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A comparison of novel electrocautery-enhanced lumen-apposing metal stents and plastic stents in endoscopic ultrasound-guided drainage of infected walled-off necrosis: a multicenter randomized study

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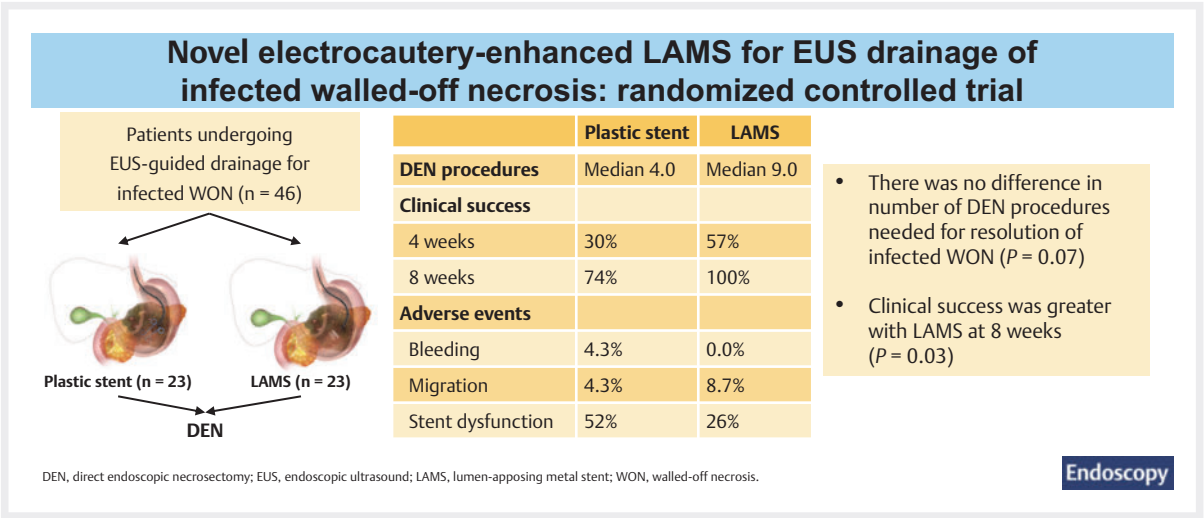
GRAPHICAL ABSTRACT



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received 24.12.2023
accepted after revision 7.6.2024
accepted manuscript online 10.6.2024
published online 7.8.2024

Bibliography
Endoscopy 2024; 56: 926–937
DOI 10.1055/a-2342-1140
ISSN 0013-726X

Georg Thieme Verlag KG, Rüdigerstraße 14,
70469 Stuttgart, Germany

Supplementary Material
Supplementary Material is available at
https://doi.org/10.1055/a-2342-1140

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ABSTRACT

Background Although lumen-apposing metal stents (LAMSs) have been increasingly used for walled-off necrosis (WON), their advantages over plastic stents in infected WON are unclear. We investigated the safety and efficacy of a novel electrocautery-enhanced LAMS for managing infected WON.

Methods Patients who required endoscopic ultrasound-guided WON drainage were randomly assigned to LAMS or plastic stent groups. The primary outcome was total number of direct endoscopic necrosectomy (DEN) procedures required to achieve clinical success. Secondary outcomes included rates of technical success, clinical success, and adverse events.

Results 46 patients were included in the LAMS (n = 23) and plastic stent (n = 23) groups. The median total number of DEN procedures did not differ significantly between the plastic stent group (4 procedures, interquartile range [IQR] 2.5–5.0) and LAMS group (9 procedures, IQR 8.0–9.0) (P = 0.07). The LAMS group demonstrated a significantly higher clinical success rate than the plastic stent group based on intention-to-treat analysis (100% vs. 73.9%, P = 0.03) at 8 weeks but not at 4 weeks. Significant bleeding occurred in one patient in the plastic stent group and no patients in the LAMS group.

Conclusions We found no significant difference in the total number of DEN procedures between LAMSs and plastic stents for managing infected WON. The only statistically significant finding was a higher clinical success rate at 8 weeks for patients treated with LAMS. The use of LAMS did not result in any adverse events, such as bleeding or buried LAMS syndrome, within the study duration.

Introduction

Infected walled-off necrosis (WON) is a challenging complication of acute pancreatitis and is characterized by the formation of organized collections with well-defined walls accompanied by bacterial infection [1]. Although surgical intervention has traditionally been considered the primary treatment for WON, endoscopic management has become the first-line therapy for this complication [2]. Endoscopy has gained popularity owing to its minimally invasive nature, reduced morbidity rate, and improved patient outcomes via direct endoscopic necrosectomy (DEN). DEN provides direct access to the necrotic collection, facilitating drainage and debridement of necrotic tissue, particularly when previous attempts at drainage are ineffective [3].

