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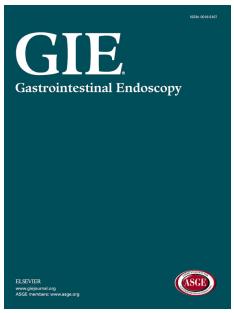

Safety and efficacy of endoscopic ultrasound-guided pelvic abscess drainage with lumen-apposing metal stents for complicated acute diverticulitis.

Andrea Lisotti, Dr., Francesca D'Errico, Dr., Pietro Fusaroli, Prof., Francesco Decembrino, Dr., Graziella Masciangelo, Dr., Tawfik Khoury, Dr., Giovanni Barbara, Prof., Sarah Leblanc, Dr., Vincent Lepilliez, Dr., Bertrand Napoléon, Dr., Gianfranco Donatelli, Prof.

PII: S0016-5107(25)00072-0

DOI: https://doi.org/10.1016/j.gie.2025.02.003

Reference: YMGE 14704

To appear in: *Gastrointestinal Endoscopy*

Received Date: 28 September 2024

Revised Date: 29 December 2024

Accepted Date: 3 February 2025

Please cite this article as: Lisotti A, D'Errico F, Fusaroli P, Decembrino F, Masciangelo G, Khoury T, Barbara G, Leblanc S, Lepilliez V, Napoléon B, Donatelli G, Safety and efficacy of endoscopic ultrasound-guided pelvic abscess drainage with lumen-apposing metal stents for complicated acute diverticulitis., *Gastrointestinal Endoscopy* (2025), doi: https://doi.org/10.1016/j.gie.2025.02.003.

Title: **Safety and efficacy of endoscopic ultrasound-guided pelvic abscess drainage with lumen-apposing metal stents for complicated acute diverticulitis.**

Running title: **EUS pelvic abscess drainage with LAMS**

Authors: Andrea Lisotti*, Dr., [1,2], Francesca D'Errico*, Dr., [3,4], Pietro Fusaroli, Prof., [1], Francesco Decembrino, Dr., [3], Graziella Masciangelo, Dr., [1], Tawfik Khoury, Dr., [2,5,6], Giovanni Barbara, Prof., [7], Sarah Leblanc, Dr., [2], Vincent Lepilliez, Dr., [2], Bertrand Napoléon, Dr., [2], and Gianfranco Donatelli, Prof. [4]

Affiliations:

1 Gastroenterology Unit, Hospital of Imola, University of Bologna, Imola (Bologna), Italy;

2 Gastroenterology Unit, Hôpital Privé Jean Mermoz, Ramsay Generale de Santé, Lyon, France;

3 Gastroenterology and Endoscopy Unit, Ente Ecclesiastico F. Miulli, Acquaviva delle Fonti, Bari, Italy;

4 Interventional Endoscopy Unit, Hôpital Privé des Peupliers, Ramsay Générale de Santé, Paris, France.

5 Department of Gastroenterology, Galilee Medical Center, Nahariya, Israel.

6 Azrieli Faculty of Medicine, Bar-Ilan University, Safed, Israel.

7 Department of Medical and Surgical Sciences – DIMEC, University of Bologna, Bologna, Italy.

Grant support: The Authors received no support or funding for this study.

Conflict of interest: Andrea Lisotti, Pietro Fusaroli, Bertrand Napoléon received consultancy from Boston Scientific Corporation; all other Authors declared no conflict of interest.

Writing assistance: No writing assistance was required to draft the manuscript.

Authors' contributions: * Andrea Lisotti and Francesca D'Errico contributed equally to the manuscript and share first co-authorship; Andrea Lisotti, Francesca D'Errico, and Graziella Masciangelo wrote the manuscript; all authors performed EUS procedures, collected data and are responsible for patients'

management; Tawfik Khoury, Pietro Fusaroli, Giovanni Barbara, Bertrand Napoléon and Gianfranco Donatelli revised the manuscript for pivotal intellectual content. All Authors approved the final version of the manuscript.

