio, E. Cisero, M. Colombo, M. Mandaletti, L. Ferrando, F. Rosi, M. Manfredi, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: Over the last years, the use of flexible ureteroscopy (F-URS) has become ever more popular among urologists thanks to its constant technical development. Nevertheless, such procedure is still considered as a challenging one due to suboptimal ergonomics, the need to carry out the procedure in a standing position and the exposure to ionizing radiations. These concerns can both cause physical harm to the surgeon and prejudge procedural outcomes. Aiming to overcome these issues, the introduction of robotic systems for F-URS allows to reduce radiation exposure and surgeon's physical strain. Among these robotic platforms, the ILY® robotic system (STERLAB, Vallauris, France) is composed by a ureteroscope holder manipulated with a wireless controller, allowing the surgeon to operate it remotely. The holder can be adapted to all kinds of ureteroscopes (disposable and single use) and with most of the ureteral sheaths (UAS). We report below the first Italian clinical experience of F-URS with the ILY® robotic system (STERLAB).

METHODS: Three consecutive cases of F-URS were carried out using the ILY® robotic system (STERLAB) in our center. All the procedures were performed with patients in lithotomy position and under general anesthesia. Firstly, semirigid ureteroscopy was executed and a guidewire positioned in the renal pelvis. Subsequently, a UAS (9.5-11.5 Fr or 10.7-12.7 Fr) was placed close to the ureteropelvic junction or close the ureteral stone and it was fixed to the ILY® robot holder (STERLAB). Then, a Pusen Flexible ureteroscope 7.5 Fr (Zhuhai Pusen Medical Technology Co., Ltd., Jiangxi, China) was introduced in the UAS and fixed to the ILY® robot holder (STERLAB) as well. Once both instruments were properly allocated, the remote control was operated performing the intervention. Preoperative and perioperative data were gathered. Surgeon satisfaction regarding platform's use was evaluated thanks to a specifically made questionnaire evaluating ease of use, ergonomics and stability during stone fragmentation on a Likert Scale (1: not very good; 5: very good).

RESULTS: The Case n1 was a right retrograde intrarenal surgery (RIRS) for a 15-mm stone in the renal pelvis, the n2 was a Right F-URS for a 10-mm ureteral stone and the n3 was a bilateral RIRS for numerous millimetric stones. The mean operative time was 94.3 (+10.2) min, and no additional time was required for robot placement as it was simple and brief. No intraoperative or postoperative complications were recorded. Catheter removal and patients' discharge took place on the first postoperative day. All the patients were stone free post-procedure. The questionnaire highlighted good (4) ease of use and very good (5) ergonomics and stability.

CONCLUSIONS: We hereby present the first Italian clinical experience regarding robot-assisted ureteroscopy with the ILY® Robotic System (STERLAB). Our preliminary results show that this technique is feasible and safe. Furthermore, it proved a good ease of use and a very good ergonomics.

SC437
Immediate *versus* deferred treatment of ureteral stones: what are we waiting for?

T. Di Vico, A. Alberti, J. Frizzi, M. Lanciotti, A. De Benedetto, M. Di Camillo, M. Bacchiani, R. Tammaro, A. Mottola (Empoli)

BACKGROUND: Ureteral stones accounts for an important share of emergency department visits and hospital admission worldwide. However, there is no clear evidence in literature, nor recommendations in the International Guidelines, regarding the best surgical strategy in case of renal colic that cannot be treated with medical therapy alone, whether it is better to place a stent first and electively treat the stone, or whether to immediately treat the stone with ureteroscopy (URS) and endoscopic lithotripsy. Our study aimed to evaluate the efficacy of immediate treatment of ureteral stones, evaluating the stone-free and complication rate compared to the same deferred procedure.

METHODS: We retrospectively collected data from all patients who underwent URS for urolithiasis at a single center from January 2020 to March 2023. All patients included in the study did not present indication for urgent urinary diversion (uncontrolled pain, inadequate renal function, sepsis, evidence of urine extravasation). All procedures were carried out by semirigid URS using Ho:YAG laser, under general anesthesia, with peri-operative antibiotic prophylaxis. After the procedure a ureteral stent was left in place when deemed necessary by the operator. Stone-free rate (SFR) was assessed based on surgical reports and postoperative image control, considering as negative the presence of residual fragments <4mm. Complications were classified according to Clavien-Dindo (CD) Classification. χ^2 test was used to compare differences between the two groups ($P \leq 0.05$).

RESULTS: Overall, 344 patients were included. Of those, 237 (68.9%) were treated within 48h from hospital admission, while 107 (31.1%) were treated in deferred regime after a median of 65 (IQR: 57-76) days from diagnosis. Median age was 52 (IQR: 44-62) years old, with a male:female ratio of 3:2. Median operative time was 43 (IQR: 38-54) minutes. Overall SFR was 79.4%; considering immediate and deferred URS, SFR was respectively 78.5% and 81.4%. Ureteral narrowing preventing a safe procedure was the main reason for treatment failure in the not presented subgroup. No relevant intraoperative complications were reported. Overall, postoperative complications occurred in 49 (14.2%) cases. CD grade 1-2 (mild hematuria, fever and urinary tract infections, urinary retention) and ≥3 (ureteral lesions and strictures, sepsis) complications respectively occurred in 31 (13.1%) and 3 (1.3%) patients treated in immediate regime and 13 (12.1%) and 2 (1.9%) patients treated in deferred regime. No statistically significant difference resulted comparing the two subgroups (immediate *vs.* deferred URS) considering stone-free rate (78.5% *vs.* 81.4%, P=0.359) and postoperative complications (14.3% *vs.* 14%, P=0.936).

CONCLUSIONS: Our experience suggests that immediate treatment of ureteric stone is a feasible and safe option with comparable success rate to the same delayed procedure. This results in considerable savings in terms of time (single intervention) and resources.

SC438
DJ substitution with a pigtail suture stent after ureteroscopy reduces stent related symptoms

A. Bosio, S. Ferretti, E. Alessandria, E. Vercelli, D. Campobasso, L. Micai, C. Gozzo, G. Bertello, G. Guarino, C. Alice, A. Bisconti, P. Gontero (Turin)

BACKGROUND: The conventional coil of double J (DJ) stents is replaced by two surgical threads reaching the bladder in pigtail suture stents (PSS). A significant decrease in stent-related symptoms (SRS) was observed with the use of PSS after ureteroscopy compared with conventional JJ stent in a RCT. The objective of our current study was the comparison of SRS through the Ureteral Stent Symptom Questionnaire (USSQ) in patients undergoing ureteroscopy (URS) for stone treatment and DJ substitution with a pigtail suture stent (PSS).

METHODS: From April 2020 to December 2022, all the DJ prestented patients waiting for stone treatment (URS) were enrolled in a prospective longitudinal study in two different Italian Centers. URS occurred not before two weeks from DJ insertion. The USSQ – a validated specific questionnaire evaluating SRS – was administered 2 weeks after DJ placement and 2 weeks after PSS placement. The primary endpoint of our study was the comparison of Urinary Symptom Index Score and the rate of patients complaining of pain 2 weeks after DJ and PSS placement. Secondary endpoints were the comparisons of single symptoms analyzed with the USSQ.

RESULTS: A total of 83 patients were enrolled in the study. Patients showed significantly lower Urinary Symptom Index Score (P<0.001), Pain Index Score (P<0.001), VAS score (P=0.001), together with better general health (P<0.001), work performance (P<0.001) and less body pain (60.2% *vs.* 88.0%, P<0.001) while keeping the PSS compared to the previous DJ. Moreover, PSS patients had better scores considering each urinary SRS, complained of less renal pain during micturition, less impact of pain on everyday life and had better scores considering each item of work performance.

CONCLUSIONS: Our work showed that patients undergoing DJ substitution with PSS after URS showed a significant reduction of SRS. Therefore, the use of PSS after URS should be considered in clinical practice also in presented patients in order to decrease SRS.

SC439
Ureteroscopy in the elderly: clinical outcomes and prognostic value of Modified Frailty Index

M. Ragonese, U. Gradilone, A. Distante, G. Costanzi Porrini, M. Bracco, F. Pinto (Rome)

BACKGROUND: Ureteroscopy (URS) and retrograde intrarenal surgery (RIRS) are the standard of care for treatment of ureteral and kidney stones up to 2 cm of diameter. Few studies in literature have described outcomes of retrograde endoscopic procedures in elderly patients despite if is estimated that geriatric stone formers comprise 10-12% of all stone formers. Moreover, in most of the published literature the cut-off for the elderly patients is considered 65 years, but it should be raised at least to 70 considering the increase in life expectancy nowadays. The aim of our study was to analyze operative outcomes and prognostic value of fragility assessment in a group of elderly patients treated for stone disease.

METHODS: We evaluated data of a group of 120 patients aged >70 years, treated URS or RIRS for ureteral and kidney stones between August 2019 and May 2021. We compared these results with data of a group of patients aged <70 years with similar clinical characteristics in terms of stone disease. The prognostic value of Modified Frailty (mFI) Index, mFI-5, was evaluated.

RESULTS: A total of 195 patients were analyzed and divided in two groups according to their age: group 1 with 120 patients aged >70 years and group 2 with 75 patients aged <70 years. Mean age in group 1 was 76.1 years (range: 70-90 years). Mean age in group 2 was 49.3 years (range: 28-69). The stone free rate was 87% in group 1 and 84% in group 2 (P=0.16). Median ASA (American Society of Anesthesiology) score was 2.5 (range: 1-4) in group 1 and 2 in group 2 (range: 1-3), median Charlson Comorbidity Index age adjusted was 5 (range: 3-7) in group 1 and 2 in group 2 (range: 1-4). Mean operative time was 65 minutes (±27) in group 1 and 61 minutes (±15) in group 2, without any statistically significant difference (P>0.05). Regarding complications, only Clavien-Dindo 1-3 complications were reported with no statistically significant difference between the two groups (P=0.17). There was no statistically significant difference in terms of length of stay was (P=0.09). At the multivariate analysis, mFI-5>2 results as a significant predictor of complications and longer length of stay (P=0.013).

CONCLUSIONS: RIRS and URS are safe and effective methods of managing urolithiasis in elderly patients. However, fragility is a relevant factor in terms of complications and length of stay and a frailty assessment should be included in the evaluation of elderly patients.

SC440
Active ureteral stone treatment in an emergency setting: experience in a single center

E. Bonacina, C. Silvani, A. Li Puma, R. Di Benedetto, S. Guzzo, D. Vizziello, E. Finkelberg, P. Acquati, L.F. Carmignani (San Donato Milanese, Milan)

BACKGROUND: Ureteral stones rank among the most prevalent conditions that warrant urological evaluation in the emergency department (ED). In case of obstructive stone causing infection, unresponsive pain or kidney impairment, surgical decompression in an emergency setting is suggested. In these cases, active stone treatment is usually postponed some weeks after primary prompt decompression. However, in selected patients, an active stone treatment performed in an emergency setting may improve outcomes and reduce treatment costs by avoiding a second procedure after first decompression with DJ/nephrostomy placement. In this study, we aimed to determine safety and feasibility of emergency ureteroscopy (URS) with laser active stone treatment compared to only DJ stent placement in selected patients.

METHODS: We retrospectively analyzed data from all patients admitted to ED at our Institution for ureteral lithiasis who underwent an emergency intervention (surgical decompression with ureteral DJ *vs.* active stone treatment) from 01/2021 to 12/2022. All patients underwent CT scan before surgery. Treatment's choice was based on clinical evaluation and risk factors for sepsis: WBC, CRP, kidney's function, body temperature and stone's characteristic. Patient's demographics, clinical and radiologic data, operative variables were evaluated. We consider postoperative infectious complications development, transfer to ICU after surgery and length of stay (LOS).

RESULTS: Ninety-two patients were included. Median age was 55 years, 59 were male (64.1%) and 33 were female (35.9%). Median BMI was 25.36 kg/m² (24.35-26.02). Forty-two patients underwent primary URS while 50 underwent placement of a DJ stent, postponing stone's removal to a second procedure. Group A (URS) and group B (DJ) were comparable in terms of age, gender, BMI, preoperative CCI

and body temperature at ED admission (36.6 *vs.* 36.8 °C). At admission, WBC count in group A and B were 9885/mm³ and 12,565/mm³ (P=0.274). Estimated preoperative GFR was lower in group B (70 *vs.* 57 mL/min/1.73m², P=0.016) while C-reactive protein was lower in group A (6.75 *vs.* 31.85 mg/dL, P=0.043). At the CT scan, rate of kidney fat stranding (43% *vs.* 68%, P=0.015) and stone volume (0.023 *vs.* 0.136 cm³, P=0.01) were lower in group A. In group A, stones were more frequently localized in the distal ureter (76% *vs.* 38%, P<0.001). Median surgical time was lower in group B (40 *vs.* 25 min, P<0.001). There was no difference among groups as for LOS (1 *vs.* 2 days, P=0.326), postoperative hypotension rate (0 *vs.* 6%, P=0.107), transfer to ICU (0 *vs.* 6%, P=0.107) and postoperative sepsis (0 *vs.* 2%, P=0.357).

CONCLUSIONS: Active treatment of ureteral stones through ureteroscopy with laser lithotripsy appears to be safe and feasible, even in emergency settings. Proper patient selection, based on clinical presentation, blood test results and CT scan characteristics, is mandatory. Primary active stone treatment can improve the quality of care for patients and reducing costs.

SC441
Intraoperative radiation exposure during ureterorenoscopy: urologist *vs.* technician, do we have a winner?

C. Vaccaro, V. Lorusso, F. Palmisano, M. Rosso, P. Giarratana, V. Parolin, E. Verzotti, M. Nicola, A.M. Granata, M. Talso, A. Gregori (Milan)

BACKGROUND: The aim of the study was to compare the radiation exposure between two groups of patients who underwent ureterorenoscopy with radiology technician (RT)-controlled fluoroscopy *versus* surgeon-controlled fluoroscopy in order to comply with the "as low as reasonably achievable" (ALARA) principle.

METHODS: This was a prospective, non-randomized, observational study; we analyzed data of 100 patients treated with ureterorenoscopy at a single center (September 2022 to March 2023). Patients were stratified in two cohorts: patients treated with RT- controlled fluoroscopy *versus* those treated with surgeon-controlled fluoroscopy. Patient characteristics and surgical data were recorded for all patients. Primary outcome was to compare the intraoperative radiation dose, expressed as dose-area product (DAP, cGy*m²), and the fluoroscopy time (FT, seconds) between the two groups. χ^2 and Mann-Whitney tests were performed to evaluate differences in proportions or medians. Secondary outcome was to assess patient and surgical characteristics associated with increased FT and DAP in patients who underwent ureterorenoscopy. Multivariable logistic regression model was performed.

RESULTS: Overall, 50 patients were treated with RT-controlled fluoroscopy and 50 patients with surgeon-controlled fluoroscopy. The median DAP was significantly lower in the surgeon-controlled fluoroscopy group (175 cGy*m², IQR: 112-300.25) than in the RT-controlled fluoroscopy group (207 cGy*m², IQR: 140.25-402) (P<0.05). The median FT before and after the change to surgeon-controlled fluoroscopy was 24 (IQR: 18-54) and 19 seconds (IQR: 12-31.5), respectively (P<0.05). At multivariable logistic regression analysis, male sex, previous ureteric stent placement, surgeon's experience ≤300 procedures and Hounsfield Unit (HU)>1000 were independently associated with both increased DAP and FT (P<0.05), while a Body Mass Index (BMI)<25 was an independent predictor of decreased DAP and FT (P<0.05).

CONCLUSIONS: Surgeon-controlled fluoroscopy during ureterorenoscopy is associated with significantly lower DAP and FT compared to RT-controlled fluoroscopy. This strategy could lead to a reduction of radiation exposure for both patients and healthcare providers.

SC442
Double-J stenting complications: a tertiary center overview

M. Della Corte, E. Cerchia, M. Catti, E. Teruzzi, B. Tadini, S. Gerocarni Nappo (Turin)

BACKGROUND: A double-J stent (JJ) is often placed after endoscopic or surgical procedures in pediatric urology. We describe JJ related complications in a single center.

METHODS: A retrospective analysis of JJs placed over 3 years was performed, including: surgical procedure, stenting-fashion (SF), stenting-duration, anatomical anomalies, JJ-type, antibiotic prophylaxis (ABXP), urinary tract infections (UTI), JJ-dislodgement. The statistical analysis included mean, standard deviation and *t*-test with different variance.

RESULTS: Fifrty patients (27 M, 23 F) aged 2 months-17 years (mean 6.28±5.65 years) consecutively received 71 JJs during: 12 open-pyeloplasty (OP), 17 laparoscopic-pyeloplasty (LP), 4 retrograde intra-renal surgery (RIRS), 6 kidney transplantation, 7 endoscopic high-pressure balloon-dilatation (EHPBD), 22 prestenting, 2 ureteral reimplant, 1 pyelotomy. Three patients presented duplicated collecting system, 1 horseshoe kidney. Thirty-three JJs were placed though retrograde-fashion, 32 anterograde, 6 at kidney transplantation. 51 JJs were fixed-length type, 20 multi-lengths. The average stent duration was 71.18(±57.39) days. Fifty patients received cefixime, 17 amoxicillin-clavulanate, 4 cotrimoxazole as ABXP during JJ-maintenance. Eight JJs (11.26%) were associated with complications. These JJs were placed: 2 OP, 1 LP, 1 RIRS, 1 EHPBD, 2 prestenting, 1 pyelotomy. The average stenting-time of 59.5(±17.39) days was not significatively different from the not-complicated patients. None had anatomical anomalies. UTIs occurred in 5 patients, 2 of them developed acute pyelonephritis. These patients received ABXP as follow: 4 cefixime, 1 amoxicillin-clavulanate. All 5 UTIs were associated with retrograde fashion placement. JJ-dislodgement interested 3 patients. All the migrated JJs were fix-length. An association between SF and dislodged ringlet figured: 2 distal-anterograde, 1 proximal-retrograde.

CONCLUSIONS: JJs are associated with a significant mobility, although their steady use. In our experience retrograde placement was associated with UTI, and fixed length JJs with displacement. We could not relate complication occurrence with the length of stenting or with any other variable evaluated.

SMART (SC443-SC457)

Prostate cancer: diagnosis and screening 2

SC443
A systematic review to evaluate patient-reported outcomes measures (PROMs) for metastatic prostate cancer according to the COSMIN methodology: a pioneer WP2 project

SC444
Impact of prostate imaging quality (PI-QUAL) score on the detection of clinically significant prostate cancer in men undergoing MRI-targeted biopsy

SC445
Can we predict the site of positive surgical margins based on the site of the Index Lesion at multiparametric MRI? A topographic, single-center study

SC446
Integrating Index Lesion Volume to better classify men with indolent prostate cancer among patients with intermediate risk disease: results from a large, multi-institutional series

SC447
When is central histological review of prostate biopsy really needed to reduce the risk of misclassification of prostate cancer? The importance of patient risk stratification

SC448
Residents and consultants have equal outcomes when performing transrectal fusion biopsies: a randomized clinical trial

SC449
Plasmatic exosomes from prostate cancer patients show increased carbonic anhydrase IX expression and activity and low PH

SC450
PSA-zinc urinary test outperform standard of care in early detection of prostate cancer

SC451
Optimized urine smart test for early detection of prostate cancer

SC452
Clinical and high-resolution micro-ultrasound risk factors for detecting clinically significant prostate cancer in biopsy-naïve patients with abnormal digital rectal examination: a large single center experience to avoid unnecessary multiparametric MRI

SC453
A dedicated screening for early detection of prostate cancer in men with pathogenetic variants in DNA-repair gene

SC454
Prospective per-target analysis of the added value of probe- tethered access cannulas in cognitive transperineal prostate biopsy of ultrasound-visible MRI targets

SC455
Can transrectal micro-ultrasound direct patients toward a conservative management instead of prostate biopsy? A descriptive single-center analysis

SC456
Predicting the risk of 5-year biochemical recurrence in patients treated with radical prostatectomy for prostate cancer: the PIPEN risk categories

SC457
The rebound effect of diagnosis of csPCA, after COVID-19 pandemic

SC443

A systematic review to evaluate patient-reported outcomes measures (PROMs) for metastatic prostate cancer according to the COSMIN methodology: a pioneer WP2 project

R. Maria Monica, G. Gandaglia, E.S. Sisca, A. Derevianko, E. Alleva, K. Beyer, C. Moss, F. Barletta, S. Scuderi, M.I. Omar, S. Maclennan, P.R. Williamson, J. Zong, S.J. Maclennan, N. Mottet, P. Cornford, O.L. Aiyegbusi, M. Van Hemelrijck, J. N'Dow, A. Briganti (Milan)

BACKGROUND: Patient-reported outcome measures (PROMs) represent important endpoints in metastatic prostate cancer (mPCa) and in the assessment of Quality of Life (QoL). However, the accurate measurement of health-related quality of life depends on the psychometric properties of the PROMs considered. We aimed to appraise, compare, and summarize the properties of PROMs used in mPCa.