Plastic stents have been commonly used during endoscopic ultrasound (EUS)-guided drainage of WONs [4]. However, these stents are limited by their relatively small lumen, leading to occlusion by debris or necrotic material within the WON. Obstruction hinders effective drainage and may necessitate additional intervention [5]. The use of a lumen-apposing metal stent (LAMS) for WON drainage has increased recently. A significant benefit of LAMS is the unique saddle-shaped design, which allows for better apposition and sealing between the two luminal walls [6]. Therefore, bidirectional anchoring flanges minimize the risk of stent migration, providing enhanced stability and reducing the risk of stent dislodgment during drainage or DEN [7]. Furthermore, LAMSs typically have larger lumens, allowing for improved and more efficient drainage of necrotic material from the WON and reducing the risk of stent occlusion and the need for frequent interventions [6]. In addition, LAMSs provide endoscopists with the flexibility to perform DEN, as needed, to achieve resolution of the WON. However, the necessity and frequency of DEN sessions are controversial and may vary based on the patient's condition and response to initial stent placement [8, 9]. More recently, an electrocautery-enhanced delivery system has facilitated simpler and quicker deployment of stents, streamlining the overall procedure and potentially reducing the procedure time [10, 11].

A recent randomized trial comparing LAMS with plastic stents reported no significant difference in clinical outcomes between the two stent types and recommended removal of the LAMS within 3 weeks due to stent-related adverse events, including bleeding [12]. However, no randomized trials have specifically compared the efficacy and safety of novel electrocautery-enhanced LAMSs with those of plastic stents for treating infected WON. Therefore, this study evaluated whether electrocautery-enhanced LAMSs were more effective than plastic stents for treating infected WON, and assessed whether the LAMS should be removed within a specific timeframe, such as 3 weeks. Additionally, this study determined whether DEN was necessary for managing infected WON and assessed the frequency with which DEN should be performed.

Methods

Study design

This multicenter, prospective, randomized study included 46 consecutive patients who underwent EUS-guided drainage of infected WON between July 2019 and May 2023. Computed tomography (CT) or magnetic resonance imaging (MRI) was performed in all patients before the intervention. WON was de-

fined according to the 2012 revised Atlanta classification [13] as a mature encapsulation of pancreatic or peripancreatic necrotic tissue contained within a well-defined wall of inflammatory tissue. Furthermore, infection presence can be inferred when infectious symptoms and signs manifest, including leukocytosis, fever, air bubbles in WON on abdominal CT, or positive bacterial culture in drainage fluid from fine-needle aspiration or the initial percutaneous drainage [14].

Adult patients aged ≥19 years with medically documented acute pancreatitis and infected WON scheduled for EUS-guided drainage were included in the study. Patients with WON with a pure cystic component or <30% solid component, lesions with only a solid component and no cystic component, suspected pancreatic cystic tumors or pancreatic malignancies, or abnormal coagulation parameters (international normalized ratio >1.5 or platelet count <60 000 cells/cm^3) were excluded from the study. Patients in whom antithrombotic therapy could not be postponed and those with cardiopulmonary instability or pregnancy were excluded from the study. Patients who refused to participate or provide informed consent, as well as those enrolled in other studies conducted by the authors, were also excluded.

The enrolled patients were randomly assigned to either the LAMS group or the plastic stent group in a 1:1 ratio. This allocation was performed using a table of computer-generated random numbers created by independent investigators employing a block randomization method with a block size of six. The allocation assignments were concealed within sealed envelopes, ensuring all endoscopists, nurses, and investigators were blinded to the group allocation before the procedure. All patients underwent deep sedation with propofol and midazolam according to previously published protocols [15].

The study protocol was approved by the institutional review board of the ethics committee of each hospital prior to its initiation. All patients provided written informed consent prior to enrollment. The study is reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidance (see **Table 1s** in the online-only Supplementary material) [16].

Endoscopic procedures

All procedures were conducted using a linear array echoendoscope by experienced endoscopists using a well-established technique [17]. Prior to the procedure, CT or MRI was used to assess the maturity of the collection for adequate endoscopic drainage and the presence of pseudoaneurysms or splenic vein thrombosis. After positioning the WON in the natural path of the expected needle track, the operators confirmed the absence of intervening vasculature using color Doppler. A 19-gauge standard aspiration needle (EZshot Plus 3; Olympus Co., Tokyo, Japan) was introduced into the WON. Once the needle was in position and was clearly visible, the stylet was removed, a suction syringe (typically supplied with the needle by the manufacturer) was applied, and suction was performed. After aspirating an adequate volume of fluid, an equal volume of contrast material was injected into the WON. A 0.025-inch guidewire (Optimos Guidewire; Taewoong Medical, Goyang, South Korea) was then advanced into the WON, coiled under fluoroscopic guidance, and the needle was removed.

Placement of LAMS

The electrocautery-enhanced LAMS (Niti-S HOT SPAXUS Stent; Taewoong Medical) (▶ **Fig. 1**) is a fully covered, self-expanding stent preloaded with the Hot SPAXUS Delivery System. This is a through-the-scope, electrocautery-enhanced delivery system designed for use with therapeutic echoendoscopes. The delivery system provides endoscopic control and uses a locked, two-step release system to prevent unintended deployment of the proximal flange. The stent is equipped with bilateral anchor flanges for lumen-to-lumen anchoring. These features reduce the risk of stent migration and leakage along the stent, prevent tissue growth, and enable easy removal.