Correspondence to:

Dott. Andrea Lisotti, MD

Gastroenterology Unit, Hospital of Imola.

Department of Medical and Surgical Sciences, University of Bologna, Italy

Via Montericco 4; 40026 Imola (BO), Italy.

E-mail: lisotti.andrea@gmail.com

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1 Gastroenterology Unit, Hospital of Imola, University of Bologna, Imola (Bologna), Italy;

2 Gastroenterology Unit, Hôpital Privé Jean Mermoz, Ramsay Generale de Santé, Lyon, France;

3 Gastroenterology and Endoscopy Unit, Ente Ecclesiastico F. Miulli, Acquaviva delle Fonti, Bari, Italy;

4 Interventional Endoscopy Unit, Hôpital Privé des Peupliers, Ramsay Générale de Santé, Paris, France.

5 Department of Gastroenterology, Galilee Medical Center, Nahariya, Israel.

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Writing assistance: No writing assistance was required to draft the manuscript.

Authors' contributions: * A.L. and F.D.E contributed equally to the manuscript and share first co-authorship; A.L., F.D.E., and G.M. wrote the manuscript; all authors performed EUS procedures, collected data and are responsible for patients' management; T.K., P.F., G.B., B.N. and G.D. revised the manuscript for pivotal intellectual content. All Authors approved the final version of the manuscript.

Keywords: EUS-PAD; diverticulitis; post-surgical collection; Hot-Axios.

Correspondence to:

Dott. Andrea Lisotti, MD

Gastroenterology Unit, Hospital of Imola.

Department of Medical and Surgical Sciences, University of Bologna, Italy

Via Montericco 4; 40026 Imola (BO), Italy.

E-mail: lisotti.andrea@gmail.com

Abstract

Background and Aims. Endoscopic ultrasound-guided pelvic abscess drainage (EUS-PAD) with lumen-apposing metal stents (LAMS) is an alternative approach for post-surgical and inflammatory pelvic collections. We assess the safety and efficacy of EUS-PAD with LAMS in a large population of complicated–acute diverticulitis (AD).

Methods: We retrieved consecutive patients who underwent EUS drainage attempts for complicated AD from 2019-2023 in three referral centers. All cases have been considered suitable for EUS-PAD after multidisciplinary discussion. Continuous variables are expressed as median [interquartile range].

Results: Sixty-six patients were retrieved; in 13 cases EUS-PAD was not indicated since no or small abscess was found. Fifty-three patients (29 female; age 74 [62-83] year-old] were finally included. Forty (75.5%) patients had pelvic abscess, while 13 (24.5%) had a para-colonic abscess, with a median size of 50 [40-60] mm. Trans-rectal and trans-colonic EUS-PAD were performed in 34 (64.2%) and 19 (35.8%) cases, respectively. Technical and clinical success rates were 92.5% and 88.7%; incidence of adverse events was 3.8% (one bleeding, one late migration). LAMS were removed after 19 [14-28] days. Median follow-up was 12 [8-12] months. Four (7.5%) patients underwent urgent Hartmann sigmoidectomy, while 12 (22.6%) patients required elective surgery; two (3.8%) patients presented recurrent diverticular abscesses. No procedure-related or disease-specific mortality was observed.

Conclusion: EUS-PAD could be considered a safe and effective rescue strategy in case of failed or contraindicated percutaneous approach for the management of complicated AD to reduce the need for urgent surgery. Comparative data is necessary to confirm these observations.

