ARTICLE

Risk of unfavorable outcomes after penile prosthesis implantation – results from a national registry (INSIST-ED)

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Like all surgeries, penile prosthesis implantation (PPI) has the potential for both postoperative complications and suboptimal patient satisfaction. In order to assess risk factors for poor satisfaction, we reviewed patients who had been prospectively recruited in a national multi-institutional registry of penile prostheses procedures (INSIST-ED) from 2014 to 20121. Patient baseline characteristics and postoperative complications were recorded. The primary endpoint of this study was unfavorable outcomes after inflatable PPI, defined as significant postoperative complications (Clavien–Dindo ≥2) and/or Sexuality with Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) scores below the 10th percentile. A total of 256 patients were included in the study. The median age was 60 years (IQR 56–67). The most common cause of erectile dysfunction (ED) was organic (42.2%), followed by pelvic surgery/radiotherapy (39.8%) and Peyronie's disease (18.0%). Postoperative complications were recorded in 9.6%. High-grade complications (Clavien ≥2) occurred in 4.7%. At 1-year follow-up, the median QoLSPP total score was 71 (IQR 65–76). In all, 14.8% of patients were classified as having experienced unfavorable outcomes because of significant postoperative complications and/or QoLSPP scores below the 10th percentile. Logistic regression analysis demonstrated patient age to be non-linearly associated with the risk of experiencing unfavorable outcomes. A U-shaped correlation showed a lower risk for younger and older patients and a higher risk for middle-aged men. ED etiology and surgical volume were not associated with PPI outcomes. Physicians should, therefore, be aware that middle-aged men may be at higher risk of being unsatisfied following PPI compared to both younger and older patients.

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INTRODUCTION

Penile prostheses have been in use for over 50 years [1]. According to the recent European Association of Urology and American Urology Association guidelines, the "stepwise" approach in the management of erectile dysfunction (ED) has been abandoned. An ED patient may have penile prosthesis implantation (PPI) as the first option if he seeks a permanent solution. Alternatively, PPI can be considered when pharmacological options are ineffective or not well-tolerated by the patient [2, 3].

Despite surgical risks such as device infection and mechanical failure [4, 5], several studies highlight generally high patient and partner satisfaction rates after PPI [4, 6]. Inappropriate patient counseling may lead to impaired satisfaction rates [7, 8]. The current literature, unfortunately, is limited and lacks high-powered

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studies investigating the risk factors for dissatisfaction in patients undergoing PPI [4–8].

This paper analyses the risk factors for unfavorable outcomes in terms of postoperative complications and low satisfaction after inflatable PPI using data from the national multi-institutional registry, the Italian Nationwide Systematic Inventarisation of Surgical Treatment for Erectile Dysfunction (INSIST-ED), to enable better patient selection and preoperative counseling.

MATERIALS AND METHODS

The INSIST-ED is a prospective national registry of implanted penile prosthesis open to all surgeons operating in Italy since December 2014 [9]. The registry has obtained ethics approval from the IRCSS Ospedale San Raffaele ethics committee (OSR – 140/2021). It includes demographics, surgical procedures, device information, surgical and functional outcomes, and duration of follow-up. Data are recorded by the implanting surgeons on a dedicated website (www.registro.andrologiaitaliana.it) and revised by a data manager. All patients and procedures included in the study were complied with ethical standards of the Helsinki Declaration and all subjects provided written informed consent. Overall, 35 surgeons practicing in 30 different centers provided data for the registry.

In the present study, data from the INSIST-ED registry relate to patients undergoing PPI from 2014 to 2021. Patients suffering from medically refractory ED undergoing inflatable PPI were included. Patients with neurological conditions, transgender males, revision cases or patients with incomplete follow-up data were excluded.

Preoperative evaluation included patient age at surgery, surgeon experience and ED etiology (iatrogenic, Peyronie's disease, vasculogenic, hormonal and metabolic).

The parameters considered for surgical outcome analysis included operative time, prosthesis model, drain placement, surgical approach (penoscrotal or infrapubic) as well as intraoperative and postoperative complications (Clavien–Dindo classification) [10] within 1 year post-PPI. Recording of complications was performed at the time of hospital discharge and on an outpatient basis at 1-, 6-, and 12-month follow-up.