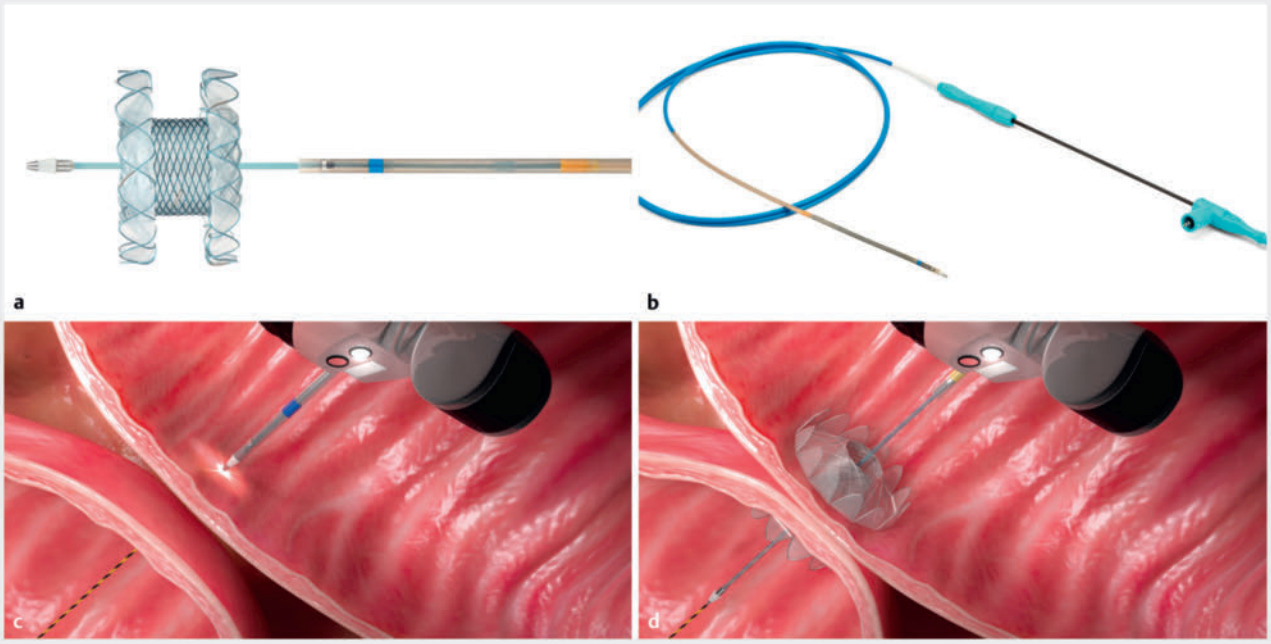
In this trial, a 16-mm stent diameter was preferred, as this larger size allowed access to the cavity, ensuring improved clearance of necrotic debris and facilitating future DEN. After puncturing the WON using the electrocautery tip, with the electrosurgical unit set to AutoCut mode (80–120 Watts, 400–500 Vp), the delivery catheter was advanced into the WON over the guidewire. The stent deployment hub was released to deploy the distal flange of the stent after positioning the catheter within the WON over the guidewire. Subsequently, the echoendoscopist carefully and gently released the proximal flange within the working channel to ensure proper luminal wall expansion and engagement (▶ **Video 1**).

Placement of plastic stents

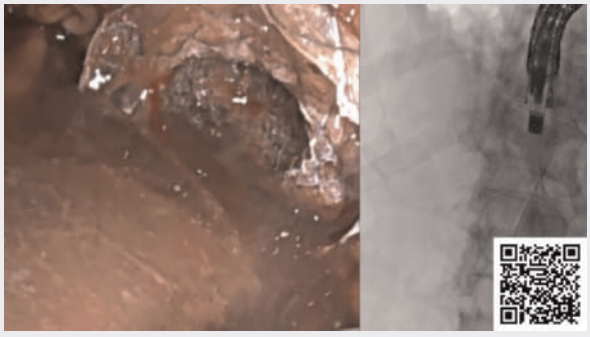
After delivering the guidewire, a 6-Fr cystotome (Taewoong Medical) was used to dilate the cystostomy tract using an electrosurgical unit set in the AutoCut mode (80–120 Watts, 400–500 Vp). Subsequently, the tract was further dilated with a 4–6 mm diameter balloon catheter (Hurricane Balloon Catheter; Boston Scientific, Marlborough, Massachusetts, USA). Following dilation, one or more 7-Fr plastic stents with a double-pigtail configuration were placed in the cyst cavity over the guidewire using endoscopy and fluoroscopy (▶ **Video 2**).