Introduction

Conservative treatments with bowel rest and systemic antibiotics represent the first-line approach for acute diverticulitis (AD); the occurrence of abdominal or pelvic abscess is a rare but severe complication of AD. [1-6]

The presence of peri-colonic, meso-colonic or pelvic abscess characterize grade Ib and grade II AD, according to modified Hinchey classification. [7] Abscess larger than 4 cm or failure to antibiotic treatments represent an indication for drainage, since antibiotic treatment often fails to reach adequate concentrations. Drainage was usually performed through a percutaneous or trans-gluteal approach under ultrasound or computed tomography (CT) guidance; however, percutaneous drainages were burdened by a high rate of technical and clinical failure (up to 35%), long healing time and hospitalization, patients' discomfort, and long-term risk of entero-cutaneous fistula development. Trans-rectal and trans-vaginal approaches, using endocavitary ultrasound probes, have been proposed due to the possibility of avoiding the peritoneal cavity for assessing pelvic inflammatory collections. On the other hand, surgical approach is more effective, but a not-negligible risk of morbidity and mortality should be taken into account. A systematic review of 42 observational studies demonstrated that patients suffering from complicated AD requiring urgent surgery presented a significantly increased mortality (up to 10 times) compared to those managed conservatively. [1,8]

Endoscopic ultrasound (EUS)-guided pelvic abscess drainage (EUS-PAD) has been reported as a safe and effective alternative approach for inflammatory and post-surgical pelvic collections. [9-12] In this field, two meta-analyses including several studies with different indications reported an optimal pooled technical and clinical success rate (100% and up to 90%, respectively) with a good safety profile, suggesting that EUS-PAD could represent a viable alternative to reduce the need for surgery. [13,14] Recently, a single-center case series suggested that EUS-PAD with lumen-apposing metal stents (LAMS) is safe and effective in this field; [15] however, to date, no robust evidence is available on the outcomes of EUS-PAD in patients complicated AD.

The aim of this study was to assess the safety and efficacy of EUS-PAD with LAMS in a large homogeneous population of patients with complicated AD, after failure of antibiotic treatment and failed or impossible percutaneous drainage approach.

Methods

Study design. A retrospective analysis of three prospectively-maintained databases was conducted, retrieving all patients with complicated AD with abscess who underwent an EUS drainage attempts between January 2019 to June 2023.

Inclusion criteria were: 1) adult patients (>18 years old); 2) complicated AD with peri-colonic, meso-colonic or pelvic mature and encapsulated abscess on CT scan; 3) failed attempt or contraindication for percutaneous drainage; 4) failure of systemic antibiotic treatment in controlling inflammation; 5) high-risk for urgent surgery assessed on multidisciplinary discussion; 6) patients undergoing attempt for EUS drainage. Exclusion criteria were: 1) previous colonic or rectal surgery; 2) clinical or radiologic signs of colonic perforation or peritonitis; 3) significant alteration of coagulative status; 4) anticoagulant agents that cannot be withdrawal; 5) patients' refusal of participating in the study; 6) cases already published in previous studies.

All patients underwent abdominal CT on admission. All cases were discussed by each Multidisciplinary Team, including interventional endoscopists, surgeons, and interventional radiologists. All patients were assessed with trans-abdominal ultrasound and CT-scan for percutaneous drainage approach; when a potential therapeutic window was identified, an interventional radiologist approach was attempted. EUS-PAD was considered a rescue strategy when percutaneous attempts failed or considered contraindicated for lack of a therapeutic window. Written informed consent was obtained specifying the off-label LAMS use. The protocol was evaluated by each Institution Review Board and conducted according to local policy on retrospective studies.

EUS-PAD procedure. All patients received systemic antibiotics and supportive treatment when necessary. Bowel preparation was prescribed if not contraindicated by colonic occlusion; in case of occlusion, two enemas were performed before endoscopic procedure. All procedures were conducted in the endoscopic

room using a linear-EUS scope (GF-UCT-180, Olympus, Tokyo, Japan) coupled with the EU-ME2 (Olympus, Tokyo, Japan) ultrasound processor; fluoroscopy was available and used upon operator decision. Patients were placed in left lateral position under deep sedation or general anesthesia, based on anesthesiologist indication. Electrocautery-enhanced LAMS (Hot-Axios, Boston Scientific, Massachusetts, US) was placed under direct EUS guidance, using the pure cut mode of the electrosurgical unit, with the "free-hand" and "intra-channel release" techniques. Stent size was chosen on a case-by-case evaluation based upon anatomical and endoscopic assessments.