METHODS: Within the framework of the work package 2 of PIONEER an IMI2 European network of excellence for big data in PCa, we assessed the psychometric properties of PROMs used in randomized controlled trials (RCTs) including patients with mPCa. All available PROMs were identified through a systematic review of the literature performed on Medline in September 2021. All identified PROMs were systematically evaluated according to the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) criteria by two independent reviewers.

RESULTS: Our systematic review identified only seven PROMs utilized in RCTs which focused on patients with mPCa. The most frequently used PROMs in RCTs of patients with mPCa were Functional Assessment for Cancer Therapy-Prostate (FACT-P) (N.=18), Brief Pain Inventory-Short Form (BPI-SF) (N.=8) and European Organization for Research and Treatment of Cancer quality of life core 30 (EORTC QLQ-C30) (N.=6). A total of 283 abstracts were screened and 12 full-text studies were evaluated. A total of 2, 1, and 2 studies reported the psychometric properties of FACT-P, Brief Pain Inventory (BPI) and BPI- SF. FACT-P and BPI showed a high content validity, while BPI-SF showed a moderate content validity. FACT-P and BPI showed a high internal consistency (summarized Cronbach's α: 0.70-0.95).

CONCLUSIONS: The use of BPI and FACT-P in mPCa patients is supported by their high content validity and internal consistency. Since BPI is focused on pain assessment, we recommend FACT-P, which provides a broader assessment of QoL and wellbeing, for the clinical evaluation of mPCa patients. However, these considerations have been elaborated on in a very limited number of studies.

SC444

Impact of prostate imaging quality (PI-QUAL) score on the detection of clinically significant prostate cancer in men undergoing MRI-targeted biopsy

G. Brembilla, S. Lavalle, M. Cosenza, T. Russo, A. Stabile, G. Gandaglia, A. Briganti, F. Montorsi, A. Esposito, F. De Cobelli (Milan)

BACKGROUND: The Prostate Imaging Reporting and Data System (PI-RADS) guidelines represented the first step towards the definition of an optimal scan protocol, providing minimal technical requirements for mpMRI acquisition. However, PI-RADS does not provide measures to evaluate the quality of mpMRI. The Prostate Imaging Quality (PI-QUAL) score represents a tool that could provide clinicians with practical information on MRI quality that can influence patient care. However, evidence on its clinical impact is still limited. We aimed to investigate the impact of PI-QUAL scores on the diagnostic performance of mpMRI in a targeted biopsy cohort.

METHODS: Overall, 200 consecutive patients who underwent both prostate mpMRI and subsequent biopsy at a single institution were included. All patients with at least one visible lesion at MRI (*i.e.*, PI-RADS Score ≥3) underwent MRI-targeted biopsies with concomitant standard 12-core random systematic biopsy (TRUS-Bx). PI-QUAL scores were retrospectively assigned by two radiologists in consensus and were correlated to prebiopsy PI-RADS scores and biopsy outcomes. Inter-reader agreement on PI-QUAL scores was determined on a subset of one-hundred men using percentage of agreement (PA), agreement coefficients (AC1 and AC2) and k coefficients.

RESULTS: Median age was 67 years while the median PSA and PSA density was 6 ng/mL and 0.12 ng/mL, respectively. The prevalence of any PCa at biopsy was 69% while the prevalence of csPCa was 46%. According to original MRI reports, 9% had a maximum score of PI-RADS 2, 31% had PI-RADS 3 and 60% had PI-RADS 4-5. Image quality was optimal (PI-QUAL≥4) in 176/200 (88%) and suboptimal (PI-QUAL<4) in 24/200 (12%). The proportion of PI-RADS 3 scores referred for biopsy was higher in scans of suboptimal quality as compared to scans of optimal quality (42% *vs.* 30%). In PI-QUAL<4 scans, the rate of false-positive findings of MRI was higher as compared to PI-QUAL≥4 scans (58% *vs.* 49%), as was the detection rate of targeted biopsies in PI-RADS ≥4 scans (50% *vs.* 66%). Agreement on overall PI-QUAL scores was good (PA=83%; AC2=0.72; k=0.24).

CONCLUSIONS: Scan quality may affect the diagnostic performance of prostate mpMRI in men undergoing MRI-targeted biopsy. Scans of suboptimal quality (PI-QUAL<4) were associated with a higher proportion of false positive biopsy referrals, especially for PI-RADS≥4 scans.

SC445

Can we predict the site of positive surgical margins based on the site of the Index Lesion at multiparametric MRI? A topographic, single-center study

G. Cirulli, F. Pellegrino, G. Gandaglia, A. Stabile, E. Mazzone, G. Rosiello, G. Sorce, L. Nocera, S. Scuderi, F. Barletta, R. Leni, M. De Angelis, A. Pellegrino, P. Scilipoti, P. Zaurito, E. Zaffuto, R. Karnes, M. Roupret, F. Montorsi, A. Briganti (Milan)

BACKGROUND: The impact of multiparametric MRI on surgical approach during radical prostatectomy (RP) and on oncological outcomes after surgery is still controversial. Previous authors hypothesized that topographic information on the site of the Index Lesion (IL) at MRI could be used to tailor the nerve sparing approach in prostate cancer (PCa) patients undergoing RP. We aimed to perform a detailed topographic description of the site of PSM according to the topographic location of IL at MRI.

METHODS: Overall, 111 PCa patients undergoing MRI-

targeted biopsy and bilateral nerve sparing RP at our center between 2016 and 2022. All patients had PSM at final pathology. All patients had a single visible suspicious IL at MRI (PIRADS≥3). We evaluated the site of PSM based on the IL location at MRI. IL and PSM location were categorized using the 3 regions scheme (right *vs.* left *vs.* bilateral). We graphically described the site of PSM based on the IL using the alluvial plot. We evaluated whether the IL was correlated with the location of PSM (right *vs.* left) using Pearson's χ^2 test.

RESULTS: PIRADS score was 3, 4, and 5 in 22 (20%), 44 (40%), and 48 (40%) patients, respectively. Median IL volume was 1.3 cc. Overall, 10 (9%), 42 (38%) and 59 (53%) ILs were bilateral, on the left and right hemigland, respectively. Clinically significant PCa (defined as a Gleason Score ≥7) was found in 93 (84%) patients at biopsy. At final pathology, extra capsular extension was found in 58 (52%) patients. Overall, 13 (12%), 41 (37%), and 57 (51%) patients had bilateral, left, and right PSM, respectively. The majority of PSMs were ipsilateral to the IL location. For instance, among the 59 patients with IL in the right hemigland, 93% (N.=55) had ipsilateral PSM, 3% (N.=2) had contralateral PSM and 3% (N.=2) had bilateral PSM. After excluding bilateral PSM, IL location was strongly associated with the site of PSM (P<0.001).

CONCLUSIONS: Our analyses demonstrated that the majority of PSM are located on the same side of the MRI-visible lesion. A conservative nerve sparing RP approach could thus be safely considered to be performed on the contralateral side of IL at mpMRI.

SC446
Integrating Index Lesion Volume to better classify men with indolent prostate cancer among patients with intermediate risk disease: results from a large, multi-institutional series

G. Sorce, A. Stabile, G. Gandaglia, F. Pellegrino, E. Mazzone, V. Cucchiara, N. Fossati, M. Moschini, A. Matei, L. Afferi, S. Serni, A. Minervini, R. Rahota, G. Ploussard, M. Valerio, J. Beauval, A. Marquis, A. Rakauskas, P. Gontero, H. Guo, J. Zhuang, R. van den Bergh, T. Soeterik, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Optimal treatment in men with intermediate (IM) risk prostate cancer (PCa) is still a matter of debate. MRI has improved pretreatment risk stratification and PCa volume estimation. However, Index Lesion (IL) Volume, which is associated with oncological outcome, is still not included in patient risk assessment. We hypothesize that men with indolent PCa among patients with IM risk disease can be identified by adding MRI IL volume in a large contemporary cohort of men treated with radical prostatectomy (RP).

METHODS: We identified 3088 patients with low and IM PCa receiving RP at 11 referral centers. All patients had a positive MRI (PIRADS≥3). The aim was to compare oncological outcomes of low risk ISUP 1 PCa (Group 1) and IM risk ISUP 2-3 PCa, stratified according to the most informative IL volume cut-off at MRI, namely IL diameter <10 mm (Group 2) and ≥10 mm (Group 3). The outcome of this study was biochemical recurrence (BCR) after RP. Multivariable Cox regression analyses (MVA) were used to compare BCR-free survival in Group 1 *vs.* 2 *vs.* 3 after accounting for the following confounders: PSA, prostate volume, PIRADS score, and percent of positive biopsy cores. We then compared BCR-free survival using the adjusted Kaplan-Meier method (KM).

RESULTS: Two hundred forty-seven (8%), 1747 (57%), and 1094 (35%) patients harbored ISUP group 1, 2, and 3 at RP, respectively. In all, 247 (8%), 2110 (68%), and 731 (24%) patients were stratified into Group 1, 2, and 3, respectively. Median follow-up was 50 months and 227 patients had BCR. The 5-year BCR-free survival probability was 84%, 86%, and 73%, among patients in group 1, 2, and 3, respectively (P<0.01). At MVA, with Group 1 as reference, only Group 3 was associated with the rate of BCR (Group 2: HR=0.94, P=0.9; Group 3: HR=2.32, P=0.03). Specifically, patients with PCa ISUP 1 and PCa ISUP 2-3 with IL <10 mm did not exhibit any differences in BCR-free survival after RP (P=0.6).

CONCLUSIONS: Patients with low volume ISUP 2-3 with IL size <10 mm appear to have comparable oncological outcomes in terms of BCR- free survival to patients with ISUP 1 disease after RP. These results should be taken into account for patient counselling and in decision making of active treatment *vs.* active surveillance in patients with low volume IM risk PCa.

SC447
When is central histological review of prostate biopsy really needed to reduce the risk of misclassification of prostate cancer? The importance of patient risk stratification

A. Pellegrino, G. Gandaglia, S. Scuderi, R. Lucianò, N.P. Tenace, F. Paparesta, L. Pepi, L. Quarta, E. Mazzone, F. Barletta, G.O. Cirulli, D. Robesti, G. Sorce, C.A. Bravi, L. Nocera, A. Stabile, R. Montironi, F. Montorsi, A. Briganti (Milan)

BACKGROUND: Although biopsy revision by dedicated uropathologists may reduce the risk of discordant findings at final pathology in prostate cancer (PCa) patients and optimize patient management, central histology review of all biopsies is associated with high healthcare expenditures. Moreover, not all discrepancies potentially found at biopsy between external and referral centers would affect clinical management. We aimed to identify patients who should receive histological review by dedicated uropathologists as part of the initial diagnostic pathway.

METHODS: Overall, 591 PCa patients who received a prostate biopsy outside our referral Center were identified. All biopsy specimens were prospectively reviewed by two dedicated uropathologists at two high-volume academic centers. Reclassification was defined as either from not clinically significant PCa (not csPCa; ISUP<2) to csPCa (ISUP≥2), or vice versa. Multivariable logistic regression analyses (MVA) assessed biopsy characteristics associated with disease reclassification. Interaction analysis tested whether the association between the number of positive cores and the probability of reclassification varied according to the initial diagnosis (csPCa *vs.* not csPCa). Patients were stratified according to the initial diagnosis and the probability of reclassification was plotted against number of positive cores using the LOESS function.

RESULTS: Overall, csPCa was diagnosed in 320 (54%) *vs.* 372 (63%) men by the initial *vs.* central pathology, respectively. Histological review reclassified 92 patients (16%). In 8 (1.4%) cases central pathological review failed to identify PCa. The number of positive cores (OR=1.07; P=0.049) and csPCa (OR=0.15; P<0.001) at diagnosis were significantly associated with PCa reclassification. The impact of the number of positive cores on the risk of reclassification varied according to the presence of csPCa in the original biopsy (P<0.001 by interaction test). The probability of reclassifica-

tion increased according to the number of positive cores in men without initial diagnosis of csPCa, whereas an opposite trend was observed in those with csPCa. In particular, in men without csPCa at initial biopsy, the reclassification rates increased from 10% to approximately 50% in men with 1 and 7 positive cores, respectively.

CONCLUSIONS: Initial biopsy characteristics can help to identify which patients can benefit from central histological review. Patients with a high number of positive cores and low grade PCa at initial biopsy have higher risk of reclassification and should receive a central histological review of biopsy tissue.

SC448
Residents and consultants have equal outcomes when performing transrectal fusion biopsies: a randomized clinical trial

G. Gallo, J. Stira, B. Turchi, C. Gravina, L. Rovesti, E. Mancini, A. Franco, S. Riolo, R. Lombardo, G. Tema, A. Cicione, F. Del Giudice, S. Salciccia, C. Leonardo, A. Pastore, A. Sciarra, A. Carbone, D. Fiasconaro, G. Franco, A. Tubaro, C. De Nunzio (Rome)

BACKGROUND: Aim of our study was to compare performance of residents *vs.* consultants in transrectal fusion prostate biopsies (FPB) as well as patient comfort.

METHODS: Between January 2021 and October 2022, a consecutive series of patients undergoing FPB were randomized in two groups: 1) FPB performed by a consultant; and 2) FPB performed by trained residents (>50 procedures). All patients underwent FPB with 12 systematic cores + 3/6 target cores. Detection rate was compared between groups, number of positive cores in the target area and patients' pain after the procedure were evaluated using VAS scale. χ^2 and Mann-Whitney were used for statistical analysis.

RESULTS: Overall, 120 patients with a median age of 69 years were enrolled. Mean BMI was 23 kg/m^2, mean and prostate volume was 61 mL. A PIRADS score >3 was recorded in 48/120 (40%) patients. Overall, 54/160 (45%) presented prostate cancer and 39/54 (73%) presented a clinically significant cancer (grade group >2). Residents presented a detection rate of 26/60 (44%) and consultants a detection rate of 27/60 (45%) (P<0.05). In patients with a PIRADS score >3, the mean number of positive cores in the index lesion was similar in both groups (1.7 *vs.* 1.7, P>0.05). In terms of patients experience the procedure was well tolerated by the patient with a median VAS score of 2 for both groups and no statistically significant differences.

CONCLUSIONS: Residents have good outcomes in terms of detection rate and patient comfort when performing prostate biopsies. Residents after adequate training can safely perform prostate biopsies.

SC449
Plasmatic exosomes from prostate cancer patients show increased carbonic anhydrase IX expression and activity and low PH

P. Viscuso, S. Salciccia, M. Lagozzi, S. Fais, A. Gentilucci, G.B. Di Pierro, G. Bevilacqua, M. Frisenda, M. Moriconi, D. Rosati, F. Del Giudice, L. Gobbi, G. Basile, A. Tubaro, C. De Nunzio, A. Carbone, A. Pastore, G. Franco, A. Sciarra (Rome)

BACKGROUND: We explored the potential use of plasmatic exosomes expressing PSA (Exo-PSA) in distinguishing healthy individuals, BPH and prostate cancer (PCa). Moreover, in our study for the first time the expression and activity of carbonic anhydrases IX (CA IX) have been investigated in the plasmatic exosomes obtained from patients with PCa.

METHODS: Exosomes were obtained from plasma samples of 80 PCa,80 BPH and 80 healthy donors (CTR). nanoparticle tracking analysis (NTA), immunocapture-based ELISA (IC-ELISA) and nanoscale flow-cytometry (NSFC), were exploited to detect and characterize plasmatic exosomes. The investigation of expression and activity of CA IX were performed through different methodological approaches, such as NTA, western blot analysis, enzyme activity assay, Nanoscale flow cytometry, ELISA, confocal microscopy.

RESULTS: PCa patients showed higher plasmatic levels of exosomes than the controls (P<0.01). Moreover, exosomes from PCa patients were more homogeneous in size distribution in respect to plasmatic exosomes from CTR. The resulting fractions were blotted for CA IX and exosomal markers (Alix and CD81). The results showed that CA IX expression was up regulated in exosomal purification lysates from PCa plasma cases as compared to the exosomal fractions of CTR plasma. The CA IX band corresponded to the typical exosome fractions as identified by the expression of Alix and CD81 in the second and third fractions of the density gradient. CA IX in PCa exosomes is evidenced by the presence of two bands (58/54 kDa). The CTR exosomes exclusively showed the Alix and CD81 bands. To support this set of results, we exploited an immunocapture-based ELISA Assay to quantify and characterize CA IX expression levels in exosomes purified from 1 mL of either PCa or CTR plasma, by seeding the same amount of exosomes preparations (50 mL). The results showed that the CA IX positive exosomes were 25-fold higher in plasma of PCa patients (558±90) than in CTR (22±2), (P<0.0001). The plasma deprived of exosomes was entirely negative for both markers (data not shown). The colorimetric CA assay showed that the CA-activity/mg protein found in exosomes isolated from PCa plasma (2.9±0.4) was 2.4-fold higher as compared to exosomes purified from CTR plasma (1.2±0.2) (P<0.0001). Thus, supporting that the increased CA IX expression in plasmatic exosomes of PCa patients was consistent with a real enzyme activity up-regulated in PCa plasma exosomes. The amount of acidic exosome was 2-folds higher in PCa plasma (10 510±2551) as compared to CTR plasma (6184±1015) (P<0.01)

CONCLUSIONS: The results evidenced for the first time that an intraluminal acidic pH characterized the exosomes of PCa plasma cases. It's consistent with the higher expression and activity of CA IX, a protein associated with both acidity and hypoxia. Furthermore our data suggest the possible use of the exosomal CA IX expression and activity as a biomarker of cancer progression in PCa.

SC450
PSA-zinc urinary test outperform standard of care in early detection of prostate cancer

D. Amparore, E. Checcucci, S.T. De Cillis, A. Piana, F. Piramide, G. Volpi, M. Sica, J. Meziere, D. Zamengo, A. Quarà, M. Della Corte, G. Busacca, F. Pini, M. Ortenzi, A. Giordano, A.G. Mesterca, S. Occhipinti, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: The use of PSA screening for prostate cancer (PCa) has declined recently due to potential overdiagnoses and overtreatment. Recent evidence indicates that multiparamentric magnetic resonance imaging (mpMRI) and targeted biopsies could potentially reduce overdiagnoses by 50%. However, concerns regarding costs and the need of expert radiologists limit the use of mpMRI in the screening setting. Therefore, there is an urgent need for new diagnostic biomarkers and standalone test to enhance diagnosis of PCa. We have observed that in the presence of PCa, the prostate loose the capacity to produce and secrete typical molecules, such as PSA and zinc. Lower amount of PSA and zinc in urine better identify PCa patients from healthy individuals compared to standard of care parameters (SOC, serum PSA, DRE, age) and their analysis improve the diagnostic performance of mpMRI.