DEN procedure

We implemented DEN based on the step-up approach policy, which involves initial EUS-guided drainage followed by monitoring for 72–96 hours. Further drainage-based intervention was considered if insufficient improvement was observed [18]. These interventions could include stent replacement or addition, EUS-guided drainage (multigateway technique), and/or percutaneous drainage (multimodality technique). DEN was considered if indicated after two rounds of drainage-based step-up interventions [19]. Use of LAMS allows direct insertion of the endoscope through the stent for easier implementation of DEN (▶ **Fig. 2a, b**). In contrast, use of plastic stents requires tract dilation to facilitate endoscope passage and the cumbersome process of reinserting the stent to prevent tract closure (▶ **Fig. 2c, d**). Upon entering the WON, the working channel of the endoscope was used to aspirate fluid and small necrotic debris. Larger necrotic debris and debris adherent to the wall were captured using instruments originally designed for differ-



▶ **Fig. 1** The electrocautery-enhanced lumen-apposing metal stent (LAMS; Niti-S HOT SPAXUS – Taewoong Medical, Goyang, South Korea). **a** The LAMS has a blue indicator incorporated into the outer sheath to verify full deployment. **b** The delivery system has a secure, two-step release mechanism to prevent unintentional deployment. **c** The electrocautery tip with an electric current facilitates facile, rapid puncture and advancement of the LAMS into the walled-off necrosis. **d** Bilateral anchor flanges are designed to establish lumen-to-lumen anchoring and diminish stent migration and leakage.



Video 1 Endoscopic ultrasound (EUS)-guided drainage using a lumen-apposing metal stent (LAMS) for infected walled-off necrosis (WON). EUS-guided drainage was performed using a linear array echoendoscope in a patient diagnosed with infected WON. Once the WON was identified from within the stomach, with the scope in a stable position, a standard 19-gauge fine-aspiration needle was used to puncture the WON. WON was confirmed by the injection of a contrast agent. A 0.025-inch guidewire was inserted as deeply as possible into the WON to facilitate the subsequent device insertion. A novel LAMS (Niti-S HOT SPAXUS; Taewoong Medical, Goyang, South Korea) featuring an electrocautery-enhanced tip was introduced into the WON with a cutting current and gradually deployed under the guidance of both echoendoscopy and fluoroscopy. Finally, the stent was fully deployed from the working channel under endoscopic observation.
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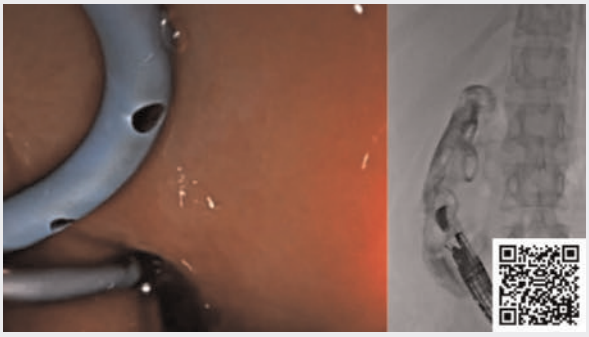

Video 2 Endoscopic ultrasound (EUS)-guided drainage using a plastic stent for infected walled-off necrosis (WON). EUS-guided drainage was performed using a linear array echoendoscope in a patient diagnosed with infected WON. The WON was identified from within the stomach and punctured using a standard 19-gauge needle. After confirmation of the WON with the contrast material, a 0.025-inch guidewire was carefully inserted and coiled within the WON for stabilization. Subsequently, the tract was dilated using a 4-mm diameter balloon catheter (Hurricane Balloon Catheter; Boston Scientific, Marlborough, Massachusetts, USA). After dilation, a plastic stent with a double-pigtail configuration was introduced into the WON and was gradually deployed.
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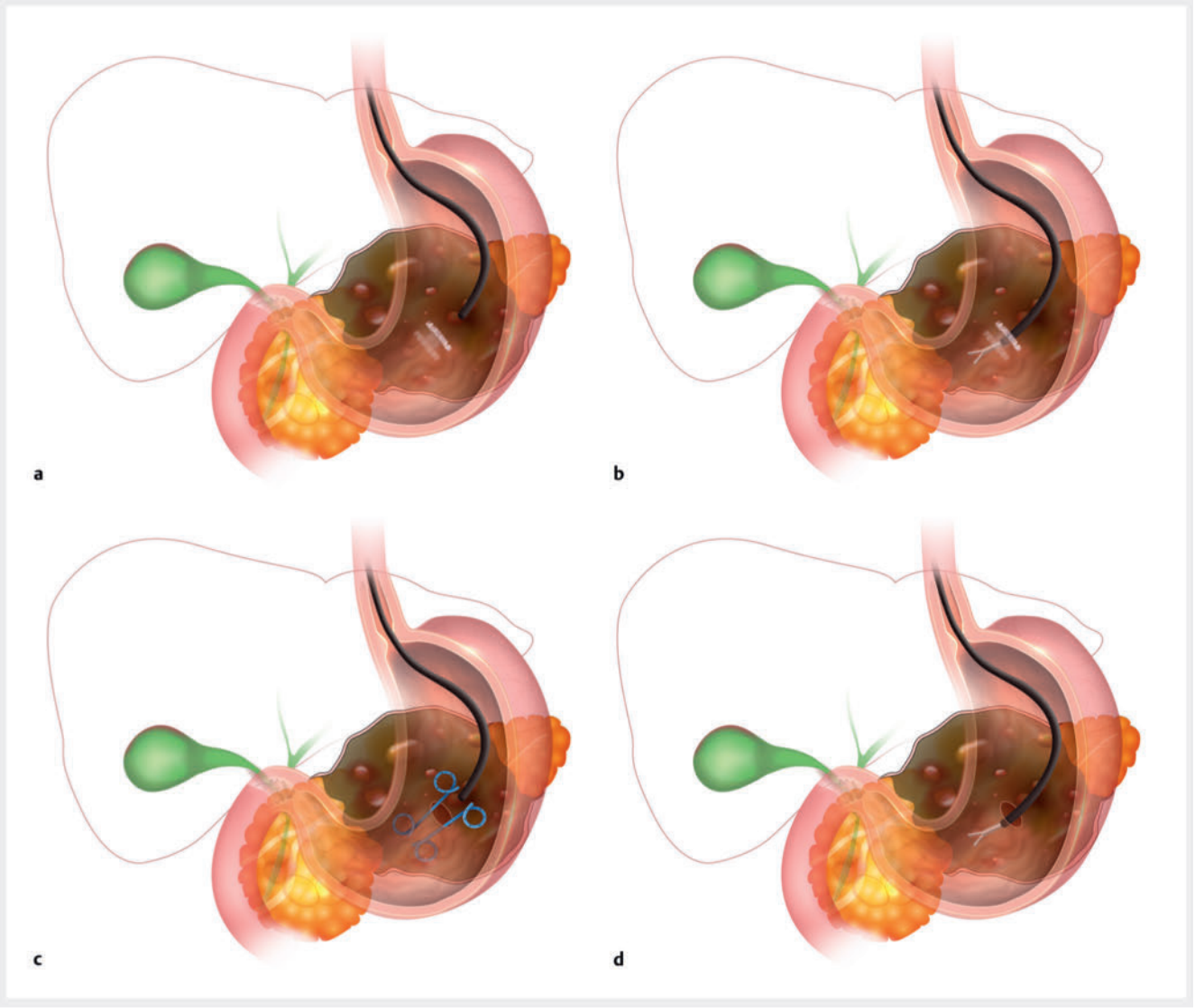