Clinical follow-up and stent removal. Oral feeding was resumed after 12-24 hours. Antibiotic treatment was maintained until clinical and biochemical resolution of sepsis. A CT scan was planned within 2 weeks. LAMS was removed upon radiological findings of abscess resolution, using an operative gastroscope and a retrieval forceps; a double pig-tail plastic stent was inserted based on operator preference. Patients were followed-up for at least 12 months or until surgery.

Definitions. Severity of AD was stratified according to Hinchey classification [7]. Technical success was defined as the proper LAMS deployment within the abscess during the index procedure, confirmed by EUS or fluoroscopy evaluation, and endoscopic observation of pus drainage into the lumen. Clinical success was defined as the resolution of sepsis and pelvic abscess, without any need for further interventional procedures (either endoscopic, percutaneous, or surgical). Abscess resolution was defined as the complete disappearance of any radiological finding of pelvic or peri-colonic collection on CT-scan. Adverse events were defined according to endoscopic and EUS lexicons [16] and graded according to the AGREE classification [17]. Abscess recurrence was defined as a *de novo* clinical and radiological presentation of complicated AD ~~with abscess~~ after the resolution of the index event; all CT findings of a >10 mm collection, both in the same location or far from the previously treated, were considered as abscess recurrence. Need for surgery was categorized into urgent or elective.

Statistical analysis. Continuous variables were reported as mean ± standard deviation (SD) or as median and interquartile range [IQR] based on their distributions. Categorical variables were reported as number and percentages (%). Factors related to technical success were analyzed using logistic regression and reported as

odd ratios (OR) and 95% confidence intervals (95% C.I.); factors with a P value <0.20 on univariate analysis were included in the multivariate model. P < 0.05 was considered statistically significant. Statistical analysis was conducted using MedCalc® Statistical Software version 22.016 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2023).

Results

Study population. Eleven previously published EUS-PAD for complicated AD have not been included in the present study. [12, 15] Sixty-six patients admitted for complicated AD with abscess underwent EUS attempts for drainage during the study period. All patients have been considered contraindicated for percutaneous ultrasound-guided approach due to the depth of the collection and gut lumen interposition with shadowing due to gas content. In 48 cases (72.7%), interventional radiologists did not identify a potential therapeutic window on CT-scan; in these cases, percutaneous approach was considered contraindicated. In 18 cases (27.3%), a CT-guided percutaneous drainage was attempted but failed due to the depth of the collection or presence of interposing organs or vessels. Therefore, 66 patients underwent EUS attempts for EUS-PAD; in 5 cases no collection was identified on EUS, while in 8 cases drainage was not indicated due to small abscess size (< 20 mm). Fifty-three patients (29 females, median age 74 [62-83] years) were finally included in the intention-to-treat analysis; study flow-chart was detailed in Figure 1. Patients' baseline characteristics were reported in table 1. In detail, no patients had fecal diversion; 10 (18.9%) were on low molecular weight heparin and 12 (22.6%) on antiplatelet agents. Thirteen patients (24.5%) had a stage Ib AD according to Hinchey classification, while the remaining 40 (75.5%) had a grade II AD. Median collection size on EUS was 50 [40-60] mm.

EUS-PAD procedures. Technical details and procedural outcomes were reported in table 2. The procedure was conducted under conscious sedation in 14 cases, deep sedation in 12 cases, and general anesthesia in the remaining 27 cases. A trans-rectal approach was used in 34 (64.2%), while trans-colonic approach in the remaining 19 (35.8%) cases. Six patients received concomitant ultrasound-guided percutaneous drainage. In four cases the procedure was aborted, and no LAMS was used or unwrapped. In one case multiple gateway

EUS-PAD was deemed indicated with the deployment of two LAMS. A 6x8 mm LAMS was used in 2 cases, 8x8 mm in 11 cases, 10x10 mm in 21 cases, 15x10 mm in 15 cases, and 15x15 mm in one case.