Functional outcomes were assessed at 1-year follow-up with a validated questionnaire: Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) [11]. The questionnaire was administered to every patient via email or during a follow-up consultation in a clinical setting. The QoLSPP questionnaire consists of 16 items and explores patient perspectives after PPI through 4 domains: prosthesis function (5 items), relationship with the partner (4 items), social domain (3 items) and self-esteem (4 items). Each item ranges from "never" (0) to "always" [5], where higher values represent more positive responses with an overall score ranging from 0 to 80. Complete follow-up data were available for 256 patients treated with inflatable PPI.

Statistical analysis

Statistical analyses were performed using Stata 14 (StataCorp. 2009. Stata Statistical Software: Release 11. College Station, TX: StataCorp LP.), with a two-sided significance level set at $p < 0.05$. Normal distribution of variables was verified with the Kolmogorov–Smirnov test. Continuous variables with normal distribution were described using mean and standard deviation, while continuous variables with non-normal distribution were presented using median and interquartile range (IQR). Categorical variables were described using frequency and percentage.

This study aimed to assess the risk of unfavorable outcomes after inflatable PPI. Unfavorable outcomes were defined as the occurrence of a significant postoperative complication (Clavien–Dindo ≥2) within 1 year after surgery and/or a QoLSPP scores below the 10th percentile at follow-up assessment. We used logistic regression models to test the association between clinical characteristics and the risk of unfavorable outcome after surgery including age at surgery, surgeon experience and ED etiology. Locally weighted regression methods were used to explore the relationship between age and the probability of unfavorable outcome. Restricted cubic-splines were applied to test for the non-linear association between age and the investigated outcome.

RESULTS

At the time of the analysis in September 2021, the national register included 1502 implants. Among them, complete follow-up data of patients with inflatable devices were available for 256 patients. Median age was 60 years (IQR 56–67 years). Table 1 summarizes the patient's baseline characteristics. The most frequent ED etiology was organic in 108 (42.2%), followed by pelvic surgery/radiotherapy in 102 (39.8%) and Peyronie's disease in 46 cases (18.0%). Surgeon experience registered a median surgical volume of 54 (IQR 30–79) cases per year.

Table 2 describes device features and surgical approach for PPI. A three-piece penile prosthesis was used in 92.2% of cases, including 205 (80.1%) Boston Scientific – AMS 700CX, 28 (10.9%) Coloplast Titan Touch and 3 (1.2%) Zephyr ZSI 475. In the remaining 20 cases (7.8%) a Boston Scientific – AMS Ambicor inflatable device was implanted.

A penoscrotal approach for PPI was the most common approach utilized and it was performed in 78.1% of cases, while the infrapubic approach was adopted in the remaining 21.9%. Median operative time was 90 min (IQR 80–100); no significant differences in terms of operative time were detected between the different prosthetic devices ($p > 0.05$). A suction drain was applied in 97 (37.9%) cases and always removed within 48 h.

Intraoperative and postoperative complications are illustrated in Table 3. Intraoperative complications were uncommon (0.8%). These included a single case of distal cylinder crossover, which was immediately recognized and corrected and one case of distal urethral lesion, which led to device implantation abortion and delayed PPI. Postoperative complications within 1 year of follow-up were recorded in 22 patients (8.6%). The most frequently observed complication was penoscrotal hematomas that occurred

Table 1. Patient baseline characteristics.

Variables	Total
Number of patients, *n* (%)	256 (100)
Age at surgery, median (IQR)	60 (56–67)
ED etiology, *n* (%)	
Organic	108 (42.2)
Pelvic surgery/radiotherapy	102 (39.8)
Peyronie's disease	46 (18.0)
Surgical volume, median (IQR)	54 (30–79)

Table 2. Patient, surgical and penile prosthesis device characteristics.

Variables	Total
Number of patients, *n* (%)	256 (100)
Operative time, min (SD)	90 (80–100)
Type of inflatable device, *n* (%)	
2-piece	20 (7.8)
3-piece	236 (92.2)
Inflatable models, *n* (%)	
Boston Scientific – AMS Ambicor	20 (7.8)
Boston Scientific – AMS 700CX	205 (80.1)
Coloplast Titan Touch	28 (10.9)
Zephyr ZSI 475	3 (1.2)
Surgical volume, median (IQR)	54 (30–79)
Surgical approach, *n* (%)	
Penoscrotal	200 (78.1)
Infrapubic	56 (21.9)
Drain placement, *n* (%)	
Yes	97 (37.9)
No	159 (62.1)

Table 3. Postoperative complications and unfavorable outcomes.