▶ **Fig. 2** Direct endoscopic necrosectomy (DEN) using each stent. **a, b** The lumen-apposing metal stent enables straightforward placement of the endoscope through the stent to simplify DEN implementation. **c, d** In contrast, the plastic stent necessitates tract dilation to ease endoscope passage and involves a cumbersome procedure of stent reintroduction to avoid tract closure after DEN.

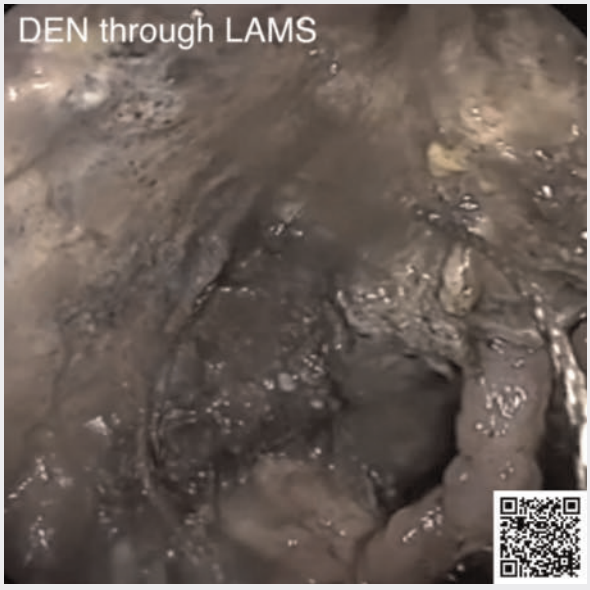
ent purposes, including polypectomy snares, Dormia baskets, Roth baskets, other stone removal baskets, and forceps of various shapes, such as grasping, tripod, rat-tooth, and pelican forceps [20, 21, 22]. The debris was released into the stomach or duodenum (▶ **Video 3**). Although no definitive indication for stopping DEN has been established, regardless of stent type, the decision is typically made by the endoscopist based on various factors, including clinical improvement, completion of necrosectomy, procedure-related adverse events, inadequate access or visualization, and deterioration of the patient's condition [18].

Outcome measurements and definitions

The primary end point was the total number of DEN procedures required to achieve clinical success. The secondary outcomes included rates of technical and clinical success, adverse events, and successful stent removal, and the occurrence of any unplanned surgical or radiological interventions.

Technical success was defined as the successful placement of the LAMS or plastic stent within the WON. Clinical success was defined as the partial or complete resolution of the WON, evidenced by a reduction in size of more than 50% at 4 weeks postoperatively compared with the initial size, accompanied by the complete resolution of clinical symptoms. Clinical failure was defined as the absence of clinical success, the need for subsequent rescue surgeries, or procedure-related mortality.