Procedural outcomes. No misdeployment was reported. Technical success was obtained in 49 (92.5%) patients. Technical failure was due to the presence of sigmoid strictures (n= 3) or distance between the abscess and the GI wall (n= 1); these patients underwent urgent Hartmann resection (n= 2), an urgent second attempt of percutaneous CT drainage with trans-gluteal approach (n= 1), and elective sigmoid resection (n= 1). Among the entire study population, clinical success was achieved in 47 (88.7%) patients. In two cases, no clinical success was obtained despite EUS-PAD; these patients underwent urgent Hartmann resection. Overall, 4 patients (7.5%) required urgent surgery. Overall incidence of adverse events was 3.8%; in detail, one minor procedural bleeding that prolonged patient's hospitalization with no specific treatment required (AGREE II), and one late proximal LAMS migration that required urgent endoscopic retrieval (AGREE IIIa). No in-hospital mortality was observed. LAMS was removed after a median 19 [14-28] days, and a double pigtail plastic stent was placed in 9 (17.0%) cases.

Table 3 showed the analysis of factors related to EUS-PAD technical success; univariate analysis showed that, nor patients' age or gender were related to technical success; trans-rectal approach showed a trend toward a higher technical success. Abscess size ≥50 mm was the only variable independently related to technical success (OR 18.0; 95% C.I. 1.63 – 198;]; P=0.0).

Long-term follow-up. Patients were followed-up for a median of 12 [8-12] months. Twelve (22.6%) patients underwent elective surgery. Two (3.8%) patients presented recurrent diverticular abscess. Nor three-months mortality or disease-specific mortality was observed during the follow-up. Overall, 1-year mortality was 7.6%. Spontaneous tract closure after stent removal was observed in all cases (n= 31) who underwent subsequent endoscopy, CT scan, or fluoroscopic contrast enema.

Discussion

EUS-PAD is a safe and effective treatment for complicated grade Ib and II AD, with an optimal technical and clinical success rate and a very low incidence of mild adverse events. The results of this study including a

homogeneous population of 53 patients with complicated (grade Ib or II) AD demonstrated that the EUS-PAD showed a 92.5% technical and 88.7% clinical success rates; moreover, we observed only two (3.8%) mild adverse events.

To date, the first-line conservative treatment for large pelvic abscess is percutaneous image-guided drainage; however, this approach is limited by possible organ interposition (i.e. bowel limbs, uterus or urinary bladder), and burdened by the high risk of entero-cutaneous fistulization or even sciatic nerve injury [18,19]; in addition, CT-guided PAD approach is burdened from up to 30% of technical failures. [20] Trans-rectal and trans-vaginal approaches, using endocavitary ultrasound probes, have been proposed due to the possibility of avoiding the peritoneal cavity or interposed organs for assessing pelvic inflammatory collections. However, even when technically and clinically effective, the drainage of deep pelvic abscess requires a prolonged and often painful recovery. A recent study showed that abscess drainage significantly reduces the need for urgent surgery and abscess recurrence, with a dramatic impact on patients' morbidity and mortality. Indeed, a significantly increased mortality (12% vs. 1%) was observed in patients requiring urgent surgery. [8] We retrieved all cases with large pelvic abscesses or non-responsive to antibiotic treatment in which percutaneous approach was not feasible; in these cases, EUS-PAD was intended as a rescue strategy to spare urgent surgery and its consequences.