Variables	Total
Number of patients, *n* (%)	256 (100)
Intraoperative complications, *n* (%)	2 (0.8)
Distal cylinder crossover, *n* (%)	1 (0.4)
Urethral lesion, *n* (%)	1 (0.4)
Postoperative complications, *n* (%)	22 (8.6)
Clavien–Dindo classification, *n* (%)	
I	10 (3.9)
II	2 (0.8)
IIIa	10 (3.9)
IIIb	0 (0)
IV	0 (0)
V	0 (0)
Low-grade complication (I), *n* (%)	10 (3.9)
Hematoma, *n* (%)	10 (3.9)
High-grade complication (≥II), *n* (%)	12 (4.7)
Wound infection and fever, *n* (%)	2 (0.8)
Malpositioning, *n* (%)	4 (1.6)
Painful intercourse, *n* (%)	1 (0.4)
Erosion, *n* (%)	2 (0.8)
Glans necrosis, *n* (%)	1 (0.4)
Prosthesis malfunctioning, *n* (%)	2 (0.8)

Table 4. QoLSPP scores at 1 year after penile implant surgery.

Variables	Scores
Number of patients, *n* (%)	256 (100)
QoLSPP domains, median/total (IQR)	
1. Functional domain score (5 items)	22/25 (20–24)
2. Personal domain score (4 items)	18/20 (17–20)
3. Relational domain score (4 items)	17/20 (15–19)
4. Social domain score (3 items)	13/15 (11–15)
Total score	71/80 (65–76)
QoLSPP score below the 10th percentile, *n* (%)	26 (10.1)
Patients with unfavorable outcomes in inflatable PPI, *n* (%)	38 (14.8)

QoLSPP Quality of Life and Sexuality with Penile Prosthesis questionnaire.

in 10 cases (3.9%): all treated with conservative measures such as ice bag application, mild compression dressing and anti-inflammatory drugs (grade 1). Clavien–Dindo grade 2 and 3 complications occurred in 2 (0.8%) and 10 (3.9%) patients, respectively. A wound infection was identified in 0.8% of patients, necessitating the administration of antibiotics (grade 2). Clavien–Dindo grade 3 complications required surgical revision, including debridement for glans necrosis (0.4%), complete penile prosthesis removal (2.8%), or replacement of the dysfunctional unit in case of prosthesis malfunction (0.8%).

Table 4 reports postoperative functional outcomes at 1-year follow-up. QoLSPP scores showed high satisfaction rates in all QoLSPP domains with 26 patients (10.1%) reporting a lower satisfaction rate with QoLSPP score being below the 10th percentile. Overall, the median total score of QoLSPP was of 71 (IQR 65–76).

Unfavorable outcomes were recorded in 38 patients (14.8%) because of significant postoperative complications (12 patients, 4.7%) and/or QoLSPP score below the 10th percentile (26 patients, 10.1%). At logistic regression analysis (Table 5), age emerged to be non-linearly associated with the risk of experiencing unfavorable outcomes ($p = 0.01$) after PPI. Younger and older patients appear to be associated with a lower risk of unfavorable outcomes as compared to middle-aged (45–70 years) men (Fig. 1).

Table 5. Logistic regression analysis: risk of unfavorable outcomes following inflatable PPI.

	OR	95% CI	*p* value
Age[a]	–	–	0.01
ED etiology			
Pelvic surgery vs. Organic	1.04	0.42, 2.58	0.9
Pelvic surgery vs. Peyronie's	0.75	0.24, 2.41	0.6
Surgical volume	1.00	0.96, 1.03	0.9

[a]Modeled with non-linear terms.

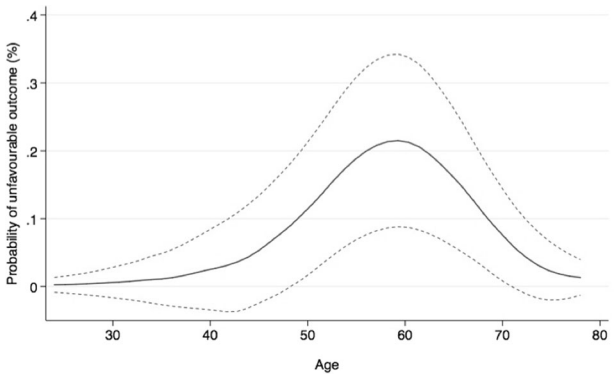

Fig. 1 Probability of unfavorable outcomes associated with age at the time of surgery.