The assessment and severity grading of all adverse events were documented using a novel classification system called Adverse Events in GI Endoscopy (AGREE), ensuring a standardized and reproducible approach [23]. Significant bleeding was defined as the requirement for transfusion, hospitalization, endoscopic hemostasis, or radiological intervention. As observed on



Video 3 Direct endoscopic necrosectomy (DEN) with or without a lumen-apposing metal stent (LAMS). Use of LAMS allows the advancement of a standard upper endoscope into the walled-off necrosis (WON) for DEN. Once inside the WON, the working channel of the endoscope can be used to aspirate fluid and small necrotic debris. Large necrotic debris and debris adherent to the wall can be captured using polypectomy snares and released into the stomach or duodenum. When a LAMS is not used, a standard upper endoscope can traverse the WON following tract dilation using a 15-mm balloon catheter (CRE Balloon Catheter; Boston Scientific, Marlborough, Massachusetts, USA). After the tract is dilated, the remaining procedure mirrors that with LAMS.
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follow-up imaging, recurrence was defined as cyst recurrence after stent removal. Following endoscopic treatment of WON, routine blood tests were conducted at 3 months post-EUS intervention. Systematic cross-sectional imaging to detect recurrence after stent removal was not routinely performed for all patients. Instead, follow-up imaging was performed selectively in cases where there was suspicion of symptoms related to WON or for diagnostic purposes unrelated to the detection of peripancreatic fluid collections (PFCs), such as a CT scan for pseudoaneurysm [24].

Statistical analysis

The sample size was determined based on a recent study [25] that focused on the total number of DEN procedures required for treatment success using LAMSs and plastic stents. The mean number of DEN procedures required was 2.74 (SD 1.48) in the plastic stent group and 1.46 in the LAMS group. To achieve a statistical power of at least 0.80 at an alpha level of 0.05, 21 patients per group were needed for Student's *t* test. Considering a dropout rate of 5%, the final sample size was set at 23 patients per group.

Categorical variables were presented as frequencies and proportions, and continuous variables were presented as medians and interquartile ranges (IQRs). Categorical data were compared using Fisher's exact test. Continuous data were compared using the Wilcoxon rank-sum test. All reported *P* values were two sided, and *P* values of <0.05 were considered statistically significant. All statistical analyses were performed using the R statistical software (version 4.3.1; R Foundation for Statistical Computing, Vienna, Austria).

Results

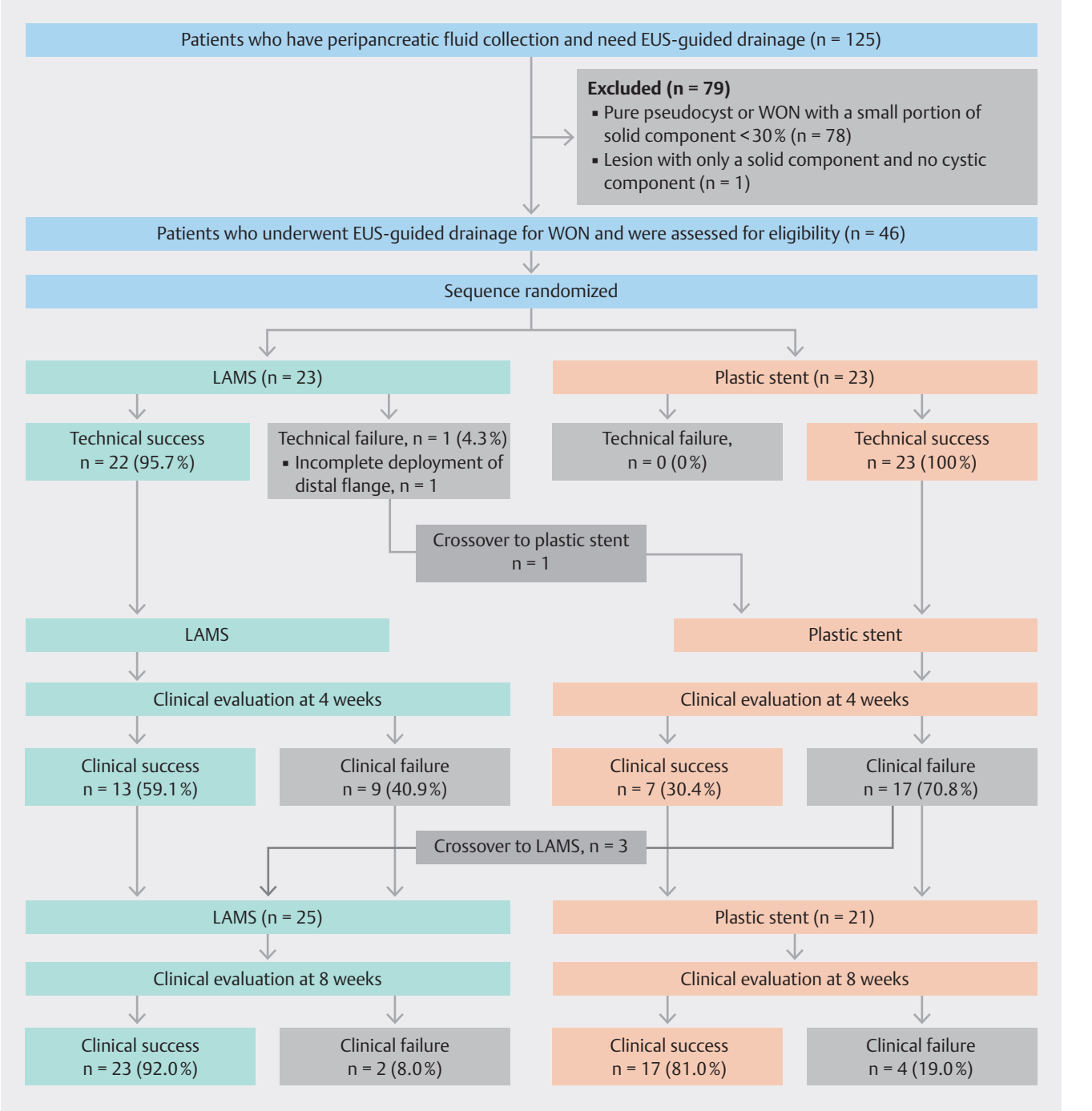
Study population and baseline characteristics