METHODS: After prostatic massage a urine sample was collected, with informed consent, from 211 subjects that received indication for prostatic biopsies. The amount of urinary PSA was determined by laboratory assays, ECLIA platform and confirmed by ELISA, and the amount of urinary zinc was evaluated by atomic absorption and confirmed by colorimetric *in-vitro* assay.

RESULTS: One hundred twenty-seven subjects were diagnosed with prostate cancer (called hereafter CP), whereas remaining 84 subjects were free from disease (healthy subjects, HS). Median urine PSA and zinc after prostatic massage was lower in CP than in HS. Moreover, there was an inverse correlation between the concentration of both urinary molecules and the tumor stage. We identified the optimal cutoff for both urinary PSA and Zinc that maximize the discrimination between CP and HS in term of sensitivity and specificity. We designed a Urine Score (uScore) scale based on the positivity of urinary biomarkers: 2 (both markers positive), 1 (only one marker positive), 0 (both markers negative). ROC curve analysis showed a higher capability in discriminating CP from HS of uScore compared to SOC (AUC: 0.789 *vs.* 0.643, P=0.005). Combination of uScore and SOC results in AUC of 0.821. Multivariate ROC curve analysis combining uScore with SOC and PiRADS obtained by mpMRI resulted in an AUC=0.867, that is statistically different from SOC or PiRADS alone, or SOC+PiRADS (P=0.0001, P=0.0001, and P=0.002 respectively). Prostate cancer risk algorithm designed considering uScore, SOC and PiRADS results in potential reduction of 50% of unnecessary biopsies.

CONCLUSIONS: The loss of PSA and Zinc production and secretion by the prostate during neoplastic transformation could potentially represent a hallmark of PCa, and its combination with standard diagnostic parameters and mpMRI could represent an interesting approach in the diagnosis of PCa.

SC451
Optimized urine smart test for early detection of prostate cancer

D. Amparore, S. De Cillis, E. Checcucci, F. Piramide, A. Piana, G. Volpi, M. Ortenzi, M. Sica, M. Burgio, A. Quarà, M. Della Corte, E. Cisero, G. Busacca, M. Colombo, C. Gatti, M. Mandaletti, A. Sterrantino, S. Occhipinti, M. Manfredi, C. Fiori, F. Porpiglia (Orbassano, Turin)

BACKGROUND: Rapid tests are popular diagnostic method that can rapidly provide *in-vitro* diagnostic results by non-trained personnel at a patient site, permitting to decentralize first line exams outside the hospitals and towards local areas. In the present study we aim to validate the diagnostic performance of a rapid urine test based on PSA and Zinc and to explore the ability to improve early prostate cancer diagnosis.

METHODS: A urine sample were collected from 174 subjects scheduled for prostatic biopsies based on standard parameters, as PSA levels, digital rectal examination (DRE) and multiparametric-magnetic resonance imaging (mpMRI). Informed consent was obtained from each participant. The amount of urinary PSA and zinc was determined by an optimize device combining lateral flow immunoassay and colorimetric dip-stick assay, respectively, and confirmed with commercial assays.

RESULTS: The test for urinary PSA and Zinc have been optimized based on values observed in previous studies, in order to return an intensity scale from 0 to 4, in relation to the quantity of analyte present in the sample. Intensity has been evaluated by the naked eye and image readers, showing a concordance of 88%. Multivariate ROC curve analysis combining Rapid test intensity with routine parameters such as PSA, Age, DRE (standard of care [SOC]) and PiRADS obtained by mpMRI resulted in an AUC=0.861, that is statistically different from SOC or PiRADS alone (AUC: 0.643 and 0.761, respectively).

CONCLUSIONS: These results suggest that our optimized rapid test for urinary PSA and zinc could be clinically useful in detecting neoplastic transformation in the prostate and spare useless invasive analysis to healthy subjects.

SC452
Clinical and high-resolution micro-ultrasound risk factors for detecting clinically significant prostate cancer in biopsy-naïve patients with abnormal digital rectal examination: a large single center experience to avoid unnecessary multiparametric MRI

P.P. Avolio, V. Fasuolo, D. Maffei, C. Saitta, N. Frego, M. Paciotti, M. Lazzeri, P. Casale, N.M. Buffi, F. De Carne, G. Lughezzani (Milan)

BACKGROUND: Multi-parametric (mp) magnetic resonance imaging (MRI) has dramatically changed the diagnostic work-up of clinically significant (cs) prostate cancer (PCa). However, its widespread adoption is limited by availability, associated costs, need for radiological expertise, and the complexity of the target biopsy (TBx). To determine the accuracy of micro-ultrasound (microUS) for the diagnosis of csPCa within prospectively collected cohort of biopsy-naïve patients with an abnormal digital rectal examination (DRE) and suspicious lesion at mpMRI.

METHODS: A total of 176 consecutive biopsy-naïve patients with an abnormal DRE and at least one Prostate Imaging Reporting and Data System (PIRADS)≥3 lesion at mpMRI were prospectively enrolled between October 2019 and January 2023. All patients received microUS before prostate biopsy (PBx) using the ExactVu™ system (Exact Imaging Inc., Markham, ON, Canada). The prostate risk identification using microUS (PRI-MUS) protocol was used to identify suspicious areas. All patients received both TBx (based on either microUS or MRI findings) and systematic biopsy (SBx). The primary endpoint was the assessment

of microUS diagnostic accuracy in detecting csPCa (grade group ≥2). Secondary endpoints were the following: 1) to compare microUS-TBx plus SBx and MRI-TBx plus SBx in identifying PCa and csPCa; 2) to compare the proportion of patients presenting extraprostatic extension (EPE) on mpMRI and microUS; 3) to assess the proportion of EPE at radical prostatectomy (RP) specimens; and 4) to determine predictors of csPCa in multivariable logistic regression model (MLRM).

RESULTS: Overall, 22 patients (12.5%) did not show microUS suspicious lesion (PRI-MUS=1-2), while at least on 1 target lesion (PRI-MUS≥3) was identified in the remaining 154 (87.5%). 128 (72.7%) and 110 (62.5%) patients harbored PCa and csPCa respectively. The sensitivity and negative predictive value of microUS for csPCa diagnosis were 98.0% and 89.3%, while specificity and positive predictive value were 36.4% and 74.8%, respectively. A combination of microUS-TBx and SBx achieved comparable detection rate to approach combining MRI-TBx and SBx in diagnosis of PCa and csPCa (PCa=69.9% [123/176] *vs.* 70.4% [124/176]; csPCa=60.2% [106/176] *vs.* 59.7% [105/176]; P=0.56) and microUS-TBx outperformed MRI-targeted (csPCa=55.1% [97/176] *vs.* 53.4% [94/176]; P=0.49). MicroUS outperformed mpMRI in identifying EPE (52/176 [29.5%] and 40/176 [22.7%]; P<0.05). Among RP specimens, EPE was diagnosed in 58/132 (43.9%) patients who undergoing RP at the same institution. In MLRM, an increasing PRI-MUS score, age, and PSA density ≥0.15 emerged as independent predictor of csPCa, with an area under the curve of 0.75 (95% CI: 0.673-0.854).

CONCLUSIONS: The value of mpMRI remains controversial for biopsy-naïve men with positive DRE. MicroUS with other predictive factors as age and PSA density could help to selectively identify men with csPCa and thus reduce unnecessary mpMRI.

SC453
A dedicated screening for early detection of prostate cancer in men with pathogenetic variants in DNA-repair gene

G. Chiarelli, G. Chiarelli, V. Fasulo, P. Arena, E. Beatrici, A. Gobbo, C. Saitta, P. Avolio, M. Paciotti, P. Diana, F. Dagnino, A. Muhannad, P. Casale, G. Guazzoni, G. Lughezzani, N. Buffi, M. Lazzeri (Milan)

BACKGROUND: The aim was to investigate feasibility of a dedicated screening for male with high genetic risk (HR) of prostate cancer (Pca) as carriers of germline DNA-repair genes (DRG) pathogenetic variants (PVs) and its sensitivity on early diagnosis. The secondary outcome is compliance at screening.

METHODS: Healthy men with DRG PVs came from families of women with breast/ovarian cancer identified reviewing the genealogical trees of patients with BRCA 1/2 variant or from HR Pca patients with Gleason Score (GS)≥4+3 or <50 years old (yo) with GS ≥3+3. If positive, a targeted DRGs mutational analysis was offered to all I degree male relatives between 35-69 yo and those with PVs were enrolled in the screening for early detection PCa. PV carrier healthy men were screened by the Prostate Health Index (PHI) and digital rectal examination (DRE) every year. In case of abnormal DRE, patients underwent an MRI and, if PIRADS≥3, a target fusion biopsy (TB) + systematic biopsy (SB) was performed, or only SB if PIRADS1-2. In case of negative DRE, patients were stratified according to PHI. If PHI≥40 patients underwent an MRI with SB or SB+TB if PIRADS≥3. In case of 20≤PHI<40 patients underwent an MRI with TB+SB when PIRADS≥3, or they were screened annually by PHI and DRE if PIRADS1-2. If PHI<20, patients were screened annually.

RESULTS: In 18 months, we enrolled 80 men with DRG PVs, all patients' relatives of breast/ovarian cancer women with a DRG variant, who all accepted to follow the screening. Mean age was 49 yo. 49 (61.3%) were BRCA2 variant carriers, 17 (21.3%) BRCA1, 4 (5%) MSH2, 3 (3.7%) PMS2, 3 (3.7%) ATM, 2 (2.5%) MLH1, 2 (2.5%) MSH6. Only 20 (30%) had Pca family history. All 80 men had negative DRE. Median PSA was 0.90 ng/mL, median PHI 17.5. Fifty-two men had PHI<20; 25 had PHI 20≤PHI<40 and 3 PHI≥40. As a result, 28 men underwent an MRI because PHI≥20, obtaining 15 PIRADS1, 12 PIRADS2 and 1 PIRADS4. The 3 patients with PHI≥40 had negative MRI, nevertheless they underwent biopsies based on their high PHI (negative biopsy). The 52 with PHI<20 will be screened annually. After the first year, 42 patients were examined again for the follow-up. Twenty-seven men had PHI <20; 12 had PHI 20≤PHI<40 and 3 PHI≥40. No Pca was detected. Nine have risen their PHI stratification. 7 had to repeat the MRI one year later, 3 refused it.

CONCLUSIONS: All those with DRG PVs accepted to follow the screening. An accurate evaluation of the genealogical trees of breast/ovarian cancer patients with BRCA1-2 variant and of men with PCa and DRG PVs allows the detection of men carriers of DRG variants and enroll them in a dedicated screening, currently absent. As a result, we set out to design a screening based on PHI and MRI aiming to improve the capacity of early diagnosis as well as a potentially personalized approach.

SC454
Prospective per-target analysis of the added value of probe- tethered access cannulas in cognitive transperineal prostate biopsy of ultrasound-visible MRI targets

L. Orecchia, A. Fasano, E. Rosato, G. Colalillo, G. D'Ippolito, V.M. Ambrosi Grappelli, L. Alteri, S. Germani, A.D. Asimakopoulos, S. Albisinni, I. Kartalas Goumas, E. Finazzi Agrò, R. Miano (Rome)

BACKGROUND: Several techniques for transperineal (TP) cognitive prostate biopsy have been presented and none clearly showed significant advantages over the other. We hypothesized that a device-assisted technique with an access cannula tethered to probe (PP) could result in better diagnostic performances over the standard double free-hand technique (DF) when ultrasound (TRUS)-visible targets are biopsied. The aim of our prospective study was to compare the diagnostic rate for clinically significant prostate cancer (csPCa) between PP and DF in patients receiving a TP prostate biopsy.

METHODS: Biopsy outcomes from MRI-based, cognitive TP prostate biopsies performed at a tertiary referral center were prospectively collected from December 2020 to December 2022. Data were stratified per technique comparing PP (Precision Point™, Perineologic, Cumberland, MD, USA) *vs.* DF biopsies. A standard anesthesia protocol with 1% mepivacaine was used for all biopsies. A primary per-target analysis of csPCa diagnostic rates was performed. Tolerability was also assessed *via* a VAS scale administered at the end of the procedure.

RESULTS: 346 patients received an MRI-based prostate biopsy, the average number of targets per biopsy was 1.28. Two hundred fifty-six (66.3%) of the targets were cognitively identified by the urologist with the TRUS during biopsy planning. Overall target visibility stratified per PIRADS (P) was: 84% (N.=91) in P5, 65% (N.=125) in P4, 42% (N.=38) in P3. Of the 256 visible targets, 225 received individual targeted biopsy (92 PP *vs.* 133 DF), with similar P distribution among groups: 83 were P5 (36 in PP and 47 in DF); 110 were P4 (46 in PP and 64 in DF); 32 were P3 (10 in PP and 22 in DF) (P=0.478). PSA density levels were comparable among the groups: 0.15 (IQR: 0.10;0.25) in PP *vs.* 0.14 (IQR: 0.10;0.23) in DF (P=0.741). csPCa diagnosis rates were: P5, 75.0% in PP and 66.0% in DF (P=0.373); P4, 56.5% in PP and 34.4% in DF (P=0.021); P3, 20.0% in PP and 9.1% in DF (P=0.387). Overall, 627 targeted cores were collected in PP biopsies, of which 52.3% were positive for PCa, while 1012 targeted cores were collected in DF biopsies, of which 45.5% were positive (P=0.007). Mean biopsy VAS was 2.82 (±1.49) for PP and 2.84 (±1.61) for DF (P=0.909).

CONCLUSIONS: The Precision Point cannula led to significantly higher diagnostic rates for csPCa in cognitive prostate biopsy of TRUS-visible PIRADS4 targets when compared to the standard DF techniques, while maintaining a similarly high tolerability. The reduced biopsy needle distortion and the overall increased simplicity of biopsy execution could be the main drivers for higher precision in cognitive targeting. These results support the design of a RCT to provide confirmatory and higher-level evidence on the role of PP both in cognitive and fusion prostate biopsy of TRUS visible lesions.

SC455
Can transrectal micro-ultrasound direct patients toward a conservative management instead of prostate biopsy? A descriptive single-center analysis

F. De Carne, N. Frego, E. Beatrici, P.P. Avolio, M. Paciotti, P. Diana, A. Uleri, D. Maffei, A. Gobbo, G. Chiarelli, P. Arena, C. Saitta, F. Sordelli, A. Saita, R. Hurle, M. Lazzeri, P. Casale, N.M. Buffi, G. Lughezzani (Basiglio, Milan)

BACKGROUND: Micro-ultrasound (mUS) is a new imaging modality that has been suggested as an alternative to multiparametric Magnetic Resonance Imaging (mpMRI) for the detection of clinically significant PCa (csPCa). We sought to assess the role of mUS as screening tool among patients with clinical suspicious of PCa to decide the subsequent diagnostic work-up.

METHODS: We prospectively enrolled patients from November 2018 to November 2020, with a clinical suspicion of PCa based on PSA value, digital rectal examination (DRE) results and/or positive family history. MicroUS assessment was performed by experienced urologists in an outpatient setting and PRI-MUS protocol was used to identify lesions suspicious for csPCa (PRI-MUS score ≥3). All patients with negative mUS were followed until November 2021 with periodic phone call to assess their subsequent diagnostic/therapeutic work-up. We evaluated the proportion of patients with negative mUS who were spared a subsequent diagnostic work-up, compared to the proportion of individuals who underwent mpMRI and/or prostate biopsy. Time to event analysis was used to evaluate the Hazard Ratio (HR) and 95% CIs of prostate biopsy-free survival among men with negative mUS.

RESULTS: Overall, 360 patients were enrolled, 243/360 of them (67.5%) were biopsy-naïve. Median age was 66 years (IQR: 59-71), median PSA was 7 ng/mL (IQR: 4-13), and median prostate volume was 44 cc (IQR: 31-62). Median follow-up was 29 months (IQR: 24-32). Micro-US detected lesion suspicious for csPCa in 163 patients, while 197 were negative. Among men with negative mUS, 24/197 (12.2%) underwent a prostate biopsy, of which 15/24 (62.5%) performed mpMRI and 5/15 (33%) had a positive finding for csPCa. Finally, 5/24 (21%) were diagnosed with csPCa and 3/5 (60%) had a suspected lesion at mpMRI. Overall, 118/197 (59.9%) did not undergo mpMRI, and 109 of them (55.3%) were spared further diagnostic evaluations, but still suggested to periodically being checked-up by their referring physician. The multivariable Cox regression model, adjusted for PSA, DRE, age and biopsy history, showed that having a negative mUS was associated with a significantly higher biopsy-free survival compared to men with positive mUS findings (HR=0.14, 95% CIs: 0.04-0.56, P=0.005).

CONCLUSIONS: Our study assesses the role of mUS in PCa screening setting. Our cohort having a negative mUS was associated with a significant lower probability to proceed with PCa diagnostic work up, potentially reducing the number of unnecessary mpMRI and prostate biopsy, and potentially reducing the overdiagnosis of clinically insignificant tumors. Further studies with greater samples and longer follow-up are necessary to validate the role of mUS in this setting.

SC456
Predicting the risk of 5-year biochemical recurrence in patients treated with radical prostatectomy for prostate cancer: the PIPEN risk categories

S. Luzzago, C. Vaccaro, A. Zago, E. Santangelo, S. Caramella, S. Nardini, M.L. Piccinelli, F.A. Mistretta, E. Di Trapani, M. Ferro, G. Cordima, D. Bottero, B.A. Jereczek-Fossa, G. Marvaso, G. Musi, O. de Cobelli (Milan)

BACKGROUND: Currently used predictive tools to estimate the risk of biochemical recurrence (BCR) after primary treatment for prostate cancer (PCa) do not consider multiparametric magnetic resonance imaging (mpMRI) information. We developed a novel tool that considers clinical and mpMRI findings to assess the risk of 5-year BCR after radical prostatectomy (RP) for PCa.

METHODS: Retrospective analysis of 1459 PCa patients who underwent mpMRI before RP (2012-2015). The outcome of interest was 5-year BCR, defined as two consecutive PSA values of >0.2 ng/mL. Patients were randomly divided into a development (70%) and test cohort (30%) for internal validation. Kaplan-Meier plots were applied on the development cohort to estimate survival probabilities. Multivariable Cox regression models tested the relationship between BCR and different sets of exploratory variables. The accuracy (C-Index) of the developed model was compared to EAU classification (Partial Likelihood Ratio). Five novel risk categories were created and used to build and validate a nomogram based on Cox regression coefficients.

RESULTS: Median duration of follow-up in the whole cohort was 59 (interquartile range: 32-81) months, with 376 (26%) patients experiencing BCR. A 5-item multivariable

Cox regression model (PIPEN model: PSA-D, ISUP grade group, PI-RADS category, ESUR-EPE score, nodes) fitted to the development data yielded a C-Index superior to that of EAU categories (0.74 *vs.* 0.70; P=0.004). Five PIPEN risk categories were identified, and five-year BCR free survival rates were 92%, 84%, 71%, 56% and 26% in very low, low, intermediate, high and very high-risk patients respectively (P<0.001). Results remained consistent in sensitivity analyses after exclusion of patients treated with adjuvant radiotherapy or with positive surgical margins.