DISCUSSION

This study presents the outcomes of a relatively large cohort of patients who underwent inflatable PPI. We observed an overall complication rate of 8.6%, with clinically significant complications (Clavien ≥2) in 4.7%, which is comparable to other studies [4]. Among all significant complications, 0.8% required the administration of antibiotics due to wound infection with fever, while the remaining cases (3.9%) necessitated surgical revision. The QoLSPP questionnaire showed an overall median score of 71 out of 80 at 1-year follow-up, with low satisfaction rates recorded in 10.1% of cases, which correlates with previously reported literature [12–16]. We report unfavorable outcomes after PPI surgery in 14.8% of cases. Patient age correlated with postoperative outcomes, with middle-aged men being at higher risk of worse outcomes in terms of significant complications and satisfaction rates, whereas ED etiology and surgeon volume did not affect postoperative outcomes. This compares similarly to other descriptions in the literature, with over 90% of patients satisfied with their surgery [17–19].

Within the current literature, several factors were associated with postoperative complications and patient satisfaction rates after PPI. The most frequently reported predictors of satisfaction were appropriate preoperative counseling by providing realistic expectations [20], surgeon experience and timing of surgery. In 2010, Kramer et al. [8] published a linear negative correlation between preoperative expectations and postoperative patient satisfaction, suggesting the importance of exhaustive and properly conducted preoperative counseling.

One of the most common complications of PPI is postoperative bleeding and hematoma formation, potentially leading to a slower recovery and patient discomfort. One procedure that may be adopted to minimize the risk of this complication is the use of closed suction drain (CSD). However, its use in penile implant surgery remains controversial [21]. Recent studies advocate for the use of drainage placement in PPI. In a single-institution retrospective study, Apoj et al. [22] demonstrated an almost linear association between surgical time and CSD output, suggesting the placement of CSD in all patients undergoing PPI, especially in cases with longer operative times. Furthermore, in a multicentric prospective nonrandomized pilot study, Osmonov et al. [23] showed that prolonged scrotal drainage for 72 h after virgin PPI significantly reduces hematoma and infection rates. Specifically, the prevalence of hematoma was 0.9% in the group with a drain placed for 72 h, compared to 9.6% in the group without a drain. In the multicenter prospective study (PROPPER study) [24], 1348 patients were stratified into drain (47%) and no-drain (53%) groups. Hematoma formation was observed solely in the drain group (0.006%), possibly due to drains being preferred in complex cases prone to bleeding. Even within this series, drainage use did not result in higher infection rates. In our study, a penoscrotal hematoma occurred in 3.9% of cases. This finding can be attributed to the application of CSD at the discretion of the individual surgeon in 37.9% of cases, and it was always removed within 48 h.

In patients who can benefit from prosthesis surgery, it is crucial to avoid delaying the indication for surgery if the patient expresses a preference for it. It is important to prevent unnecessary delays and to maintain the penile length. A recent paper by Van Huele et al. [25] aimed to assess whether patients and their partners would have preferred earlier implantation of a penile prosthesis. The results indicate that a significant proportion of patients (59.4%) and partners (46.2%) expressed a preference for earlier PPI, even more than 5 years earlier in some cases. When considering PPI in a later setting, it is important to implement length maintenance strategies for patients with refractory ED to prevent penile fibrosis, penile shortening and impaired quality of life [26, 27]. Deveci et al. [28] reported that 71% of men undergoing PPI complained of subjective length loss. Likewise, Wang et al. [29] reported a statistically significant decrease in erect penile length at 6 weeks, 6 months and at 1 year after PPI in 45% of patients. To minimize penile length loss, Pryor et al. [16] showed that a postoperative penile rehabilitation program with maximal inflation of the device for 1 or 2 h daily for 6, 12, and 24 months can preserve penile length and ultimately improve patient satisfaction after PPI.

Whilst counseling is important, surgeon volume (with high volume defined as at least 15 procedures performed per year) is associated with shorter operative time, fewer complications and decreased risk of PPI surgical revision [30–32]. In fact, Capogrosso et al. [15] observed a non-linear association ($p < 0.03$) between surgeon experience and QoLSPP scores (total and individual domains. Higher scores were achieved as the surgeon conducted a greater number of procedures per year, reaching a plateau after 15 procedures annually.