While large and robust evidence on the efficacy of EUS interventions is mainly focused on biliary drainage and management of pancreatic fluid collections, [21-23] data on the feasibility of EUS drainage of pelvic collections and abscess are scant and usually based on small and inhomogeneous populations. Moreover, most studies report about the use of plastic stents. A large French study reported a 5-year clinical success rate of 86.5% in 37 patients; however, only 4 patients were treated with LAMS and experienced poor results in terms of adverse events and need for subsequent surgery. [9, 24]

In our study, EUS-PAD technical failure was reported in four patients, due to the presence of a sigmoid stricture in three cases and to the distance between the abscess and the GI wall in one case; among them, two underwent urgent Hartmann resection, one a second attempt of percutaneous CT drainage with trans-gluteal approach, and one an elective sigmoid resection. On the other hand, we observed clinical success in

47 out of 49 patients with technically successful EUS-PAD. Both cases with no clinical success required urgent Hartmann resection. Overall, when EUS-PAD was not technically feasible the need for urgent surgery was up to 50% (2 patients out of 4); on the other hand, when EUS-PAD was performed with technically successful LAMS deployment, a dramatic reduction in the need for surgery was observed (2 out of 49, 4.1%). We speculate that EUS-PAD with LAMS provided effective local inflammatory control, allowing to avoid urgent surgery.

LAMS placement from the rectum or left colon is usually avoided due to the theoretical risk of fecal contamination due to the large stent diameter, compared to double pigtail plastic stents. To the best of our knowledge, no data on an increased risk of infectious adverse event is available. [9,11] Moreover, LAMS use has been proposed to perform entero-colonic anastomoses in patients with lower malignant occlusion. [25]

We speculate that the negative pressure of the gut lumen together with the high-pressure of an infected collection allows pus drainage from the abscess, preventing from fecal contamination. However, we suggest a tight follow-up (CT scan within 2 weeks) to remove the LAMS at the time of the resolution of the collection. As demonstrated in the setting of EUS-guided drainages for pancreatic fluid collections, also in this setting we do not have any evidence supporting a difference between LAMS and double pig-tail plastic stents use in terms of safety and efficacy. During the study period, only 7 cases of EUS-PAD have been performed using double pig-tail plastic stents in patients with complicated AD, mostly when there is the suspicion of an incompletely capsulated collection. Therefore, we did not perform comparative studies and limited our population to patients with capsulated abscess drained with LAMS to provide a homogeneous and reproducible setting. Thus, the results of this study do not provide evidence to support that LAMS should be preferred over plastic stents. [22,23]

Our results underlined a significantly higher technical success rate in patients with larger (≥50 mm) abscess. This finding could be easily explained by the need for an adequate space to insert the electrocautery-enhanced tip of the delivery system and to deploy the distal flange of the LAMS. However, independently from the collection size, no misdeployment was observed and the reported technical failures were caused by the presence of sigmoid strictures or distance between the abscess and the gut wall. Therefore, an increased

probability of technical success could be expected in case of large abscess; on the other hand, smaller size cannot be considered a contraindication to EUS-PAD, since no increased risk of adverse events was observed. [26-28]

Our study presents several limitations. First, the EUS procedures have been conducted by expert operators from tertiary-referral centers; we acknowledge that these results cannot be translated to operators or centers with lower volume and expertise. [29] Secondly, the retrospective design of this study could not allow to exclude a possible selection bias that led to an overestimated technical success rate; we tried to overcome this limitation through systematic retrieval of patients with complicated AD who underwent an EUS attempt for pelvic abscess drainage from prospectively-maintained databases. Moreover, we analyzed the results with an intention-to-treat approach. Another intrinsic limitation of retrospective studies is the lack of treatment standardization; in this case, several different LAMS size, in terms of both length and diameter, were used. We tried to analyze the potential different outcomes related to the use of different stent sizes. The cases of technical failure were not related to the type of stent, but to anatomical conditions (i.e., luminal strictures and distance between abscess and gut) and no stent was even used. On the other hand, the two clinical failures observed after LAMS deployment occurred when small (< 15 mm diameter) LAMS were used. Due to the small number of observed clinical failures, any analysis results underpowered. However, since the indication for EUS-PAD is usually also related to the size of the collection, we consider the use of large (≥ 15 mm diameter) LAMS, when possible. Finally, a large amount of the included patients (up to 30%) underwent surgery during the follow-up period; therefore, the observed rate of abscess recurrence could be underestimated.