CONCLUSIONS: We developed and internally validated a novel 5-item (PIPEN) model for predicting the risk of 5-year BCR after RP in PCa patients and identified five risk categories based on clinical and mpMRI findings. External validation is needed.

SC457
The rebound effect of diagnosis of csPCA, after COVID-19 pandemic

A. Fanelli, U. Falagario, F. Guzzi, A. Ninivaggi, M. Finati, L. Montrone, O. Selvaggio, P. Annese, G.M. Busetto, C. Bettocchi, F. Sanguedolce, L. Cormio, G. Carrieri (Foggia)

BACKGROUND: COVID-19 pandemic has changed hospital care due to public health system oversaturation. The aim of this study was to evaluate the impact of COVID-19 pandemic on prostate cancer diagnosis.

METHODS: A retrospective review of patients underwent for a prostate biopsy in two institutions. A period from January 2018 until December 2022 was considered for analysis. This period was divided in pre-COVID, COVID, after COVID. All specimens were analyzed from the same fellowship trained team of uropathologist. Primary and secondary outcomes of this study were diagnosis of clinically significant prostate cancer and number of biopsies performed. First, we performed descriptive statics. Medians and interquartile ranges were used for continuous variables. Then we evaluated the number of biopsies per months and the number of csPCa diagnosed per months and compared it before during and after the procedure. The loess function was used to assess changes during over the study time period.

RESULTS: 2502 prostate biopsies were analyzed during these 4 years. Median age of patients was 68 (62-74). Prostate cancer was diagnosed in 1447 (57.8%) patients, 935 (37.4%) patients with diagnosis of csPCa. The median number of biopsies per months performed was 46 (IQR: 43-56), 39 (IQR:27-43) and 46 (IQR: 40-58) before during and after COVID respectively. The less active months were March to May 2020 with a significant decrease of biopsies per month performed (P=0.022). The median number of csPCa diagnosed per month before, during and after Pandemic was 18 (IQR: 13-21), 12 (IQR: 8-17) and 20 (IQR: 15-23) (P=0.015). Notably, csPCa detection rates after the pandemic were the highest (37% vs. 34% vs. 39%, P=0.009). The LOESS function demonstrated a rebound effect on number of biopsies performed and csPCa diagnosed after COVID and particularly starting November 2020 and still ongoing.

CONCLUSIONS: COVID-19 pandemic has caused a significant decrease in the number of prostate biopsies performed and csPCa diagnosed. We demonstrated a rebound effect on csPCa diagnosis after the pandemic. Future study should address if this diagnostic delay could have an impact in cancer specific survival.

SMART (SC458-SC469)

Functional diseases 1

SC458
Introduction of a multiprofessional pathway for patients with pelvic dysfunction: the birth of a pelvic center

SC459
The oral association of colostrum and Serenoa repens extract can reduce urinary symptoms and pain in patients affected by non-bacterial chronic prostatitis: a prospective observational study

SC460
Bone marrow transplant and urological dysfunctions

SC461
A randomized controlled trial on the efficacy of binaural beats in reducing anxiety and pain levels in patients undergoing conventional urodynamic study: preliminary data and perspectives

SC462
Duration and strength of detrusor contraction in women with underactivity

SC463
Italian urodynamics big data: correspondences between clinical and urodynamics diagnosis

SC464
Q_{max} during pressure flow study: what is the impact of the catheter? Data from a single-center urodynamic database

SC465
A novel urodynamic scoring system to assess continence quality outcomes of ileal orthotopic neobladders

SC466
Impact of PAD wetness on health-related quality of life after radical cystectomy and orthotopic neobladder

SC467
Impact of risk-adapted periprocedural antibiotic strategies on infectious complications development after nephrostomy tube exchange

SC468
Flat magnetic stimulation for stress urinary incontinence: a 3-month follow-up study

SC469
Magnetic stimulation for stress urinary incontinence: a quasi-experimental study

SC458
Introduction of a multiprofessional pathway for patients with pelvic dysfunction: the birth of a pelvic center

G. Gaia, S. Terzoni, C. Mora, M.B. Pinna, M. Afonina, S. Maruccia, A. Morandi, B. Mangiarotti, M. Sangalli, A. Ramondo, P. Dell'Orto, G. Bozzini, S. Micali, E. Panio, T. Calcagnile, S. Assumma, P.P. Bianchi, A.M. Marconi, M.C. Sighinolfi, B. Rocco (Milan)

BACKGROUND: Pelvic floor dysfunction includes many different problems which often have common characteristics: prolapse and prostatic hyperplasia, for instance, are clinically different but share the same effect on urine voiding. The same applies to recurrent infections in both genders. Pelvic surgery often yields functional issues of pelvic muscles, requiring integration between surgery and rehabilitation. Finally, many collateral issues may accompany pelvic dysfunction, *i.e.*, psychological ones. Pelvic centers offering a multiprofessional approach are not commonly found in Italy, even in major facilities. In our healthcare organization, which includes two major university hospitals in Northern Italy, a nurse-led outpatient clinic has been active for 15 years; we decided to incorporate such service into an integrated pathway, as suggested by the literature, as an optimal management strategy to restore wellbeing and quality of life of patients with pelvic dysfunction. The present study aimed to present the characteristics of the project above mentioned.

METHODS: A multiprofessional team was built by involving physicians, nurse specialists and psychologists, each of whom reviewed the respective international guidelines regarding pelvic dysfunctions and related topics. The literature they published over the years was also considered, to further benefit patients with the experience acquired on the field. After 4 consensus rounds, a clinical pathway was produced, involving urology, gynecology, general surgery, internal medicine, radiology, neurology, pain therapy, psychiatry, infectious diseases, digestive endoscopy, clinical psychology, clinical nutrition, the nurse-led clinic, and the reservation office to manage shared clinical documentation. The final team is led by a gynecologist and includes a case manager nurse, who will act as a reference person throughout the pathway, and a nurse scientific coordinator for documenting the outcomes with scientific publications.

RESULTS: The project has been ongoing for 12 months so far, and it is coming to its definitive shape. As a preliminary result, we've been increasing the sessions in the outpatient clinics of urogynecology by 4 times (from twice per month to twice per week) with 123 women undergoing surgery under the label "pelvic center." Consequently, the waiting list was reduced by 66%. An increase in the number of patients accessing rehabilitation was observed as well. In the coming months, we are going to measure quality of life with validated questionnaires (*i.e.*, SF-12) to check if there are statistically significant improvements in clinical outcomes.

CONCLUSIONS: As suggested by the guidelines, the approach adopted in this project is problem-oriented, instead of being focused on medical specialties. This pathway provides healthcare professionals with criteria for referring patients to the appropriate services, shared documentation and multidisciplinary meetings.

SC459
The oral association of colostrum and Serenoa repens extract can reduce urinary symptoms and pain in patients affected by non-bacterial chronic prostatitis: a prospective observational study

M. Sibona, M. Oderda, P. Destefanis, F. Bracco, E. Vercelli, G. Montefusco, L. Micai, C. Mangione, P. Gontero (Turin)

BACKGROUND: Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a bothering condition characterized by lower urinary tract symptoms (LUTS) and pain localized to the pelvic, perineal and/or genital area. Traditionally known as a difficult-to-treat condition, it recognizes phytotherapy as a viable therapeutic alternative. A pharmacological association of two or more active compounds is often proposed to achieve better control of symptoms. The association of colostrum and Serenoa repens extract already showed efficacy in the treatment of benign prostatic hyperplasia (BPH) symptoms. In our study, we investigated the role of the same association in the treatment of CP/CPPS.

METHODS: Local ethical committee approval was obtained. Our investigation was conceived as a prospective observational, non-randomized study. All eligible patients were administered validated questionnaires: International Prostate Symptom Score (IPSS), International Index of Erectile Function (IIEF5), Chronic Prostatitis Symptom Index (CPSI). Pelvic or genital pain was also measured by means of a Numerical Rating Scale (NRS) numbered 0 to 10 points. Inclusion criteria were: 1) age >18; 2) clinical history consistent with the diagnosis of chronic prostatitis; and 3) CPSI "pain" domain score ≥5. All patients underwent a Meares-Stamey microbiological test, to exclude chronic bacterial prostatitis (CBP). Subsequently, included patients were treated with oral association of colostrum and Serenoa repens for 6 months. Follow-up evaluation with questionnaires and adverse events recording was scheduled at 3 and 6 months.

RESULTS: We included 39 patients in our analysis. Median (IQR) age was 43 (31-55). Baselines questionnaire scores: 1) IPSS 10 (8-21); 2) IPSS bother score 4 (3-4); 3) IIEF5 19 (13-23); 4) total CPSI score 22 (17-26); 5) CPSI "pain" domain 8 (7-11); and 6) NRS 5 (3-6). After 3 months, we registered the subsequent questionnaire scores: 1) IPSS 9 (6-16), P=0.032; 2) IPSS bother score 3 (2-4), P=0.202; 3) IIEF5 20 (14-24), P=0.361; 4) total CPSI 14 (9-18), P<0.001; 5) CPSI "pain" domain 6 (3-9), P<0.001; and 6) NRS 3.5 (1-5), P=0.024. After 6 months, we registered a stability of urinary symptoms and erectile function, while we noticed a slightly increasing trend in pain. Anyway, a significant benefit compared to baseline was maintained: 1) total CPSI score 19 (10.5-20.5), P<0.001; 2) CPSI "pain" domain 7 (3.5-9.5), P=0.002; and 3) NRS 4.5 (2-6), P=0.235. During the observation period, 5 patients discontinued treatment, in 2 cases due to gastro-intestinal intolerance.

CONCLUSIONS: The oral association of colostrum and Serenoa repens showed efficacy in the treatment of symptoms related to CP/CPPS. Compared to baseline, a significant improvement was achieved after 3 and 6 months. Adherence to therapy and tolerability issues should be considered before proposing long-term treatments.

SC460
Bone marrow transplant and urological dysfunctions

J.A. Rossi de Vermandois, E. Illiano, M. Gioè, G. Vacilotto, E. Costantini (Terni)

BACKGROUND: Few data in the literature report the relationship between Bone marrow transplant and urological dysfunctions. Aim of this study was to analyze the state of the art of hematological and urological situation in patients who underwent bone marrow transpantation (BMT). We focused on pathology and physiology, effects on the genitourinary tract diagnostic evaluation and treatment of the urologycal dysfunctions.

METHODS: All the adult patients who underwent BMT and referred to our urological unit were evaluated. The patients underwent urological evaluation with personalized diagnostic framework. Symptoms, signs and conditions were classified on the basis of ICS standardization of terminology of lower urinary tract symptoms. Urological evaluation included clinical assessment, ultrasound, urodynamic evaluation when indicated. Literature research on urological manifestations in patients undergoing BMT was performed.

RESULTS: We recruited 21 patients (all female). Most patients present with genitourinary symptoms ranging from urgency, urge incontinence, and pollakiuria. The symptoms were not attributable to a urological pathologist, but to be traced back to the various treatments to which the patients had undergone for bone marrow transplantation. Urodynamic evaluation plays an important role in determining proper bladder management. The urodynamic evaluation was carried out on 21 female patients who had emergency symptoms. Nineteen of the 21 patients showed a detrusor hyperactivity. In the pressure-flow study, no patient presented alterations in the voiding phase with not significant post-voiding residual. 14 of these patients were treated with anticholinergic therapy demonstrated statistically significant improvements in urinary symptoms at the PGIC score ($P \leq 0.025$).

CONCLUSIONS: Although genitourinary consequences in patients undergoing BMT are rarely life-threatening, they can cause significant patient morbidity and frustration. For these patients, a multidisciplinary treatment is necessary especially given the increase in life expectancy of these patients.

SC461
A randomized controlled trial on the efficacy of binaural beats in reducing anxiety and pain levels in patients undergoing conventional urodynamic study: preliminary data and perspectives

F. Vedovo, J.L. Martini, C. Morreale, M. Balzarro, E. Rubilotta, M. Marini, M. Gubbiotti, V. Giommoni, P. Capogrosso, L. Di Blas, C. Trombetta (Trieste)

BACKGROUND: The aim of the study was to investigate the effects of binaural beats (BB) on anxiety and pain scores in patients undergoing conventional urodynamic study (UDS).

METHODS: Multicenter, prospective, single-blinded, randomized controlled trial. Exclusion criteria were: 1) to wear a hearing aid; 2) history of epilepsy, psychiatric disorder or chronic pelvic pain; 3) use of antidepressants, anxiolytic and/or analgesic drugs; and 4) history of previous UDS. Eligible patients scheduled to undergo UDS were randomly allocated in three groups: 1) classic music (CM) who listened by headphones to Samuel Barber's Adagio for Strings; 2) binaural music (BM) who listened by headphones Adagio for Strings embedded with a BB frequency of 6 Hz; and 3) no music group (NM) who did not listen to music during UDS. State-Trait Anxiety Inventory Form Y (STAI-Y) and Visual Analogue Scale (VAS) were used for measuring anxiety and pain scores, respectively. Blood pressure and heart rates were measured for pain and anxiety-related physiological outcomes before and after the UDS. The main outcome was to assess differences between groups in post-procedure improvement of the state STAI-Y (Y1) score from baseline and in VAS scores. Kruskal-Wallis's Rank Test and Pearson's χ^2 were used to compare differences in continuous and categorical factors between groups. Differences in pre- *vs.* post-UDS psychometric scores were analyzed with paired *t*-test. Statistical analyses were performed using STATA 14.0 (StataCorp, College Station, TX, USA), with a two-sided significance level set at $P<0.05$.

RESULTS: A total of 90 patients were enrolled until February 2023. Demographics, comorbidities, baseline STAI-Y levels and procedure time were comparable between groups. Post-UDS STAI-Y1 levels decreased significantly in NM and CM groups (P=0.0002, P=0.0001 respectively). No statistically significant differences were detected between groups for VAS score.

CONCLUSIONS: According to these preliminary data, binaural beat does not seem to reduce anxiety and pain levels in patients undergoing UDS. In contrast with previous studies published on this topic, classic music seems to reduce anxiety in patients performing UDS. Classic music could be a non-harmful, non-pharmacological and inexpensive tool to alleviate anxiety in patients undergoing UDS. Further data are needed to understand the effects of binaural beats on anxiety and pain due to UDS.

SC462
Duration and strength of detrusor contraction in women with underactivity

E. Rubilotta, M. Marini, G. Pettenuzzo, F.A.M. Saccà, M. Gubiotti, A. Antonelli, M. Balzarro (Verona)

BACKGROUND: The aim of this study was to assess strength, duration and main characteristics of detrusor contraction (DC) in DUA women.

METHODS: This was a comparative prospective study (2021-2022) on DC characteristics in females with DUA (DUA-G) compared with those of women without DUA (control group [CG]) underwent urodynamics (UD) for LUTD. DUA was defined when at least one of the following UD criteria was met: 1) Jeong; 2) Abarbanel and Marcus; 3) BVE criteria; and 4) PIP1. We used for statistical analysis *t*-test, Youden, AUC and sensibility/specificity calculation.

RESULTS: Data were completed on 206 women: 104 DUA (50.5%), 102 CG (49.5%). Median DC duration was 61.5 sec in DUA-G and 73 sec in CG, median voiding duration 50 sec in DUA-G and 38 sec in CG. Median P_{det}/Q_{max} was 12.5 cmH_2O in DUA-G and 20 cmH_20 in CG. Thresholds of Ratio DC duration/voiding time <1.375, P_{det}/Q_{max}<14 cmH_2O, Q_{max}<14 mL/s had the higher AUC and good both sensibility and specificity. Combining these parameters, in CG 49% had none of the markers below these cut-offs, 41.2% with at least 1, 8.8% 2,

0.9% 3. In DUA-G the rate of women with no parameter with lower cut-off was 3.9%, at least 1 31.4%, 2 48%, all 18.6%. DC duration lower than 45 sec showed the higher specificity for DUA (90%) but with a very low sensibility (28%).

CONCLUSIONS: As expected, and according to ICS definition, duration (1 min) and strength (12 cmH_20) of DC were significantly reduced in DUA-G, with prolonged voiding time and larger post-void residual of urine. In the average, DUA DC lasted 10 sec less than normal DC, and was 9 cmH_20 weaker than in no DUA DC. Ratio DC duration/voiding time, P_{det}/Q_{max}, Q_{max} were the parameters most related to DUA and we found thresholds with high AUC and good sensibility and specificity. Interestingly, the majority of women with normal DC showed none or at least 1 of these parameters under reported cut-off (91%), while only 9% had concomitancy of 2 or 3 markers below thresholds. In DUA-G 66% of the women had 2 or 3 concurrent parameters with lower thresholds. Therefore, the coexisting occurrence of 2 or 3 of these parameters with lower cut-off could be a warning for detrusor impairment. Our study defined how the duration and strength of the DUA DC were reduced compared to normal DC also reporting parameters that could be red flags for detrusor impairment.

SC463
Italian urodynamics big data: correspondences between clinical and urodynamics diagnosis

E. Rubilotta, F. Ditonno, F.A.M. Saccà, M. Balzarro, M. Gubbiotti, E. Ammirati, S. Chierica, G. Masiello, S. Manodoro, M.C. Bevacqua, E. Fragalà, R. Carone, G. De Rienzo, E. Finazzi-Agrò, A. Giammò, L. Gemma, S. Giannone, M. La Martina, V. Li Marzi, L. Martino, S. Musco, E. Russo, M. Spilotros, V. Mancini (Verona)

BACKGROUND: The aim of this study was to assess the use relationship between clinical and urodynamics (UD) diagnosis.

METHODS: This was a national multicenter study on correspondence between clinical indications and UD results in Italy in the pre-COVID era 2018-19. Additional UD diagnoses were also recorded. This period has been chosen to have a real UD management scenario, because access to hospitals and UD offices has been reduced in the last 2 years due to the COVID-Sars limitations. Urological and gynecological centers were involved. Data on men and women were retrospectively collected between January and December 2022.

RESULTS: Centers involved were 13: 11 urological, 2 gynecological. Data were collected on 2358 patients, 1329 (56.4%) women with median age 62 yo and 1029 men (43.6%) with median age 68 yo. In males, correspondences were as follows: bladder outlet obstruction (BOO) in 79.1%, urinary retention (UR) in 81.9%, iatrogenic urinary incontinence (UI) in 81%, overactive bladder syndrome (OAB) in 81.7%, voiding dysfunctions (VD) in 86.9%, concomitant BOO and OAB in 87.2%.

CONCLUSIONS: The correlation between clinical indications and UD outcomes was high in males, so outpatient evaluation was highly reliable. In females, the match rate was >50% in SUI and VD conditions only. The most misleading clinical diagnoses were those related to urgency (UUI and MUI); in the latter, UD demonstrated different diagnoses in many patients. This finding highlights the relevance of UD investigation in female UI to obtain a correct diagnosis and avoid further unnecessary treatment. Among women with SUI, approximately 10% had detrusor overactivity (DO) or voiding disorders. In patients with symptomatic POP, UD demonstrated that VD and DO were often associated, while DUA occurred only in a smaller proportion of women. A high relationship between clinical indications and UD results was found in men, while in females only in case of SUI and VD. UD was still useful in helping to reach a correct diagnosis avoiding potential further unnecessary treatments.

SC464
Q_{max} during pressure flow study: what is the impact of the catheter? Data from a single-center urodynamic database

F. Fanara, G. Farullo, S. Maliziola, A. Grasso, N. Abbate, E. Rosato, E. Finazzi Agrò (Rome)

BACKGROUND: This study aims to compare the parameters of free and invasive uroflowmetry among female patients with different referral diagnoses in order to describe if the known difference between these two measurements may be significant (in terms of changing the final urodynamic findings) or if it varies in different clinical settings as previously reported.