Other negative predictor factors for satisfaction and complications include tobacco smoking, diabetes, previous pelvic radiotherapy, and corporal fibrosis. Smoking and diabetes have demonstrated a negative impact on postoperative wound healing, increasing the risk of infection [33, 34]. However, this issue remains a subject of debate in the PPI literature. Indeed, Osman et al. [35], in a multi-institutional retrospective review involving 932 diabetic patients undergoing primary PPI, concluded that preoperative hemoglobin A1c and preoperative blood glucose levels are not associated with an increased risk for postoperative infection, or explantation within this group of patients. In another study conducted by Habous et al. [36], a threshold hemoglobin A1c level of 8.5% was found to predict infection with a sensitivity of 80% and a specificity of 65%. Therefore, this value was recommended for clinical use in identifying patients at an increased risk of infection. Radiotherapy-induced corporal fibrosis has been shown to negatively interfere with PPI outcomes, particularly for the onset of de novo chronic penile pain [37]. Akin-Olugbade et al. [38] reported that patients with prior radical prostatectomy, Peyronie's disease, or body mass index higher than 30 kg/m^2 have a higher relative risk (from 2 to 4.2) for lower satisfaction rates after PPI compared to patients without these characteristics. This finding may be partly explained by the fact that patients with BMI >30 kg/m^2 or affected by Peyronie's disease are generally the ones experiencing greater degrees of relative penile shortening. Peyronie's disease-affected patients, because of complex penile deformities, may have residual curvature, penile plaques or shortening after PPI, heavily influencing postoperative expectations [38, 39]. Similarly, patients with preoperative normal erectile function prior to radical prostatectomy may demonstrate lower satisfaction rates after PPI due to the significant difference between pre- and postoperative sexual function [38, 40].

A further potential in PPI satisfaction was the age of the patient at the time of implantation. Several studies show equivalent satisfaction rates for older patients undergoing PPI [41]. Chung et al. [42] showed that men aged ≥75 years reported comparable satisfactory outcomes and device survival rate with inflatable PPI compared to men aged <75 years. Unfortunately, studies analyzing satisfaction rates after PPI in young patients are lacking due to a lower incidence of ED in this population. Our study is in line with the previously published data about older men, having demonstrated a higher risk for poor outcomes in middle-aged patients compared to younger and older groups.

Although evidence free, this finding may be explained by the fact that middle-aged patients may have better recall of sexual activity quality and penile length before PPI implantation, as well as the finding of penile shortening after PPI. Or perhaps older patients may have lower expectations from surgery to restore sexual function. Furthermore, middle-aged patients may be more likely to require surgical revision in consideration of the longer time interval in which PPI will be used compared to older patients. Unfortunately, there are no comparative data between the middle-aged and the younger population. It is not clear why younger patients demonstrated higher satisfaction rates. We postulate that they finally achieved satisfactory penetrative sexual activity compared to the preoperative difficulties, which may have always interfered with their previous quality of sexual intercourse. It is also true that over time, even for these young patients, the risk of PPI revision is increased compared to older patients.

The main limitation of the study is its retrospective nonrandomized nature. Whilst it is a multicenter, relatively large-sized study and that several surgeons are involved, data entry and subsequent follow-up were on a voluntary basis. The 12-month follow-up could be a further limitation as some of the complications related to penile prosthesis can occur over a longer period of time (prosthesis malfunctioning or pending erosion) and therefore the reported general satisfaction may be somewhat overestimated.

The preliminary data reported in our study should be confirmed in future multicenter randomized trials with a larger number of patients and longer follow-ups.

CONCLUSION

Unfavorable outcomes in terms of both postoperative complications and low QoL scores are not uncommon after inflatable PPI. Our findings suggest that physicians should adequately counsel middle-aged men regarding the higher risk of being dissatisfied after PPI compared to both younger and older patients. Further comparative studies with larger series and longer follow-ups are needed to confirm the preliminary results.

DATA AVAILABILITY

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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COMPETING INTERESTS

The authors declare no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was performed in accordance with the Declaration of Helsinki and was approved by the local ethics committee of IRCSS Ospedale San Raffaele (OSR – 140/2021). A written informed consent was obtained from all subjects enrolled in the present study.

ADDITIONAL INFORMATION

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