In conclusion, EUS-PAD with LAMS could be considered a safe and effective rescue strategy among conservative treatments for complicated grade Ib or II AD, especially when antibiotic treatment failed, and percutaneous drainage is impossible or contraindicated. EUS drainage with LAMS was confirmed as an effective treatment modality for encapsulated collections larger than 5 cm and close to colonic wall, even in patients with no fecal diversion. Further comparative data is necessary to confirm these observations in reducing the need for urgent surgery in this difficult setting.

Declaration of Generative AI and AI-assisted technologies: During the preparation of this work the authors did not use any AI tool for writing or editing this manuscript.

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Figure legend

Figure 1 – Study flow chart

Figure 2a-f – Endoscopic ultrasound-guided pelvic abscess drainage (EUS-PAD) with lumen-apposing metal stent (LAMS). a) CT scan showing large pre-sacral collection (white arrow) with air coefficient suggesting abscessualization; b) deployment of the distal flange of the lumen-apposing metal stent (LAMS) under EUS view; c) deployment of the proximal flange of the LAMS under endoscopic view, with immediate drainage of purulent content; d) LAMS removal with foreign body removal forceps under endoscopic view three weeks after the procedure; e) rectal wall defect immediately after LAMS removal; f) long-term CT scan showing complete resolution of the collection.

Table 1. Baseline characteristics of the study population

Characteristic	**Total** (n= 53)
Demographic	
Gender (female), *n (%)*	29 (54.7%)
Age (years), *median [IQR]*	74 [62-83]
Complicated acute diverticulitis, *n (%)*	53 (100%)
Hinchey stage Ib, *n (%)*	13 (24.5%)
Hinchey stage II, *n (%)*	40 (75.5%)
Collection size (mm), *median [IQR]*	50 [40-60]
Fecal diversion, *n (%)*	0 (0%)
Concomitant medication	
Low molecular weight heparin, *n (%)*	10 (18.9%)
Antiplatelet agents, *n (%)*	12 (22.6%)
Aspirin, *n*	8
Ticlopidin, *n*	2
Clopidogrel, *n.*	1
Aspirin + clopidogrel, *n*	1

Abbreviations: n: number; IQR: Interquartile Range.

Table 2. Technical details and outcomes

Characteristic	**Total** (n= 53)
Procedure details	
Conscious sedation, *n (%)*	14 (26.4%)
Deep sedation, *n (%)*	12 (22.6%)
General anesthesia, *n (%)*	27 (50.9%)
Trans-rectal EUS-PAD approach, *n (%)*	34 (64.2%)
Trans-colonic EUS-PAD approach, *n (%)*	19 (35.8%)
LAMS characteristics	
Hot-Axios stent, *n (%)*	50* (100.0%)
Size 6 x 8 mm, *n*	2
Size 8 x 8 mm, *n*	11
Size 10 x 10 mm, *n*	21
Size 15 x 10 mm, *n*	15
Size 15 x 15 mm, *n*	1
Main outcomes	
Technical success, *n (%)*	49 (92.5%)
Clinical success, *n (%)*	47 (88.7%)
Need for urgent surgery, *n (%)*	4 (7.5%)
3-month mortality, *n (%)*	0 (0%)
Adverse events	
Adverse events (overall), *n (%)*	2 (3.8%)
Minor procedural bleeding, *n*	1 (AGREE II)
Late proximal migration, *n*	1 (AGREE IIIa)

Long-term outcomes	
LAMS removal time (days), *median [IQR]*	19 [14-28]
LAMS exchange to DPPS, *n (%)*	9 (17.0%)
Follow-up (months), *median [IQR]*	12 [8-12]
Elective surgery, *n (%)*	12 (22.6%)
Recurrent diverticular abscess, *n (%)*	2 (3.8%)