METHODS: This is a retrospective study. We reviewed urodynamic studies performed from 2021 to 2022. Urodynamics were conducted following ICS good practices. Female adult patients were selected. Only patients who voided at least 150 mL in both free and invasive flowmetry were included. Patients were classified into different groups (urinary stress incontinence, USI, detrusor underactivity, DU using the Abarbanel and Marcus criteria, bladder outlet obstruction, BOO using the Blaivas parameters; detrusor overactivity[DO]) on the basis of the urodynamic diagnosis. The difference between both $Q_{ma}x$ (freeQ_{max} [fQ_{max}] *vs.* invasiveQ_{max} [iQ_{max}]) was calculated in all patients and in the different subcategories of patients. A $P<0.05$ was considered as statistically significant.

RESULTS: A total of 100 urodynamic studies of female patients (age range 18-75 years) were evaluated. These patients were classified into groups: DO (37%), DU (9%), BOO (7%), USI (13%), DO+BOO (6%), and patients without normal urodynamic findings (28%). Considering all patients, a 11% reduction of fQ_{max} was observed compared to iQ_{max}, the mean fQ_{max} being 24,6 mL/s and the mean iQ_{max} being 22,8 mL/s (a difference of 2.8 mL/sec, P=0.009). Patients with BOO showed the greatest difference between fQ_{max} and iQ_{max} (difference 4.5 mL/sec [26%]). Differences of negligible values between fQ_{max} and iQ_{max} were identified only in patients with isolated stress urinary incontinence. Despite these findings, using the fQ_{max} value instead of the iQ_{max} value as a basis for formulating a DU or BOO diagnosis would change the final urodynamic findings for only 4 of the patients (4%, 2 in DU and 2 in BOO group).

CONCLUSIONS: Our data demonstrate that there is a variation between fQ_{max} and iQ_{max} values, and this difference is major in patients with BOO. Conversely, patients diagnosed with USI are not significantly related to this condition. Nevertheless, the find urologic diagnosis would change in only 4% of patients, if fQ_{max} would be used. This phenomenon may be supported by a reduction of the cross-sectional area of the urethra or poor relaxation of the urethral-pelvic floor. The presence of a bladder catheter has a significant effect on the measurement of urine flow. This phenomenon changes between the different types of patients, but it does not significantly modify the final urodynamic diagnosis.

SC465
A novel urodynamic scoring system to assess continence quality outcomes of ileal orthotopic neobladders

U. Anceschi, F. Di Maida, F. Prata, L. Lambertini, C. Fede Spicchiale, M. Mattioli, A. Cadenar, A. Brassetti, S. Nardoni, G. Tuderti, F. Valastro, M. Bacchiani, A.M. Bove, V. Salamone, R. Mastroianni, S. Giudici, L. Misuraca, S. Cartolano, G. Spadaro, A.A. Grosso, A. Mari, A. Tuccio, E. Finazzi Agrò, C. De Nunzio, A. Minervini, G. Simone (Rome)

BACKGROUND: Despite robot-assisted radical cystectomy (RARC) is gathering a growing interest over open radical cystectomy (ORC), a comprehensive system for standardizing quality of functional outcomes of ileal orthotopic neobladders (iONs) is still unavailable. In this study we propose a novel urodynamic trifecta for both ORC and RARC that summarizes iONs outcomes regardless the surgical technique used and predicts continence outcomes.

METHODS: Between June 2017 and October 2022 two prospective, institutional review board approved, radical cystectomy datasets were matched and queried for "iONs" "and "urodynamic evaluation" (N.=149). Urodynamic assessment was performed between 6 and 9 months after surgery. Trifecta was defined as the coexistence of: 1) cystometric capacity ≥250 cc; 2) neobladder compliance ≥35 cmH_20; and 3) negative Valsalva and abdominal leak point pressure testing. Simultaneous achievement of only two of the presented criteria was considered a suboptimal result. Logistic regression analyses were built to identify predictors of daytime and night-time urinary continence. For all analyses, a two-sided P<0.05 was considered significant.

RESULTS: Overall, at a median follow-up of 25 months (IQR: 16-37), 149 patients achieved a complete urodynamic evaluation. In the current series, the complete trifecta rate was 40.2% while a suboptimal trifecta achievement was observed in 35.6% of patients. At univariable logistic regression analysis, male gender (OR=2.4; 95% CI: 1.04-5.53; P=0.039) and complete trifecta achievement (OR=7.01; 95% CI: 1.99-24.6; P=0.002) were predictors of daytime urinary continence while complete trifecta achievement (OR=8.18, 95% CI: 2.99-22.3; P<0.001) was the only predictor of night-time urinary continence. On multivariable analysis, complete trifecta achievement was the only independent predictor of daytime (OR=7.29, 95% CI: 2.05-25.9) and night-time (OR=8.13; 95% CI: 2.94-22.4) urinary continence, respectively (each P<0.003).

CONCLUSIONS: This novel urodynamic trifecta for iONs is based on standardized parameters and seems to be predictor of either daytime or night-time urinary continence at a mid-term follow-up. Satisfactory continence outcomes may be also expected when a suboptimal trifecta rate is achieved.

SC466
Impact of PAD wetness on health-related quality of life after radical cystectomy and orthotopic neobladder

R. Mastroianni, G. Tuderti, U. Anceschi, A.M. Bove, A. Brassetti, S. D'Annunzio, M. Ferriero, L. Misuraca, S. Guaglianone, M. Gallucci, G. Simone (Rome)

BACKGROUND: Radical cystectomy (RC) with orthotopic neobladder (ON) is a complex surgery. Functional outcomes and their impact on HRQoL (Quality of Life) are still poorly investigated. We aimed to evaluate the impact of day- and night-time pad wetness on 2-year-QoL after RC with orthotopic neobladder (ON) from an ongoing randomized controlled trial (RCT) comparing ORC and RARC with intracorporeal (i)-UD.

METHODS: Patients were eligible with a cT2-4cN0cM0, or recurrent HG NMIBC and no anesthesiologic contraindications to robotic surgery. Between January 2018 and September 2020, 116 patients were enrolled with a covariate adaptive randomization process based on: BMI, ASA score, baseline hemoglobin, planned UD, neoadjuvant chemo and cT-stage. Data from self-assessed questionnaires (EORTC-QLQ-C30 and QLQ-BLM30) were collected. Unmodified HRQoL was defined as a 2-yr Global Health status/QoL increase ≥0 (ΔQL≥0) from baseline. Quantitative analysis of continence status was evaluated through 3-day voiding diaries. We previously defined day-time continence "totally dryness" (0 gr) and night-time continence as pad wetness ≤50 gr. Categorical variables were compared using χ^2 tests, respectively.

RESULTS: Out of 116 patients enrolled, 88 received ON, and 71 with a minimum 2-year follow-up were included. Two patients were lost to follow-up and 17 patients died within 2 years after surgery. Particularly, 44 patients (62%) were completely dry during the day, while 40 patients (57%) experienced night-time pad wetness ≤50 gr. However, a day pad wetness >0 gr significantly impact on 2 years unmodified global health status (P=0.029), while only a night-time pad wetness ≤500 gr significantly impact on 2 years unmodified global health status (P=0.005).

CONCLUSIONS: This study strengthen the need for a strict definition of day-time urinary continence after RARC-iON, confirming completely dryness as a main driver off patients' HRQoL. Conversely, nigh-time continence status seems to play a negligible role on subjectively assessed HRQoL.

SC467
Impact of risk-adapted periprocedural antibiotic strategies on infectious complications development after nephrostomy tube exchange

S.P. Zanetti, C. Silvani, A. Marmiroli, A. Nogara, G. Lucignani, M. Turetti, M. Nizzardo, E. Lievore, L. Boeri, F. Longo, G. Albo, E. Montanari, E. De Lorenzis (Milan)

BACKGROUND: To date there is not clear evidence whether the use of antibiotic prophylaxis (AP) for nephrostomy tube (NT) exchange is useful to reduce post-procedural infectious complications (ICs) rate. We aimed to evaluate the incidence of ICs after NT replacement in an outpatient setting using different periprocedural antibiotic therapy (PAT) strategies and to identify potential predictors for ICs.

METHODS: We considered all NT exchanges performed in our center between January 2017 and October 2022. NT were exchanged every 45 days. Ten days before the procedure all patients underwent urine culture (UC) from nephrostomy and blood exams (complete blood count, C-reactive protein [CRP], renal function) 10 days before the procedure. In case of a positive UC, we used 4 different PAT strategies: 1) no AP in case of absence of symptoms and normal exams; 2) one-shot AP if 1.5 mg/dL <CRP<5 mg/dL and absence of symptoms; 3) short-term post-procedural therapy (48 hours) after complicated procedures (encrusted NT, bleeding, prolonged operative time);

and 4) long-term therapy if CRP>5 mg/dL and/or leukocytosis and/or symptoms. We collected patient's demographics, laboratory and operative data. χ^2 and Mann-Whitney *U* Test were performed to compare groups.

RESULTS: We considered 742 NT exchange in 137 patients. 70.1% of patients were male, 40% had bilateral NT. Mean (SD) age, BMI were 74.4 (±12.4) and 25.3 (±4.7), respectively. Considering blood exams, mean (SD) serum creatinine, hemoglobin, WBC and CRP were 1.7 (±1.4) mg/dL; 11.9 (±1.8) g/dL; 7.4 (±3.1) 109/L and 2.8 (±5.2), respectively. UC was positive before 85.8% of our procedure. Most common isolated bacterium was *E. faecalis*; MDR pathogens' rate was 23.5%. We observed 26 ICs: 22 (84.6%) required hospitalization and 12 were sepsis (without need of ICU) and. Considering PAT's strategies, we observed 4/204 (2%) ICs in the one-shot AP group, 7/180 (3.9%) in the no AP group, 0/77 and 15/281 (5.3%) in the short- and long-term therapy groups, respectively. Eight sepsis occurred in the long-term group. At the statistical analysis, the type of PAT was not associated with ICs' development (P=0.07). ICs more frequently occurred in males compared to women (88.5% *vs.* 69,4%, P=0.037); in anemic patients (90.5% *vs.* 60,7%, P=0.006); in patients receiving anticoagulation therapy (57.7% *vs.* 28.5%, P=0,001) and with lower BMI (22.9 *vs.* 25.4 kg/m^2, P=0.02). A positive UC or the absence of antibiotic were not associated with ICs development (P=0.5 and P=0.7, respectively) and with hospitalization (P=0.4 and P=0.2).

CONCLUSIONS: We demonstrated that, in selected patients with asymptomatic bacteriuria, NT substitution can be safely performed avoiding AP administration. In the current MDR pathogens era, antibiotics stewardship should include a reasoned strategy in patient candidate to frequent NT exchange.

SC468
Flat magnetic stimulation for stress urinary incontinence: a 3-month follow-up study

S. Maruccia, S. Terzoni, M. Barba, A. Cola, G. Rezzan, C. Costa, T. Melocchi, D. De Vicari, M. Frigerio (Milan)

BACKGROUND: Flat magnetic stimulation is based on a stimulation produced by electromagnetic fields with a homogenous profile. Patients with stress urinary incontinence (SUI) can take advantage of this treatment. We aimed to evaluate medium-term subjective, objective, and quality-of-life outcomes in women suffering from stress urinary incontinence to evaluate possible maintenance schedules.

METHODS: This was a prospective interventional study. At baseline (T0), at the end of treatment (T1), and at 3-month follow-up (T2) the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), the Female Sexual Function Index (FSFI), and the Incontinence Impact Questionnaire (IIQ7) were completed. The stress test and the Patient Global Impression of Improvement questionnaire (PGI-I) defined objective and subjective outcomes, respectively.

RESULTS: A total of 25 consecutive patients were enrolled. A statistically significant reduction in the IIQ7 and ICIQ-SF scores was noticed at T1, but at T2 returned to levels comparable to baseline. However, objective improvement remained significant even at a 3-month follow-up. Moreover, the PGI-I scores at T1 and T2 were comparable, demonstrating stable subjective satisfaction.

CONCLUSIONS: Despite a certain persistence of the objective and subjective continence improvement – the urinary-related quality of life decreases and returns to baseline values three months after the end of Flat magnetic stimulation. These findings indicate that probably a further cycle of treatment is indicated after 3 months since benefits are only partially maintained after this timespan.

SC469
Magnetic stimulation for stress urinary incontinence: a quasi-experimental study

S. Maruccia, S. Terzoni, M. Barba, A. Cola, S. Volontè, G. Marino, D. De Vicari, M. Frigerio (Milan)

BACKGROUND: The management of stress urinary incontinence (SUI) includes both conservative and surgical treatment. Among the conservative treatments, magnetic stimulation (MS) is a therapeutic option for patients with pelvic floor disorders. MS is a non-invasive therapeutic device that interacts with the neuromuscular tissue through an electromagnetic field, thus inducing intense contractions that stimulate pelvic floor muscles. Recently, the TOP flat magnetic stimulation (TOP FMS) has been developed as an innovation of traditional magnetic chairs. This new technology generates electromagnetic fields with a homogenous profile optimized for the stimulation of the pelvic area, allowing greater recruitment of muscle fibers without creating areas of uneven stimulation intensity. This study aimed to evaluate short-term outcomes, both subjective and objective, as well as quality of life in women suffering from SUI.

METHODS: This was a quasi-experimental study. A clinical interview was performed to investigate the presence of isolate or predominant stress urinary incontinence (SUI), which was confirmed by a positive stress test. A urogenital examination was carried out to exclude the presence of a significant prolapse (stage >2 according to the POP-Q system). Patients were divided according to their preference into a treatment group (magnetic stimulation) and a control group. Treatment patients underwent eight sessions of 25 minutes each of TOP FMS in one month. Controls underwent home pelvic floor muscles training (PFMT) following the Italian version of International Urogynecological Association leaflets for one month. At baseline (T0) and at the end of the treatments (T1) the following questionnaires were administered: 1) the International Consultation on Incontinence Questionnaire-Short Form questionnaire (ICIQ-SF); and 2) the Incontinence Impact Questionnaire (IIQ-7- SF). Moreover, at the end of the treatment stress test was repeated and the Patient Global Impression of Improvement (PGI-I) questionnaire was administered.

RESULTS: Twenty-five patients were enrolled in each group. No complication was reported either with TOP FMS or PFMT. According to the stress test at T1 (1 month), the objective cure rate resulted 40% for TOP FMS and 0% for PFMT (P<0.001). According to the PGI-I score, an improvement was reported by 72% after TOP FMS *versus* 20% after PFMT (P<0.001) after 1 month. According to Quality-of-Life questionnaires, significative differences were observed either in TOP FMS T1 *versus* TOP FMS T0, and in TOP FMS T1 *versus* PFMT T1 comparisons for IIQ-7 and ICIQ-SF, while no differences were observed in the FSFI-19 scores.

CONCLUSIONS: Our findings suggest the efficacy of TOP FMS in patients with isolated or predominant SUI. This treatment resulted significantly more effective than unsupervised, non-individualized PFMT in treating SUI in these patients.

SMART (SC470-SC482)

Urinary lithiasis 3

SC470
Improving outcomes of same sitting bilateral flexible ureteroscopy for renal stones in real-world practice: lessons learnt from a global multicenter experience of 1250 patients

SC471
Percutaneous nephrolithotomy video consensus: a simple and effective way to improve awareness of patients undergoing percutaneous nephrolithotomy

SC472
Ureteral canalization after mini-percutaneous nephrolithotomy is associated with stone volume and location: insight for personalized postoperative management

SC473
Ureteroscopic stone extraction is not always needed after urgent drainage for obstructive uropathy due to ureteric stones

SC474
Optimizing long-term renal function preservation in cystinuric patients through ureteroscopy: results from a tertiary care referral center

SC475
In patients at high risk for infections vacuum-assisted mini-percutaneous nephrolithotomy is associated with lower rates of infectious complications compared to vacuum-cleaner procedure: a single-center experience

SC476
Comparing outcomes of thulium fiber laser *versus* high-power Holmium:YAG laser lithotripsy in pediatric patients managed with RIRS for kidney stones: a multicenter retrospective study

SC477
Correlation between health-related quality of life measured by IT-WISQOL and perioperative characteristics of patients with upper urinary tract stones

SC478
MiniPerc for treatment of renal stones between 10 and 20 mm: a comparison between high-power Holmium:YAG laser (Cyber Ho) *versus* thulium fiber laser (Fiber Dust) generators

SC479
Evaluation of pneumoRIRS for the treatment of kidney stones associated to kidney anomalies or in difficult percutaneous access

SC480
A proposed mathematical model to help preoperative planning between RIRS and MiniPerc for renal stones between 10 and 20 mm using Holmium:YAG laser (Cyber Ho): the stone management according to size-hardness (SMASH) score

SC481
The use of neutrophil to lymphocyte ratio (NLR) in the decision making of hospitalization of patients with urinary stones and obstruction in emergency setting

SC482
Diagnostic efficacy of a clinical and molecular screening in patients affected by primary hyperoxaluria type 1

SC470

Improving outcomes of same sitting bilateral flexible ureteroscopy for renal stones in real-world practice: lessons learnt from a global multicenter experience of 1250 patients

V. De Stefano, S. Stramucci, C. Giulioni, A. Antezza, P. Tramanzoli, C. Nedbal, C. Brocca, A. Cormio, D. Castellani, V. Gauhar, A.B. Galosi (Ancona)

BACKGROUND: The aim of our study was to evaluate outcomes after same-sitting bilateral retrograde intrarenal surgery (SSBRIRS) for renal stones.

METHODS: A retrospective analysis of all consecutive patients who had SSB-RIRS for renal stones between January 2015 and June 2022 in 21 centers was performed. Inclusion criteria were age ≥18 years, stone(s) of any size and location located in both kidneys. Exclusion criteria were concomitant ureteral lithotripsy, stone located in a calyceal diverticulum, in-tandem procedure and RIRS done as a combined procedure for endoscopic combined intrarenal surgery. Stone size was calculated as the largest diameter. In the case of multiple stones, data from the largest stone was reported. Antibiotic prophylaxis was given in each center with a single on-table dose. Lithotripsy was carried out either by Holmium:YAG laser (HL) or thulium fiber laser (TFL). SFR was assessed 3 months after surgery according to the local standard of care with KUB X-Ray and/or ultrasound or non-contrast computed tomography (CT) and was defined as absence of any residual fragment (RF)>3 mm. Categorical data are presented as absolute numbers and percentages and continuous data as median and (25^{th}-75^{th} percentiles. Variables significantly associated with sepsis and SFR were analyzed in a multivariable logistic regression model. Data are presented as Odds Ratio (OR) and 95% confidence interval (CI). Statistical significance was set at two tails P<0.05.

RESULTS: 1250 patients were included. Median age was 48.0 (36-61) years. 58.2% of patients were presented. Median stone diameter was 10 mm on both sides. Multiple stones were present in 45.3% and 47.9% of left and right kidneys. Surgery was stopped in 6.8% of cases. Median surgical time was 75.0 (55-90) minutes. Complications were transient fever (10.7%), fever/infection needing prolonged stay (5.5%), sepsis (2%), blood transfusion (1.3%). Bilateral and unilateral SFR was 73.0% and 17.4%, respectively. Female (OR=3.00 95% CI: 1.19-7.57, P=0.02), no antibiotic prophylaxis (OR=5.67 95% CI: 2.17-14.81, P<0.001), kidney anomalies (OR=5.52 95% CI: 1.84-16.60, P<0.001), surgical time ≥100 minutes (OR=2.70 95% CI: 1.06-6.85, P<0.04) were factors associated with sepsis. Female (OR=1.81 95% CI: 1.31-2.50, P<0.001), bilateral prestenting (OR=3.15 95% CI: 1.16-8.56, P=0.03), high-power holmium laser (OR=1.64 95% CI: 1.16-2.33, P<0.01), thulium fiber laser (OR=3.40 95% CI: 1.84-6.29, P<0.001) were predictors of bilateral SFR.