A total of 125 patients who underwent EUS-guided drainage for PFCs were initially considered for this study (▶ **Fig. 3**). From this cohort, 79 patients were excluded based on the following criteria: pure pseudocyst or WON with a solid component of <30% (n = 78) and lesions with only a solid component and no cystic component (n = 1). Consequently, 46 patients were included in the final analysis. After randomization, all 46 patients received their allocated intervention; none were lost to follow-up or excluded. During the study, three patients initially assigned to the plastic stent group were transitioned to the LAMS group because of poor clinical response, and one patient initially assigned to the LAMS group was crossed over to the plastic stent group owing to technical failure.

The median patient age was 49 and 56 years in the plastic stent and LAMS groups, respectively (▶ **Table 1**). The distribution of male patients was similar between groups. The median body mass index, clinical symptoms, etiology of pancreatitis, and all laboratory findings, excluding total bilirubin, did not differ significantly between the plastic stent and LAMS groups.

WON characteristics and procedure-related findings

The distribution of WON locations did not differ significantly between the plastic stent and LAMS groups (▶ **Table 2**). The median degree of necrosis, calculated based on the solid portion within the WON, was 70% (IQR 60.0%–80.0%) in the plastic stent group and 80% (IQR 70.0%–80.0%) in the LAMS group. The largest WON diameter was similar between the groups (plastic stent 7.2 cm [IQR 5.5–9.8 cm]; LAMS 8.0 cm [IQR 5.7–12.8 cm]). EUS-guided drainage via the transgastric route was the preferred approach in most patients in the plastic stent (87.0%) and LAMS (95.7%) groups. The main pancreatic duct was intact in 82.6% of patients in the plastic stent group and in 91.3% of patients in the LAMS group. The total procedure time was not significantly different between the plastic stent (8.5 minutes [IQR 7.8–9.9 minutes]) and LAMS (6.8 minutes [IQR 4.5–10.7 minutes]) groups. Additional procedures, including percutaneous catheter drainage, additional stent placement, and transpapillary pancreatic duct drainage via endoscopic retrograde cholangiopancreatography, were more frequently performed in the plastic stent group than in the LAMS group, although the differences were not significant.



▶ **Fig. 3** Study flow diagram. Categorical variables were presented as frequencies and proportions using the as-treated analysis. EUS, endoscopic ultrasound; LAMS, lumen-apposing metal stent; WON, walled-off necrosis.

Clinical outcomes and adverse events

The technical success rates were 95.7% in the plastic stent group and 100% in the LAMS group (▶ **Table 2**). At 8 weeks, the LAMS group had a significantly higher clinical success rate than the plastic stent group (100% vs. 73.9%, respectively; P = 0.03) (▶ **Table 3**), although the clinical success rates did not differ significantly between the groups at 4 weeks. Stent dysfunction, including stent occlusion, was observed in 52.2% of patients in the plastic stent group and 26.1% of patients in the LAMS group (P = 0.10). The median duration of stent placement was 51 days (IQR 30.1–71.9 days) in the plastic stent group and 33 days (IQR 29.2–36.8 days) in the LAMS group.

The use of DEN did not differ between the plastic stent and LAMS groups (13% vs. 21.7%, respectively; P = 0.70), and the total number of DEN procedures required to achieve clinical success was not significantly different between the groups

▶ **Table 1** Baseline characteristics and clinical details of the included patients.