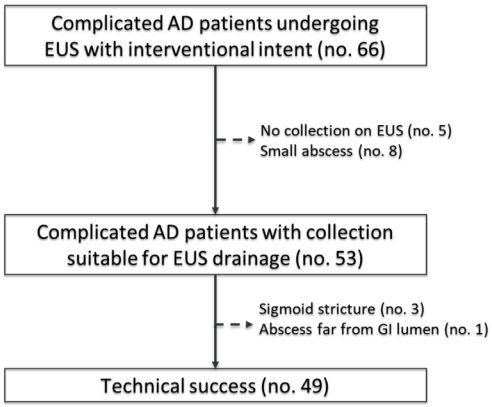
* Four cases had a technical failure due to sigmoid strictures or distance between the abscess and the GI wall; in these cases, no LAMS was used. In one case, two 10 x 10 mm LAMS were placed, according to the multiple gateway technique.

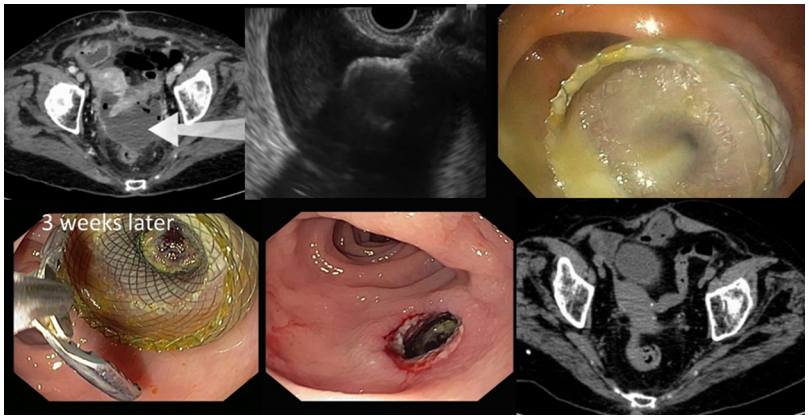
Abbreviations: n: number; EUS-PAD: endoscopic ultrasound-guided pelvic abscess drainage; LAMS: lumen-apposing metal stent; DPPS: double pig-tail plastic stent; IQR: interquartile range.

Table 3. Factors related to EUS-PAD technical success.

	Technical success			
	Univariate (OR [95% C.I.])	P value	*Multivariate* (OR [95% C.I.])	P value
Age (years)	0.97 [0.91 – 1.05]	0.20	---	---
Gender (male)	2.65 [0.26 – 27.3]	0.41	---	---
Trans-rectal approach	6.19 [0.60 – 64.3]	0.13	Ns	Ns
Concomitant percutaneous drainage	0.88 [0.11 – 12.4]	0.54	---	---
Abscess size ≥ 50 mm	**18.0 [1.63 – 198]**	**0.02**	**18.0 [1.63 – 198]**	**0.02**

Abbreviations: OR – Odd ratio; 95% C.I. - 95% confidence interval.





Title: **Safety and efficacy of endoscopic ultrasound-guided pelvic abscess drainage with lumen-apposing metal stents for complicated acute diverticulitis.**

Running title: **EUS pelvic abscess drainage with LAMS**

Authors: Andrea Lisotti* [1,2], Francesca D'Errico* [3,4], Pietro Fusaroli [1], Francesco Decembrino [3], Graziella Masciangelo [1], Tawfik Khoury[2,5,6], Giovanni Barbara[7], Sarah Leblanc [2], Vincent Lepilliez [2], Bertrand Napoléon [2], and Gianfranco Donatelli [4]

Abbreviations:

95% C.I. – 95% confidence intervals; AD – Acute diverticulitis; AE - Adverse event; CT – Computed tomograpghy; EUS – Endoscopic Ultrasound; EUS-PAD – EUS Pelvic Abscess Drainage; IQR – Interquartile range; LAMS – Lumen Apposing Metal Stent; OR – odd ratio; SD - standard deviation.