CONCLUSIONS: Our study demonstrates that SSB-RIRS is an effective treatment for patients with bilateral stones with a short postoperative stay and an acceptable rate of complications. Prestenting, the use of high-power HL and TFL, and avoiding a large stone burden are key factors to achieve bilateral SFR. We recommend that using prophylactic antibiotics, having operative time not exceeding 100 minutes, and using a ureteral access sheath will help to mitigate the risk of sepsis in SSB-RIRS.

SC471

Percutaneous nephrolithotomy video consensus: a simple and effective way to improve awareness of patients undergoing percutaneous nephrolithotomy

A. Testa, F. Esperto, L. Cacciatore, A. Iannuzzi, A. Salerno, A. Minore, F. Tedesco, N. Deanesi, R. Papalia, R.M. Scarpa (Rome)

BACKGROUND: In the age of information technology, new platforms are consulted by patients (patients) to acquire their own consciousness about medical treatments, even if often information found are not reliable. The European Association of Urology Patient Information (EAU PI) delivers, with the support of EAU guidelines, high quality video-content about surgical procedures with a language easy to understand for patients. The aim of this study was to assess the level of understanding and feasibility of video consensus administration in patients scheduled for Percutaneous nephrolithotomy (PCNL) comparing it with standard written informed consensus.

METHODS: The EAU PI video content was translated in Italian and implemented with possible complication explanation at the end of it. After Ethical Committee approval, from January 2022 to September 2022 all patients who underwent PCNL at our institution were prospectively included in this study. A print-based traditional consensus was administered and, after that, a video information about PCNL with potential complication explanation was showed to all patients. After paper-based consensus and after video consensus, patients received a preformed Likert 10 Scale questionnaire to evaluate: 1) comprehension; 2) satisfaction; and 3) simplicity; with a score from 1 to 10. Descriptive and variance analysis was performed through SPSS v27 (SPSS Inc., Chicago, IL, USA) with an alpha value of significance set at 0.05, comparing the different types of consensuses.

RESULTS: 50 patients were included in our study and 100 questionnaires for both paper and video-based consensus were evaluated. Fifty-six percent (28) of patients were female and 44% (22) were male, 91% (45 patients) aged 30-70 years, 9% (5 patients) over 70 years. Mean score±standard deviation (SD) for different domains analyzed was the following: mean comprehension score±(SD) was 6.4±(0.68) in standard consensus group *versus* 8.7±(0.715) in the video consensus group, P=0.0001. Mean satisfaction score±(SD) was 6.6±(0.55) in standard consensus group *versus* 8.8±(0.9) in the video consensus group, P=0.0001. Mean simplicity score±(SD) was 6.2±(0.65) in standard consensus group *versus* 8.9±(0.45) in the video consensus group, P=0.0001. Mann-Whitney *U* Test was used for independent samples.

CONCLUSIONS: All the domains analyzed showed a higher statistically significant appreciation for video consent compared to traditional informed consent. Overall satisfaction, with a mean score of 8.8 out of 10, showed to our advice the way to chase for the future. In the age of information, video consent represents a simple and comprehensive tool for patients and can improve their awareness and satisfaction and can reduce preoperatory anxiety.

SC472

Ureteral canalization after mini-percutaneous nephrolithotomy is associated with stone volume and location: insight for personalized postoperative management

M. Nizzardo, M. Turetti, A. Marmiroli, A. Nogara, G. Lucignani, C. Silvani, L. Boeri, E. Lievore, S.P. Zanetti, F. Longo, E. De Lorenzis, G. Albo, E. Montanari (Milan)

BACKGROUND: Mini-percutaneous nephrolithotomy (mPCNL) is one of the preferred techniques for the treatment of kidney stones. mPCNL without internal drainage might be associated with postoperative lack of ureteral canalization, because of local edema and associated complications. We aimed to evaluate factors associated with lack of ureteral canalization in a cohort of patients treated with mPCNL for kidney stones.

METHODS: We retrospectively analyzed data from 263 consecutive patients who underwent mPCNL at a single tertiary-referral academic between January 2016 and September 2022. mPCNL were performed with the vacuum-cleaner or vacuum-assisted set according to the surgeon's preference. A nephrostomy tube was placed as the only exit strategy in each procedure. Patient's demographics, stones characteristics and operative data were collected. Stone-free was defined as no residual stones. Complications were recorded and graded according to modified Clavien classification. At postoperative day 2, an antegrade pyelography was performed to assess ureteral canalization. The nephrostomy tube was removed if ureteral canalization was successful. Descriptive statistics and logistic regression models were used to identify factors associated with lack of ureteral canalization.

RESULTS: Overall, median (IQR) age and stone volume were 56 (47-65) years and 1.7 (0.9-4.2) cm^3, respectively. The vacuum- cleaner and the vacuum-assisted set were used in 53 (20.2%) and 210 (79.8%) patients, respectively. After mPCNL, 225 (85.5%) patients were stone free and 61 (23.2%) had postoperative complications (any Clavien). Of 263, 55 (20.9%) patients showed absence of ureteral canalization during pyelography. Patients without ureteral canalization had larger stone volume (3.1 *vs.* 1.4 cm^3, P<0.001), longer operative time (105 *vs.* 90 min, P<0.01) and higher rate of stones in the renal pelvis (27.5% vs.12.3%, P<0.01) than those with normal pyelography. Length of stay was longer (5 *vs.* 4 days, P<0.02) and postoperative complications (36.1% *vs.* 16.5%, P=0.01) were more frequent in patients without ureteral canalization. Observation and steroids were used to treat postoperative edema in 38 (69.1%) and 17 (30.9%) cases, respectively. The nephrostomy tube was removed earlier in patients treated with steroids than observation (2 *vs.* 3 days, P=0.01). Multivariable logistic regression analysis revealed that stone volume (OR=1.1, P=0.02) and stone located in the renal pelvis (OR=2.2, P=0.03) were independent predictors of lack of ureteral canalization, after accounting for operative time.

CONCLUSIONS: One out of five patients showed impaired ureteral canalization after mPCNL, which is associated with longer hospital stay and complications. Patients with higher stone burden and with stones in the renal pelvis are those at higher risk of inadequate canalization. Internal drainage might be considered in these cases to avoid potential complications.

SC473
Ureteroscopic stone extraction is not always needed after urgent drainage for obstructive uropathy due to ureteric stones

M. Nizzardo, L. Boeri, A. Nogara, G. Lucignani, M. Turetti, A. Marmirolo, E. Lievore, S.P. Zanetti, F. Longo, E. De Lorenzis, G. Albo, E. Montanari (Milan)

BACKGROUND: Ureteral stones can cause obstructive uropathy needing emergency kidney drainage. Spontaneous stone passage (SSP) is not an infrequent event after this kind of procedure, such event makes unnecessary a subsequent ureteroscopy. Our aim was to evaluate the rate of and predictors of SSP after urgent drainage by ureteric stenting for obstructive uropathy.

METHODS: We performed a retrospective analysis of data from 249 consecutive patients evaluated at the emergency department for obstructive uropathy between January 2013 and September 2022 and treated with double J stent drainage. We collected demographic, clinical and laboratory characteristics. Before stenting a computerized tomography (CT) was performed due to collect stone parameters. One months after stenting a non-contrast enhanced CT scan was requested to evaluate SSP. Descriptive statistics and logistic regression models tested the association between predictors and SSP.

RESULTS: Median (IQR) age and stone diameter were 56 (45-68) years and 7.1 (4.4-9.8) mm, respectively. Stones were located in the proximal, medial and distal ureter in 102 (41.0%), 48 (19.3%) and 99 (39,8%) cases. Overall SSP was observed in 65 (26.2%) cases at the postoperative CT scan. SSP occurred in patients with smaller stone diameter (3.2 *vs.* 7.7 mm, P<0.001) and lower Hounsfield units (HU) of the stone (416 *vs.* 741 HU, P<0.001). Distal ureter was the most frequent location (76.9% *vs.* 26.7%, P<0.001) in cases with spontaneous stone passage. Multivariable logistic regression analysis showed that distal ureteral stone location (OR=7.9, P<0.01) and lower HU (OR=0.9, P<0.01) were associated with SSP, after accounting for stone volume. The ROC analysis showed that HU<500 (76.3% sensitivity and 74.1% specificity) and stone diameter of 5 mm (75.2% sensitivity and 73.4% specificity) had a good predictive ability for SSP (both AUC>0.7). Considering 1-point for each positive variable of the model, the PPV of SSP increased incrementally as a function of positive variables ranging from 0.0% to 25.6% and 74.9% among patients with risk scores of 0, 1, and 2, respectively.

CONCLUSIONS: SSP occurred in 26% of patients with obstructive uropathy treated with internal stent in an urgency setting. Distal location and lower density of the stone were independent predictors of stone passage. Patients that satisfy these criteria should undergo follow-up imaging instead of upfront ureteroscopy.

SC474
Optimizing long-term renal function preservation in cystinuric patients through ureteroscopy: results from a tertiary care referral center

L. Candela, E. Ventimiglia, M. Chicaud, C. Solano, L. Villa, F. Panthier, S. Doizi, E. Letavernier, J.P. Haymann, M. Daudon, F. Montorsi, A. Salonia, O. Traxer (Milan)

BACKGROUND: Patients suffering from cystinuria experience high stone recurrence rate which results in a considerable number of surgical interventions during lifetime. These patients are at higher risk of developing early chronic kidney disease compared to other urinary stone formers and general population. To improve renal prognosis, non-invasive urological interventions should be preferred to manage stone recurrences. We sought to evaluate long-term renal function

modification of cystinuric patients exclusively treated with retrograde ureteroscopy (URS).

METHODS: Data from 112 cystinuric patients treated for ureteral/renal stones from 2001 to 2021 at a single academic referral center were retrospectively analyzed. Stone analysis confirmed the diagnosis of cystinuria. Estimated Glomerular Filtration Rate (eGFR) was calculated using the first and the last available serum creatinine level according to the Modification of Diet in Renal Disease (MDRD) formula. Chronic kidney disease (CKD) stage was assessed according to the National Kidney Foundation (NKF) classification. Severe CKD was defined as CKD stage ≥3 (*i.e.* eGFR <60 mL/min). Regular nephrological management (NM) was defined as 1 nephrological consultation every 12-18 months, according to our internal protocol. Descriptive statistics were used to analyse the cohort data.

RESULTS: Complete data including serum creatinine levels of 46 cystinuric patients exclusively treated with URS were available. Median (IQR) age at diagnosis and at first URS in our center were 18 (10-26) and 32 (22-46) years, respectively. Twenty- eight (60.8%) patients were male, and 13 (28%) patients had a CCI≥1. Median (IQR) follow-up was 101 (70-146) months. Median (IQR) interval between the first and the last available creatinine level was 64 (45-78) months. Median (IQR) number of fURS and recurrences during FU were 6 (3.75-10.25) and 2.5 (1-4), respectively. At the end of follow-up, 18 (39%) patients were stone-free. Thirty-nine (85%) patients had at least 1 nephrological consultation in our center and 19 (43%) had regular NM during follow-up. Median (IQR) first and last eGFR were 72 (57-97.5) and 74 (66-88) mL/min, respectively. Eight (17%) and 5 (10.8%) patients had severe CKD at the beginning and the end of the follow-up, respectively. Overall, 40 (87%) patients had stable or improved renal function within the follow-up.

CONCLUSIONS: Severe CKD is a not neglectable complication that occurs in more than 1 out 6 cystinuric patients at an early stage of life. However, most of patients treated conservatively with URS in a referral center have stable or improved renal function within a long-term follow-up. Current findings should be considered for the surgical management of cystinuric patients.

SC475
In patients at high risk for infections vacuum-assisted mini-percutaneous nephrolithotomy is associated with lower rates of infectious complications compared to vacuum-cleaner procedure: a single-center experience

S.P. Zanetti, C. Silvani, A. Marmiroli, A. Nogara, G. Lucignani, M. Turetti, M. Nizzardo, E. Lievore, L. Boeri, F. Longo, E. De Lorenzis, G. Albo, E. Montanari (Milan)

BACKGROUND: Previous studies have shown that vacuum-assisted mini-percutaneous nephrolithotomy (vamPCNL) is associated with shorter operative time and lower risk of infectious complications compared to vacuum-cleaner mPCNL (vcmPCNL) in the general population. We aimed to compare outcomes of vamPCNL and vcmPCNL in a cohort of patients with kidney stones at high risk for infectious complications base on specific clinical features.

METHODS: Data from 405 consecutive mPCNL performed in a single tertiary-referral academic between January 2016 and September 2022 were retrospectively analyzed. Out of 405, we identified 145 (35.8%) patients with risk factors for infectious complications (preoperative positive urine culture, stone volume >2.5 cm3, hydronephrosis, history of previous UTIs, immune system disease,). Based on the surgeon's preference, vamPCNL or vcmPCNL was performed. For every procedure we collected patient's demographics, stones characteristics and operative data. We defined stone-free status as no residual stones. Complications were recorded according to modified Clavien classification. Descriptive statistics and logistic regression models were used to identify factors associated with postoperative infectious complications.

RESULTS: Among the cohort of 145 patients at high risk for postoperative infections, median (IQR) age, BMI and stone volume were 56 years (46-64) years, 24.5 (21.2-28.2) kg/m^2 and 3.5 (2.1-9.0) cm^3, respectively. vcmPCNL and vamPCNL were performed in 51 (35.2%) and 94 (64.8%) patients, respectively. After mPCNL, 121 (83.4%) patients were stone free and 56 (38.9%) had postoperative complications (any Clavien). Postoperative infectious complications occurred in 43 (29.7%) cases. Patients who developed infectious complications had larger stone volume (3.8 *vs.* 2.9 cm^3, P<0.001) and higher rate of multiple (36.5% *vs.* 16.3%, P=0.01) and staghorn stones (46.3% *vs.* 20.5%, P<0.01) than those who did not. Infectious complications occurred more frequently after vcmPCNL than vamPCNL (47.1% *vs.* 20.1%. P=0.001) in this cohort of high-risk patients. Longer operative time (142 *vs.* 100 min, P<0.01) and length of stay (7 *vs.* 4 days, P<0.01) along with lower rate of stone free status (55.8% *vs.* 44.2%, P=0.004) were observed in cases with infectious complications. Multivariable logistic regression analysis revealed that vcmPCNL procedures (OR=3.1, P=0.03) and longer operative time (OR=1.1, P=0.02) were independently associated with infectious complications development, after accounting for stone volume.

CONCLUSIONS: In a cohort of patients with kidney stones and high-risk factors for infections, approximately 30% of participants developed infectious complications after mPCNL. Patients with infectious complications had higher stone burden and longer length of stay than those who did not, as expected. vamPCL and shorter operative time were independent protective factors for infections after surgery. vamPCNL confirmed to be associated with lower infectious complications even in high-risk patients.

SC476
Comparing outcomes of thulium fiber laser *versus* high-power Holmium:YAG laser lithotripsy in pediatric patients managed with RIRS for kidney stones: a multicenter retrospective study

L. Candela, D. Castellani, E. Ventimiglia, C. Solano, J. Yuen-Chun Teoh, Y. Tanidir, K. Yung Fong, V. Chandramohan, M. Mani Sinha, D. Ragoori, B.K. Somani, F. Montorsi, A. Salonia, O. Traxer, V. Gauhar (Milan)

BACKGROUND: Retrograde intrarenal surgery (RIRS) with laser lithotripsy is increasingly used as an alternative to shock wave lithotripsy for pediatric patients with upper urinary tract stones. Holmium:YAG (Ho:YAG) laser represents the gold standard for RIRS lithotripsy due to its proven efficacy and safety in pediatric patients. Recently, thulium

fiber laser (TFL) has been introduced in clinical practice for stone lithotripsy as a promising alternative to Ho:YAG laser. We sought to evaluate TFL safety and efficacy compared to high-power (HP) Ho:YAG laser in pediatric patients who have undergone RIRS for kidney stones.

METHODS: We retrospectively reviewed data from pediatric patients who underwent RIRS for kidney stones <2cm in greatest diameter between 2018 and 2020 in 4 Urology Departments. Outcomes of interest were: 1) safety of the procedures, assessed through intra- and postoperative complications; and 2) efficacy of the technique assessed through surgical operative time (OT), stone-free rate and reintervention rate. Complete perioperative data were collected. Complications were assessed 4 to 6 weeks postoperatively. Stone-free (SF) was defined as the absence of visible fragments or as the presence of a single residual fragment ≤2 mm at 3 months postoperative imaging. Student's *t*-test for continuous variables, and χ^2 and Fisher's Exact Test for categorical variables were used to compare outcomes between patients treated with HP Ho:YAG (Group 1) and TFL (Group 2). Univariate (UVA) and multivariate (MVA) logistic regression analyses were performed to predict SF-associated factors.

RESULTS: Data from 126 pediatric patients were analyzed, 97 in group 1 and 29 in group 2. Mean (SD) age was 10 (4.7) and 7 (4.73) years in group 1 and 2 (P=0.004), respectively. Mean (SD) largest stone diameter was 9.7 (4.23) *vs.* 10.97 (3.69) mm in group 1 and 2, respectively (P=0.325). Rate of elevated serum creatinine, positive urine culture, ureteral prestenting, preoperative administration of tamsulosin and antibiotics, normal kidney anatomy, and number and location of stones were comparable between group 1 and 2 (all P>0.05). All the procedures were successfully performed, and no intraoperative complications were reported in both groups. No major postoperative complication occurred. SF rate was 81.4% and 89.7% (P=0.45) and reintervention rate was 14.4% and 6.89% (P=0.046) in group 1 and 2, respectively. At UVA and MVA, the type of laser did not influence SF rate. However, prestenting and single stones were positively associated with SR rate.

CONCLUSIONS: Both laser technologies are safe and effective and showed similar SF rates. TFL showed less OT and lower re-intervention rate. These results provide the opportunity to urologists to use either TFL or Ho:YAG laser during RIRS in pediatric patients since both technologies demonstrated satisfactory outcomes. Further prospective comparative studies are needed to corroborate our findings.

SC477
Correlation between health-related quality of life measured by IT-WISQOL and perioperative characteristics of patients with upper urinary tract stones

E. Serafin, G. Mazzon, A. Veccia, A. Franceschini, S. Ferretti, F. Claps, C. Fiori, G. Celentano, G.G. Guarino, D. Zamengo, A. Piasentin, M. Creta, N. Longo, R. Dordoni, N. Pavan, A. Panunzio, C. Brancelli, A. Celia, M.A. Cerruto, A. Antonelli (Verona)

BACKGROUND: Urolithiasis is a worldwide spread condition with a significant impact on patients' health-related Quality of Life (HRQOL), which measurement is an important tool in clinical practice. The Wisconsin Stone-QOL (WISQOL) has been validated in different languages. The study aimed to investigate the correlation between perioperative patients' characteristics and pre- and postoperative HRQOL measured by the Italian version of WISQOL (IT-WISQOL).

METHODS: Patients undergoing any elective surgical treatment for upper urinary tract stones between January 2021 and March 2022 were enrolled in six Italian urological centers, after ethical committee approval. Patients were evaluated within 15 days preoperatively and then at 1, 3, and 6 months postoperatively and administered both IT-WISQOL and SF-36v2 (36-Item Short Form Health Survey) for comparison. Baseline characteristics and postoperative data were collected. Stone complexity was calculated using S.T.O.N.E. score and Guy's Stone Score (GSS). Multivariate linear regression analysis was used to investigate the association between perioperative characteristics and questionnaire scores.

RESULTS: Two hundred twenty-one patients were enrolled. One hundred thirty-six (61.5%) were male and 85 (38.5%) were female. Fifty-six (25.6%) underwent ureterolithotripsy, 64 (29.2%) retrograde intrarenal surgery, 61 (27.9%) extracorporeal shock wave lithotripsy, and 38 (17.3%) percutaneous nephrolithotomy. Ninety-seven (43.9%) patients had a previous history of surgery for urinary stones. A ureteral stent or nephrostomy was placed in 163 (77.6%) cases and was left for 24 (10-45) days. Stone-free status (SFS) was reached in 155 (74.5%) patients. We found a statistically significant association between preoperative IT-WISQOL score and both GSS (β: -5.87; P=0.013) and S.T.O.N.E. score (β: -1.87; P=0.034), as well as with the positioning of a ureteral stent or nephrostomy (β: -13.29; P=0.001). SFS was the only factor that significantly correlated to IT-WISQOL score at 1 month (β: 12.46; P<0.001), 3 months (β: 17.72; P<0.001), and 6 months (β: 18.86; P<0.001) postoperatively. No statistically significant correlation was found between patients' preoperative characteristics and SF-36v2. As for IT-WISQOL, SFS was the only predictor of a better SF-36v2 score at 1, 3, and 6 months postoperatively.

CONCLUSIONS: We observed that the IT-WISQOL questionnaire is more sensitive than SF-36v2 to preoperative characteristics of patients with upper urinary tract stones, confirming that it is a good performing and clinically useful tool to assess HRQOL in this group of patients. We also observed that the stone-free status is the best predictor of a better outcome in terms of QOL.

SC478
MiniPerc for treatment of renal stones between 10 and 20 mm: a comparison between high-power Holmium:YAG laser (Cyber Ho) *versus* thulium fiber laser (Fiber Dust) generators

D. Perri, U. Besana, A. Pacchetti, E. Morini, L. Berti, F. Mazzoleni, M.C. Sighinolfi, B. Rocco, A.L. Pastore, A.S. Gozen, J.B. Roche, J. Romero-Otero, F. Bruyere, G. Bozzini (Como)

BACKGROUND: We performed a comparison between mini-percutaneous nephrolithotripsy (MiniPerc) performed with high-power Holmium:YAG (Ho:YAG) laser *versus* thulium fiber laser (TFL) for the treatment of stones between 10 and 20 mm.

METHODS: One hundred seventy-six patients with a renal stone between 10-20 mm underwent MiniPerc using the high-power Holmium:YAG Cyber Ho laser generator (80 patients, 45.5%, Group A) *versus* the TFL Fiber Dust laser generator

(96 patients, 54.5%, Group B). A preoperative computed tomography (CT) scan was performed to assess side, location, size and hardness of the stone. Patients with acute infection, coagulation impairments, anticoagulant therapy or concomitant ureteral stones were excluded. Three months after surgery a CT scan was performed to assess the stone-free rate (SFR). A negative CT scan or the presence of stone fragments <3 mm were the criteria to assess the stone-free status. A statistical analysis was carried out to assess differences in intraoperative parameters, efficacy and complication rate between groups.

RESULTS: Preoperative features were comparable between groups. Mean stone size was 13.8 mm and 14.9 mm in Group A and B, respectively (P=0.18). Mean Hounsfield units were 1213 in Group A and 1189 in Group B (P=0.21). Mean dusting time was higher in Group A (21.8±9.9 min *vs.* 15.2±4.4, P=0.04). Mean delivered energy was 105 J for Group A and 60 J for Group B (P=0.04). A higher stone-free status rate was observed with the Fiber Dust over the Cyber Ho device, but without a statistically significant difference. Specifically, the overall SFR was 86.2% for Group A and 91.6% for Group B (P=0.06) respectively. Complication rate was 5.1% and 4.8% for Groups A and B, respectively (P=0.18).

CONCLUSIONS: MiniPerc using Cyber Ho (high-power Ho:YAG) and Fiber Dust (TFL) laser generators is equally safe and effective in the treatment of renal stones between 10 and 20 mm. A comparable SFR with a trend in favor of the Fiber Dust was observed. Complication rate was similar despite a higher delivered energy with the Cyber Ho.

SC479
Evaluation of pneumoRIRS for the treatment of kidney stones associated to kidney anomalies or in difficult percutaneous access

A. Pacchetti, D. Perri, F. Mazzoleni, E. Morini, R. Spasciani, U. Besana, L. Berti, M.C. Sighinolfi, B. Rocco, S. Micali, A.S. Gozen, E. Liatsikos, J.B. Roche, G. Bozzini (Como)

BACKGROUND: Percutaneous lithotripsy (PCNL) is indicated in case of stones associated to conditions that impair a retrograde access to renal cavities, such as ureteral/ureteropelvic junction (UPJ) stenosis. PCNL access can be difficult in case of colon interposition, anatomical anomalies such as kidney malrotation or previous kidney surgery. PneumoRIRS describes the endoscopic access to renal cavities during a laparoscopic/robotic procedure. A flexible ureterorenoscope is inserted through a trocar for kidney stones retrieval using the UPJ surgical incision. Our aim was to show the feasibility of this procedure.

METHODS: Between January 2019 and June 2022, a multicentric evaluation was carried out. Patients treated with PCNL were included in group A, while patients undergoing PneumoRIRS were included in group B. Preoperative characteristics, intraoperative variables and postoperative outcomes were prospectively recorded. Three months after surgery a CT scan was performed to assess the stone-free rate (SFR). Primary outcomes were SFR, hemoglobin drop, and hospital stay. Secondary outcome was a cost analysis of both procedures.

RESULTS: During the study period a total of 102 patients were treated with PCNL (group A), while 82 patients underwent PneumoRIRS (group B). Mean age was 61.9 years for group A and 57.9 years for group B. Mean stone size was 18.4 mm for group A and 16.9 mm for group B, respectively. Operative time was 84.7 min for group A and 94.9 min for group B. Major complications occurred in 3 cases in group A and in 2 cases in group B. SFR was reached in 89 cases (87.2%) in group A and in 80 cases (97.6%) in group B (P=0.02). Mean hospital stay showed no significant difference between procedures (2.8±1.9 days for group A *vs.* 2.1±1.1 days for group B; P=0.12). PneumoRIRS showed a better safety profile regarding blood loss with a hemoglobin drop of 1.9 g/dL for group A *vs.* 0.4 g/dL for group B (P=0.03). Cost analysis revealed a mean cost of 3180±765 euros for group A and 5270±1232 euros for group B (P=0.02).

CONCLUSIONS: In our multicentric cohort of patients PneumoRIRS showed optimal SFR, with a good safety profile. This procedure allows to treat kidney stones associated to UPJ stenosis, difficult percutaneous access to the kidney due to colon interposition or previous kidney surgery. This approach could allow the surgeon to achieve a good SFR and treat the condition that caused the urolithiasis at the same time. A deeper cost analysis must be carried out to demonstrate the real advantage of this approach.

SC480
A proposed mathematical model to help preoperative planning between RIRS and Mini-Perc for renal stones between 10 and 20 mm using Holmium:YAG laser (Cyber Ho): the stone management according to size-hardness (SMASH) score

D. Perri, U. Besana, L. Berti, F. Mazzoleni, A. Pacchetti, E. Morini, R. Spasciani, M.C. Sighinolfi, B. Rocco, J. Romero-Otero, J.B. Roche, G. Bozzini (San Fermo della Battaglia, Como)

BACKGROUND: We performed a prospective randomized comparison between retrograde intrarenal surgery (RIRS) and MiniPerc (MP) for stones between 10 and 20 mm to evaluate the performance of a mathematical model to drive preoperative planning.

METHODS: Patients with a single renal stone between 10-20 mm were enrolled. Exclusion criteria were age <18 or >75, presence of acute infection, coagulation impairments, cardiovascular or pulmonary comorbidities. For each patient a mathematical model named Stone Management According to Size-Hardness (SMASH) score was so calculated: Hounsfield units (HU) × stone maximum size (cm)/100. Patients were divided into 4 groups according to type of treatment and SMASH score: RIRS with score <15 (Group A), RIRS with score ≥15 (Group B), MP with score <15 (Group C), MP with score≥15 (Group D). In all groups the Cyber Ho laser device was used. A CT scan after 3 months was performed. A negative CT scan or asymptomatic patients with stone fragments <3 mm were the criteria to assess the stone-free status. A statistical analysis was carried out to assess efficacy and safety of each procedure.

RESULTS: Three hundred fifty patients were enrolled (87 in Group A, 88 in Group B, 82 in Group C, 93 in Group D). Mean stone size was 13.1 *vs.* 13.3 mm in Group A *vs.* B (P=0.18) and 16.2 *vs.* 18.1 mm in Group C *vs.* D (P=0.12). The overall stone free rate (SFR) was 82%, 61%, 75% and 85% for Group A, B, C and D, respectively. SFR was comparable

when comparing Group C and D (P=0.32) and Group A and C (P=0.22). On the contrary, SFR was significantly higher in Group A over B (P=0.03) and in Group D over B (P=0.02). Complication rate was 2.2%, 3.4%, 12.1% and 12.9% for Groups A, B, C and D, respectively. The difference was significant between Groups A and C (P=0.02) and Groups B and D (P=0.02).

CONCLUSIONS: RIRS and MP are both safe and effective to obtain a postoperative SFR with Cyber Ho. The mathematical model taking into account HU with the proposed cut-off allowed a proper allocation of the patients between endoscopic and percutaneous approach.

SC481
The use of neutrophil to lymphocyte ratio (NLR) in the decision making of hospitalization of patients with urinary stones and obstruction in emergency setting

D. Baiamonte, I. Lampasona, S. Altomare, P. Mannone, N. Pavan, G. Tulone, R. Giaimo, L. Agnello, B. Lo Sasso, C.M. Gambino, M. Vidali, M. Ciaccio, A. Simonato (Palermo)

BACKGROUND: Obstruction due to urinary stones is a frequent condition encountered in the Emergency Department. The decision to hospitalize a patient is often based on clinical parameters (pain, fever, etc.) and instrumental findings (radiological exams, biochemical markers – like White Blood Cells, C Reactive protein C-RP, etc.). Neutrophil to Lymphocyte Ratio (NLR) is a simple marker that evaluates innate and adaptive immune response. NLR can be used as a prognostic factor for mortality and morbidity in several settings, with elevated values observed in conditions such as traumas, sepsis, stroke and others. A sudden NLR increase has been shown to be an early marker of acute stress. The aim of our study was to evaluate NLR in the decision making of hospitalization of patients with obstruction due to urinary stones in emergency setting and to obtain a cut-off value for this purpose.

METHODS: Patients who accessed the Emergency Room for obstruction due to urinary stones from April 2021 to October 2022 were enrolled. Patients with ureteral stents/nephrostomies, hematological disorders, missing NLR and with a urinary obstruction without lithiasis were excluded. Complete blood counts (CBC), NLR, creatinine, C-Reactive protein, and radiological examinations (ultrasound or CT) were evaluated. Patients were divided into two groups: hospitalized *vs.* not hospitalized. For each patient, the NLR Ratio was calculated from the first CBC performed in the Emergency Room. Predictors of hospitalization were evaluated by logistic regression. A receiving operator curve (ROC) analysis was performed to evaluate NLR.

RESULTS: In the study period, 439 patients (M: F 63:37%; median age 51 [IQR: 41-61] y.o.) were evaluated and 107 (24%) were hospitalized. Among hospitalized patients, prevalence of preoperative fever was significantly higher (51% *vs.* 1%; P<0.001). At the multivariate analysis, Neutrophil-Lymphocyte Ratio (OR=1.05, 95% CI: 1.01-1.09; P=0.012), age (OR=0.97, 95% CI: 0.94-0.99; P=0.015), stone size >1 cm (OR=9.73, 95% CI: 4.30-22.03; P<0.001), C-Reactive Protein (OR=1.02, 95% CI: 1.01-1.03; P<0.001) and creatinine (OR=10.11, 95% CI: 3.72-27.43; P<0.001) were independent predictors of hospitalization. The ROC analysis of NLR as a biomarker for predicting hospitalization showed good performance, with an Area Under the Curve AUC of 0.71 (95% CI: 0.65-0.77). The AUC of multivariate model was 0.91 (95% CI: 0.88-0.95). The optimal NLR cut- off calculated by the Youden's Index was 5.75 (sensitivity: 0.61, specificity: 0.73, positive predictive value: 0.42, negative predictive value: 0.85).

CONCLUSIONS: The Neutrophil to Lymphocyte Ratio is a promising biomarker to evaluate the risk of comorbidities and mortality in patients with obstruction due to urolithiasis. The proposed cut-off is in line with the current literature. Being simple to calculate, fast and cheap, NLR can be a valid support in deciding whether or not to hospitalize patients with stones on an emergency setting.

SC482
Diagnostic efficacy of a clinical and molecular screening in patients affected by primary hyperoxaluria type 1

L. Veronesi, N. Morisi, A. Pescina, S. Ferretti, S. Micali, G. Donati, R. Magistroni, M. Ballestri (Modena)

BACKGROUND: Primary hyperoxaluria type 1 (PH1) is a rare congenital disease characterized by increased urinary oxalate excretion. Typically, PH1 presents in pediatric patients with recurrent nephrolithiasis, nephrocalcinosis, and progressive renal failure, although late onset can also occur. Atypical presentations in adults can result in sporadic episodes of nephrolithiasis, leading to diagnostic delays. The diagnostic work-up begins with screening for metabolic abnormalities (daily urinary oxalate excretion), followed by genetic testing for AGXT. However, due to a lack of appropriate criteria for identifying patients in need of genetic testing, molecular analysis for PH1 is not widely used in clinical practice. The aim of our study was to retrospectively evaluate the efficacy of a clinical and molecular screening performed on patients with recurrent nephrolithiasis and suspected PH1 by confirming a checklist of clinical and laboratory criteria for inclusion in the PH1 screening pathway. Our goal was to optimize the diagnostic algorithm.

METHODS: The study population consisted of 383 patients with recurrent nephrolithiasis. Of these, 67 patients (17.5%) underwent genetic investigation of AGXT using NGS technology on a salivary sample. The selection criteria included family history of renal stones, age of onset <20 years and presence of hyperoxaluria (>45 mg/24 h). Clinical, laboratory and genetic data were collected and retrospectively analyzed to determine the effectiveness of the screening in identifying subjects carrying pathogenic variants of AGXT.

RESULTS: Among the patients who underwent genetic testing, 46 (69%) had a family history of recurrent nephrolithiasis, while 24 (36%) reported symptom onset before the age of 20 years (median age of presentation, 23 years; range: 9-69 years). Of these patients, 22 (33%) had urinary oxalate levels >45 mg/24 h upon initial measurement. However, only 18 patients (27%) exhibited persistent hyperoxaluria despite following dietary measures and receiving pyridoxine treatment. Only 4 patients (6%) met all the selection criteria. Genetic testing identified 4 subjects with AGXT mutations: one homozygous pathogenic variant (c.508G>A; p.Gly170Arg), two heterozygous pathogenic variants (c.601G>A; p.Asp201Asn), and one heterozygous variant of unknown significance (c.777-12C>T).

CONCLUSIONS: Our algorithm was successful in identifying 1 PH1 patient and 3 carriers of AGXT mutations. The criteria with the highest predictive values were: 1) a family history of nephrolithiasis; and 2) increased oxaluria. Early onset did not show a significant predictive value, as the only PH1 patient had a late onset (43 years of age). Given the rare nature of this condition, our algorithm proved effective in identifying patients who required genetic testing. However, it is crucial to diagnose late-onset forms of PH1 in a timely manner to initiate treatment before irreversible complications, such as end-stage kidney disease and systemic oxalosis, develop.

UROLOGIA PEDIATRICA

DSD, exstrophy, hypospadia

- Psychosocial and psychosexual adjustment in adult patients born with classic bladder exstrophy: long-term outcomes of a high-volume tertiary referral center
- Transition of care of DSD patients: our proposal
- Preliminary results of tailored daily transdermal testosterone treatment before surgical repair of severe hypospadias

Psychosocial and psychosexual adjustment in adult patients born with classic bladder exstrophy: long-term outcomes of a high-volume tertiary referral center

I. Paraboschi, M. Gnech, E. De Marco, D.G. Minoli, F. Mitzman, U.M. Pierucci, R. Darisi, G. Manzoni, W. Rigamonti, M. Di Grazia, A. Berrettini (Milan)

BACKGROUND: The aim of the study was to examine long-term psychosocial and psychosexual outcomes of adult patients born with classic bladder exstrophy (BE).

METHODS: The validated Sex Relation Evaluation Schedule Assessment Monitoring (SESAMO) questionnaire was used to assess the psychosocial and psychosexual adjustment of BE patients followed up for at least 20 years. Section I investigated items common to all patients, section II singles, section III couples. Z-scores were calculated for each item and compared in relation to patients' gender, relationship status, and the voiding technique used to empty the bladder.

RESULTS: A total of 33 (F:M 12:21; singles:couples 11:22) BE patients were enrolled in the study at a median age of 39 (32-47) years. The results of the questionnaire showed mild to moderate dysfunctions in all the items investigated, with no significant differences between the different voiding techniques used to empty the bladder. Lower z-scores were recorded for psychosexual identity (z-score: -1.282), pleasure (z-score: -0.915) and desire (z-score: -0.583); singles for relational attitude (z-score: -1.751) and imaginative eroticism (z-score: -0.806); couples for extramarital sexuality (z-score: -1.175) and sexual communication (z-score:-0.255). Women performed significantly worse than men regarding psychosexual identity, areas of pleasure, and actual masturbation, men on relational attitude and sexual intercourse. Several psychosocial and psychosexual outcomes were affected in BE adults, regardless of the voiding technique used to empty the bladder.

CONCLUSIONS: A long-term psycho-sexuological follow-up is required to help them cope with their past medical experience and actual clinical condition.

Transition of care of DSD patients: our proposal

A. Lesma, L. Triglia, F. Passarelli, A. Salonia (Milan)

BACKGROUND: Disorders of sexual development (DSD) encompasses a heterogeneous group of conditions characterized by a discrepancy between chromosomal, gonadal, and anatomical sex, commonly based on the karyotype. The common denominator of these disorders lies in genital abnormalities, caused by alterations occurring during throughout the stages of the embryogenesis. These disorders present with phenotypes of different severity. Given the patients' complexity, a multidisciplinary management is crucial for their assessment especially during a crucial phase such as the transition to adult care healthcare system.

METHODS: The study is a retrospective study on DSD patients, with the aim of analyzing the process of care which has been used up to now, thereof providing a more comprehensive and customized approach. Regarding the population of DSD patients raised as males, the entire patient cohort has been longitudinally followed-up with regular outpatient clinical assessments. Regarding the population of DSD patients raised as females, apart from regular outpatient clinical assessment, data regarding previous procedures were collected.

RESULTS: Overall, sociodemographic, clinical, surgical and therapeutic data were collected about a cohort of 19 DSD patients referred to out transition of care program; an in-depth investigation of their hormonal production, genetic profile, gonadal function and fertility was carried out. Regarding DSD patients raised as females, data regarding a cohort of 71 patients, both 46,XX and 46 XY enrolled in our transition of care, were collected. Major complaints of DSD patients raised as males that emerged during the medical appointments were collected and interpretated following evidence-based literature. Regarding patients raised as females, 46,XX patients' main problems were related to the presence of vaginal stenosis, the need of a psychological support, LUTS, non-satisfactory genital cosmetic aspect, poor endocrinological management and altered clitoris sensation; while for the 46,XY cohort the main complaints were the need of gonadectomy, the presence of vaginal stenosis, need of psychological support, one case of gender dysphoria was reported.

CONCLUSIONS: Through a multidisciplinary assessment, we have explored the main needs expressed by these patients regarding their therapeutic journey, as well as collected their uncertainties on various topics, including fertility, sexual functioning, therapeutic possibilities, and implications related to the diagnosis. In this context we have outlined a protocol of transition of care, involving both pediatric and non-pediatric specialists. Finally, we have examined the challenges encountered in the pathway of care and explored future perspectives with the goal of improving the quality of life for these patients.

Preliminary results of tailored daily transdermal testosterone treatment before surgical repair of severe hypospadias

L. Lucaccioni, F. Ghidini, V. Durante, A. Insalaco, S. Vandelli, L. Iughetti, P.L. Ceccarelli (Modena)

BACKGROUND: The severity of hypospadias is considered the main predictor of the surgical outcomes. Complications could affect up to 60% of children suffering from proximal hypospadias. For this reason, several factors have been investigated. The effect of preoperative testosterone treatment is still controversial, as well as the best regimen of administration. The aim of the study was to report our preliminary experience with the use of transdermal testosterone (TDT) before severe hypospadias repair. Secondary aims were the assessment of the penile tissue response and surgical short-term outcomes.

METHODS: The design was single-centered and retrospective. The study period ranged from December 2020 to February 2023. Inclusion criteria for preoperative TDT were midshaft/proximal hypospadias with glans circumference (GC)<14 mm or clinically relevant penile ventral curvature. Daily treatment with topical testosterone gel (2%) at a standard dose of 2 mg/day was administered for 30 to 60 days, according to the clinical response. The surgical repair was ideally performed after one-month from the interruption of TDT. Clinical records were reviewed to collect the following outcomes: penile length (PL) and GC, adverse events (painful

erection, scrotal hyperpigmentation, pubic hair, skin irritation) and surgical complications. TDT administration and its clinical response was monitored by the same pediatric endocrinologist, as well as the surgical repairs were performed and followed-up by the same pediatric surgeon.

RESULTS: Ten patients (aged 2.67±1.60 years) were enrolled. Six of them (60%) were proximal hypospadias. The mean length of TDT was 43±15 days. The mean interval between TDT and surgery was 52±23 days. A staged surgical correction was performed in five patients (50%). TIP urethroplasty was used for single-stage repair. No adverse events secondary to TDT were reported. A mean increase of 0.76±0.27 cm (+37%) for PL and of 0.42±0.26 cm (+40%) for GC were measured. After a mean follow-up of 9.9±10 months, three patients (50%) with proximal hypospadias suffered from urethral fistula or glandular dehiscence. No complications were reported in mid-shaft cases. The complication rate was 30% in the overall population. These preliminary results highlighted the feasibility of preoperative TDT. First, this regimen was well-tolerated without any adverse event or parental complain. Second, the increase of PL and GC was considered clinically relevant. Finally, the rate of surgical complications was consistent with the current literature. However, the sample size and the follow-up should be implemented to gather further evidence.

CONCLUSIONS: TDT is a non-invasive and well-accepted treatment which might positively impact on severe hypospadias repair. Further studies were needed to confirm these preliminary results.

UROLOGIA PEDIATRICA

Obstruction, vesicoureteral reflux

- Is there any difference in the incidence of urinary tract infections during stenting in patients undergoing pyeloplasty *vs.* high-pressure balloon dilation of the vesico-ureteral junction?

Is there any difference in the incidence of urinary tract infections during stenting in patients undergoing pyeloplasty *vs.* high-pressure balloon dilation of the vesico-ureteral junction?

A.L. Lopes Mendes, M. Innocenzi, G. Collura, E. Mele, L. Del Prete, A.C. Barneschi, M. Castagnetti (Rome)

BACKGROUND: Children with severe ureteropelvic junction obstruction (UPJ) and vesico-ureteral junction (VUJ) obstruction are at increased risk of urinary tract infection (UTI). Minimally invasive approaches including pyeloplasty and high-pressure balloon dilation for megaureter are currently used worldwide and the placement of ureteral double J (DJ) stent for urinary diversion remain the standard of care after treatment. However, every type of catheter is an ideal surface for bacterial colonization, with consequent risk of urinary tract infection (UTI). Aim of this study was to evaluate the UTI rate in patients treated for Obstructive UPJ and VUJ with DJ placement, pointing out possible risk factors and comparing pyeloplasty with balloon dilatation.

METHODS: A retrospective review of all medical records of patients how had DJ stent placement after pyeloplasty and high-pressure balloon dilation of the VUJ for primary megaureter between November 2017 to May 2020 was performed. The primary outcome was the incidence of urinary tract infection from the time of postoperative discharge until ureteral stent removal. Ureteral stent dwelling time, urinary tract infection, age, gender and more than one procedure were analyzed. We had two groups: group 1 pyeloplasty and group 2 balloon dilation. All patients were under antibiotic prophylaxis after the procedures until the ureteral stent removal.

RESULTS: 160 patients were included. Median age was 2.3 (3 months-17 year) years; 76.3% were boys. One hundred thirty-five (84%) underwent pyeloplasty and 25 (16%) high pressure balloon dilatation. The median DJ dwelling time was 45 days (IQR: 21-146) and was comparable between the two groups 48 and days and 45 days respectively for group 1 and group 2 (P=0.5). Overall, 12/160 (8%) of patients required hospital admission for UTI without difference between groups, 6% *vs.* 12%, P=0.4. Patients with UTI had a lower age even if not statistically significant 2.1 *vs.* 4.8 years old (P=0.07). Comparing patients who had UTI to those without UTI there was no statistical difference in term of age, gender, and dwelling double J time and previous UTI. A significantly higher incidence of UTI was observed in patients undergoing more than one procedure 25% *vs.* 6% (P=0.02). Indwelling ureteral stent are known to become colonized with bacterial in 90% of patients increasing the risk for symptomatic UTI. There is a cumulative risk for UTI correlated with stent dwelling time from 2% at 30 days to 9.2% at 90 days. In our study all patients received antibiotic prophylaxis after the procedure until DJ stent removal with 8% incidence of UTI. This result question the indication for antibiotic prophylaxis in these patients. In our study DJ stent dwelling time was not a risk factor for UTI, as suggested in literature, probably because of the short dwelling time, comparable with patients without UTI. However, in our experience, patients undergoing more than one procedure presented a higher risk of UTI. We believe that more surgical urinary tract manipulation increase the bacterial exposition and urinary tract may become more susceptible to bacterial colonization and infection.

CONCLUSIONS: The rate of UTI is comparable between patients undergoing pyeloplasty *vs.* balloon dilation and no predictive factor including age, gender and previous UTI correlated to the incidence of UTI. Patients undergoing more than one procedure were more likely to have UTI suggesting the need of different approaches preventing UTI in these patients.

UROLOGIA PEDIATRICA

Posterior urethral valves, neurogenic bladder, urorectal

- Sexuality in women with spina bifida: a challenge to overcome
- The value of preoperative urodynamics in preventive spinal cord untethering surgery: seeking help to prognosticate long-term voiding function

Sexuality in women with spina bifida: a challenge to overcome

M. Taverna, I. Infantin, G. Bortot, N. Firenzuoli, L. Olivera, A. Zulli, A. Mantovani, L. Landi, C. Cini, A. Elia, L. Masieri (Florence)

BACKGROUND: Spina bifida (SB) is a neural tube defect with a wide range of neurological sequelae, including motor, sensibility and continence disfunctions. Impact of this condition on sexual life may vary from irrelevant to prominent. Our aim was to investigate the impact of SB on young women sexuality.

METHODS: An anonymous questionnaire divided in four sections (demographic data with self-awareness, sexual activity with related problems, sexual education and eventual pregnancies), addressed to female patients older than 13 years old registered to regional and national SB associations, was uploaded through a link on the association's websites.

RESULTS: There were 83 responders to the questionnaire, of which 76% (57/83) older than 30 years old. Ninety-four percent (78/83) had different degree of urinary and fecal incontinence. Fifty-seven percent (48/83) were sexually active, with 83% (40/83) asserting that their experience was significantly influenced by SB. The major problems reported were sensibility (8%, 7/83) and continence (15%, 12/83), however 86% (71/83) patients felt pleasure during sex. Only 51% (42/83) of responders affirmed to have an appropriate sexual education. Thirty-nine percent (32/83) of sexually active subjects used contraceptives, especially condoms. Fifty-six percent (46/83) have not approached a gynecologist till date. From the questionnaire it was found that young women with SB are not less interested in sexual life, contrary to what society and medical professionals tend to believe. Incontinence was found to be a highly discouraging parameter as it induces shame with consequent decrease in libido and sexual pleasure. SB is a condition which needs deep understanding regarding the consequences in everyday life, including the sexuality, and there is no consensus described so far as such regarding sexual education for SB patients. Awareness regarding safe sexual practices such as the use of condoms and other contraceptives must be given in order to improve the quality of life of people suffering from this condition and to reduce the incidence of sexually transmitted infections and unplanned pregnancies, remembering that there is a high prevalence of severe latex allergy in these patients.

CONCLUSIONS: Sexuality is an often-overlooked topic in clinical practice with regards to this particular population; our study demonstrates how both patients and their clinicians do not understand and adequately apply the need for specific sex education, based on the peculiarities and needs of these patients.

The value of preoperative urodynamics in preventive spinal cord untethering surgery: seeking help to prognosticate long-term voiding function

C. Gatti, F. Caravaggi, M. Zucchelli, E. Casolari, M. Babini, B. Gardenghi, M. Lefosse (Parma)

BACKGROUND: In asymptomatic tethered cord, the role of preoperative urodynamics (UDS) is still controversial as it has failed to reveal the benefit in surgical decision and expectation of urological outcome. The main objective of this study was to reveal important preoperative UDS relevant to long term voiding pattern outcome.

METHODS: We retrospectively reviewed the data of 30 patients with asymptomatic tethered cord who underwent preventive spinal cord untethering (SCU). All patients underwent preoperative UDS and renal ultrasound. We considered the following UDS parameters: residual volume, compliance, detrusor-sphincter synergia. Postoperative voiding function was evaluated 6 months postoperatively and after the completion of toilet training (spontaneous or CIC). Voiding pattern distribution at each period was described. The relationship between preoperative UDS and voiding parameters and urinary continence after toilet training was assessed.

RESULTS: The mean age at preoperative UDS and SCU was 5.2 and 7.5 months respectively. Spinal lipoma was found in 81% of cases and lower lying conus in 69%. Regarding preoperative UDS,75% of the patients presented normal residual volume, normal compliance in 86.4% and detrusor-sphincter synergia in 94% of the cases. Patients completed toilet training at the mean of 3,6 years. Spontaneous voiding was noticed in 68.4% and 89.3% after 6 months from SCU and after completed toilet training. There is a significant correlation between detrusor-sphincter synergia and spontaneous voiding after 6 months of SCU and urinary continence after toilet training.

CONCLUSIONS: This study try to clarify the role of preoperative UDS in asymptomatic tethered cord patients. Our data assess that preventive untethering is highly associated to spontaneous voiding after toilet training. Only detrusor-sphincter synergia is correlated with spontaneous voiding after 6 months of SCU and urinary continence after toilet training.

UROLOGIA PEDIATRICA

Laparoscopy, robotics

- Robotic-assisted pyeloplasty in children: outcomes from two tertiary referral centers

Robotic-assisted pyeloplasty in children: outcomes from two tertiary referral centers

C. Cini, L. Olivera, A. Mantovani, G. Bortot, A. Zulli, A. Pili, M. Taverna, L. Landi, A. Elia, M. Gnech, F. Molinari, D.G. Minoli, E. De Marco, C. Bebi, I. Paraboschi, B. Giustozzi, G. Manzoni, A. Berrettini, L. Masieri (Florence)

BACKGROUND: We aimed to report outcomes and complications of patients (patients) treated with robot-assisted Anderson-Hynes pyeloplasty in two tertiary referral centers.

METHODS: We prospectively included all the consecutive patients treated from July 2012 to September 2021. We analyzed patients' characteristics, intra-operative(op) data, postop outcomes, and follow-up planned as ultrasound (US) and clinical evaluation at 3, 6 and every 12 months. Exclusion criteria were follow-up <12 months or age >20 years. Pelvis diameter (PD) reduction was used as early marker of success.

RESULTS: One hundred forty-two patients matched our criteria. da Vinci Si robot (Intuitive Surgical, Inc., Sunnyvale, CA, USA) was used in 92 patients (64.7%), da Vinci Xi (Intuitive Surgical, Inc.) in 50 (35.2%). Mean operative time was 147 min (55-360). In 135 patients (95.1%) the colon was medialized; in 7 (4.9%) the approach was transmesocolic (2 right side, 5 left). 55 (38.7%) presented a crossing vessel. The 3 children with urolithiasis were treated with trans-trocar intraoperative RIRS in 2 cases and with pyelolithotomy in 1 case. Two (1.4%) required conversion to open surgery. Abdominal drain was placed in 45 patients (31.6%) and removed after a mean of 3.7 days (3-7). A stent was placed in 99.3% of patients and maintained a mean of 44.6 days (23-201). No other intraoperative complications or bleedings >50 mL were reported. Mean length of hospital stay was 3.8 days (2-14). Five patients (3.5%) presented Clavien-Dindo I complications (3 paralytic ileus, 2 colic pain following the removal of the ureteral stent). Seven patients (4.9%) presented Clavien-Dindo III complications (5 stent malfunctioning or displacement, 2 laparoceles). Mean follow-up was 35.2 months (12-99). Mean postop PD was 13.8 mm (1-50). Mean reduction of the PD was 20.9 mm (-11 to 57) (57.3% [-68.8% to 98.0%] of the preopPD) (P<0.001). It was reduced in 135 patients (95.1%), the same in 4 (2.8%) and increased in 3 (2.1%). Two patients (1.4%) required reintervention. The rest showed acceptable renography and did not manifest recurrent symptoms, therefore they continued the follow-up. Our results are in line with the current literature in terms of success and complications reported. The main limit of our study is the variability of the preoperative evaluation and of the follow-up. We also aimed to increase the number of patients.

CONCLUSIONS: Robot-assisted pyeloplasty confirms to be safe and effective in pediatric patients.

UROLOGIA PEDIATRICA

Complex clinical case to discuss

- 3D-virtual reconstruction: usefulness in preoperative planning for oncologic renal surgery in children

3D-virtual reconstruction: usefulness in preoperative planning for oncologic renal surgery in children

E. Cerchia, S. Gerocarni Nappo, E. Teruzzi, P. Quarello, M. Della Corte, M. Mandaletti, M. Allasia, F. Fagioli, P. Gontero (Turin)

BACKGROUND: Preoperative planning for surgery of complex renal masses in children can be challenging, particularly in those cases where nephron sparing surgery (NSS) is desirable. We report our experience on the use of 3D virtual reconstruction (3D-VR) for complex renal masses in children.

METHODS: Included in the study were patients with a diagnosis of a renal mass with high grade of complexity either for extension and vascular anomalies or for definition of surgical approach. DICOM data were obtained from a preoperative abdominal MRI or CT scan, submitted to a process of a 2D manual segmentation and followed by a 3D reconstruction using specialized computer software. All data were deidentified. 3D-VR were used to assess anatomy (tumor, arteries, veins, and urinary collecting structures), and help in the decisional process on nephrectomy *versus* NSS.

RESULTS: 5 patients (3♂, 1♀) were studied. Age range was 1-15 years. 3D reconstructions were presented and discussed at the oncologic multidisciplinary meetings. One patient underwent open right nephrectomy, two open NSS, two robotic-assisted NSS. Mean operative time 230±48 mins (range: 200-260). No intraoperative or postoperative complications occurred. The volumetric reconstruction in case 1, 3, 4 and 5 defined the relationship between tumor and healthy renal tissue, the feasibility of NSS and optimized the selective clamping strategy. In case 2, the 3D-VR made clear the extent of the mass and identified vascular anomalies. 3D-VR construction proved a useful tool in the preoperative evaluation of children with complex renal masses.

CONCLUSIONS: 3D-VR limits of the study are the reduced number of patients and the subjective nature of the evaluation. Future research and multicenter prospective studies should be aimed at improving the speed, accuracy, and automation of the segmentation process for the 3D visualization and expanding its clinical use in pediatric oncologic surgery.

UROLOGIA PEDIATRICA

Stones, transplantation

- Epidemiology and treatment of pediatric urinary stone disease in two large-volume centers

Epidemiology and treatment of pediatric urinary stone disease in two large-volume centers

A. Morlacco, M. Gnech, A. Berrettini, M. Bianco, P. Beltrami, G. Montini, F. Taroni, M.C. Mancuso, M. Bruniera, E. Vidal, M. Sangermano, G. Longo, F. Dal Moro (Padua)

BACKGROUND: Pediatric stone disease is a relevant problem in clinical pediatric urology. Given the nature of the disease and the patients' population, choosing the most appropriate treatment is key and this is best accomplished in a specialized center. The aim of this study was to describe the patients' population and the results of urological treatment of urinary stones at two referral centers.

METHODS: Data of pediatric patients evaluated at two referral centers from 2009 to 2022 were retrospectively collected. Detailed information about patients' characteristics were gathered, including family history, associated urological conditions, and presenting symptoms. For patients who underwent active treatment, data about treatment modality, complications and stone-free rate were analyzed. Descriptive statistics were used to present the results.

RESULTS: Three hundred fifty-four patients were included. Median age at diagnosis was 69.5 months (IQR: 25.2-125). Median age at treatment was 88.5 months (IQR: 42.7-143). The size (mm) of the largest stone at the diagnosis was 9 (IQR: 5-14). Fifty-six percent of the patients were male and 44% female. One hundred two patients (30.5%) had familiarity for stone disease. 81 patients (24.3) were diagnosed under the age of 2 years, and 46 (13.8) under one year. Overall, 65 children (19.5%) had other urological conditions (VUR in 2.5%, GPU in 2.3%, POM in 1.7%, duplex system in 1.1). Two hundred sixteen patients underwent urological treatment of the stone disease. Specifically, ESWL was performed in 19.3%, URS in 20.8%, RIRS in 28.8%, PCNL in 18.4%; surgical treatment was carried out in 8% (including pyelolithotomy, pyeloplasty, ureterolithotomy). Intraoperative complications presented in 2% of the cases, including bleeding and urine leak, while 22 (10.8%) had early complications (more commonly fever). Nineteen patients (9.2%) experienced late complications. Regardless of the procedure modality, 124 patients (58.2%) were stone-free after the 1st procedure. Among the treated patients, 52 (25.4%) presented a relapse or worsening at a median follow-up of 47.5 months. Pediatric stone disease is rather uncommon in the general population, and the presentation modalities are rather peculiar of the pediatric age, with a quarter of all patients presenting under the age of 2. Overall, retrograde endourology is the preferred treatment modality. Regardless of treatment choice, 60% of the patients are stone-free after one procedure, with the others requiring additional treatments. Long follow-up is mandatory since more than 25% of the patients will experience relapse.

CONCLUSIONS: Urolithiasis is a relevant clinical problem for pediatric urology centers. Overall, for patients requiting operative treatment, the stone-free rate after a single procedure is about 60% and the relapse rate about 25%: appropriate patients' selection for each treatment modality and long follow-up are key.