Variable	ITT analysis			As-treated analysis		
	Plastic stent (N = 23)	LAMS (N = 23)	*P* value	Plastic stent (N = 21)	LAMS (N = 25)	*P* value
Age, median (IQR), years	49.0 (41.5–62.0)	56.0 (38.5–60.0)	0.91	49.0 (42.0–63.0)	53.0 (40.0–60.0)	0.67
Male sex, n (%)	11 (47.8)	16 (69.6)	0.23	9 (42.9)	18 (72.0)	0.09
BMI, median (IQR), kg/m2	21.6 (19.1–24.0)	22.8 (21.2–24.6)	0.12	21.6 (18.4–22.9)	23.1 (20.9–24.5)	0.08
Clinical presentation, n (%)						
▪ Abdominal pain	19 (82.6)	19 (82.6)	>0.99	17 (81.0)	21 (84.0)	>0.99
▪ Vomiting	4 (17.4)	1 (4.3)	0.34	4 (19.0)	1 (4.0)	0.25
▪ Fever	5 (21.7)	8 (34.8)	0.51	6 (28.6)	7 (28.0)	>0.99
▪ Distention	12 (52.2)	9 (39.1)	0.55	10 (47.6)	11 (44.0)	>0.99
Etiology of pancreatitis, n (%)						
▪ Alcohol	9 (39.1)	8 (34.8)	>0.99	8 (38.1)	9 (36.0)	>0.99
▪ Gallstones	1 (4.3)	0 (0.0)	>0.99	1 (4.8)	0 (0.0)	0.93
▪ Idiopathic	1 (4.3)	3 (13.0)	0.60	0 (0.0)	4 (16.0)	0.16
▪ Hypertriglyceridemia	1 (4.3)	1 (4.3)	>0.99	1 (4.8)	1 (4.0)	>0.99
▪ Post-operation	4 (17.4)	3 (13.0)	>0.99	4 (19.0)	3 (12.0)	0.80
▪ Chronic pancreatitis	4 (17.4)	5 (21.7)	>0.99	4 (19.0)	5 (20.0)	>0.99
▪ PEP	1 (4.3)	2 (8.7)	>0.99	2 (9.5)	1 (4.0)	0.88
▪ Others	1 (4.3)	2 (8.7)	>0.99	0 (0.0)	3 (12.0)	0.30
Laboratory finding, median (IQR)						
▪ WBC, cells/μL	8.8 (5.6–11.2)	9.4 (6.7–10.6)	0.97	8.8 (5.5–11.0)	9.4 (6.8–11.0)	0.60
▪ Hb, g/dL	10.8 (9.9–12.9)	11.0 (10.1–12.0)	0.83	10.5 (9.8–12.2)	11.2 (10.1–12.2)	0.57
▪ Platelet, cells/μL	307.0 (206.5–441.5)	353.0 (220.5–379.0)	0.63	242.0 (193.0–399.0)	356.0 (267.0–390.0)	0.09
▪ AST, IU/L	31.0 (18.0–40.0)	22.0 (17.0–28.5)	0.10	30.0 (15.0–39.0)	25.0 (18.0–34.0)	0.57
▪ ALT, IU/L	20.0 (12.0–29.0)	15.0 (11.0–29.0)	0.65	16.0 (10.0–28.0)	19.0 (13.0–30.0)	0.65
▪ Alkaline phosphatase, IU/L	123.0 (93.5–159.0)	103.0 (79.0–139.5)	0.23	122.0 (91.0–160.0)	105.0 (81.0–140.0)	0.41
▪ GGT, g/dL	70.0 (45.5–147.0)	66.0 (33.5–102.0)	0.42	68.0 (45.0–169.0)	70.0 (36.0–95.0)	0.48
▪ Total bilirubin, mg/dL	0.7 (0.5–1.4)	0.5 (0.4–0.8)	0.03	0.6 (0.5–1.2)	0.5 (0.4–0.8)	0.05
▪ Amylase, IU/L	54.0 (31.5–104.0)	93.0 (51.5–162.0)	0.10	66.0 (34.0–116.0)	82.0 (42.0–157.0)	0.34
▪ Lipase, IU/L	48.0 (22.0–167.0)	147.0 (51.0–248.5)	0.11	57.0 (22.0–187.0)	142.0 (47.0–233.0)	0.29

ALT, alanine transaminase; AST, aspartate transaminase; BMI, body mass index; GGT, gamma-glutamyl transpeptidase; Hb, hemoglobin; IQR, interquartile range; ITT, intention-to-treat; IU, international unit; LAMS, lumen-apposing metal stent; PEP, post-endoscopic retrograde cholangiopancreatography pancreatitis; WBC, white blood cell.

(plastic stent 4 procedures [IQR 2.5–5.0 procedures]; LAMS 9 procedures [IQR 8.0–9.0]; $P = 0.07$).

Overall, the rates of adverse events were not significantly different between the groups. The incidence of stent occlusion did not show a statistically significant difference between the plastic stent and LAMS groups (52.2% vs. 26.1%; $P = 0.13$). Furthermore, no notable differences were detected between the groups regarding the incidence of significant bleeding and stent migration.

Table 2s provides further information regarding the main outcomes, including technical and clinical success, the total number of DEN procedures, and other outcomes based on a well-balanced assignment according to each institution. There were no differences in the main outcomes, including the total number of DEN procedures, according to each institution.

▶ **Table 2** Walled-off necrosis characteristics and procedure-related findings.

Variable	ITT analysis			As-treated analysis		
	Plastic stent (N = 23)	LAMS (N = 23)	*P* value	Plastic stent (N = 21)	LAMS (N = 25)	*P* value
WON location, n (%)			0.83			0.73
▪ Head/uncinate process	2 (8.7)	2 (8.7)		2 (9.5)	2 (8.0)	
▪ Body/tail	20 (87.0)	19 (82.6)		17 (81.0)	22 (88.0)	
▪ Whole	1 (4.3)	2 (8.7)		2 (9.5)	1 (4.0)	
Degree of necrosis, median (IQR), %	70.0 (60.0–80.0)	80.0 (70.0–80.0)	0.84	80.0 (60.0–80.0)	70.0 (70.0–80.0)	0.82
WON size (maximal diameter), median (IQR), cm	7.2 (5.5–9.8)	8.0 (5.7–12.8)	0.49	7.0 (5.5–9.7)	8.0 (5.6–12.8)	0.47
Route of drainage, n (%)			0.60			0.48
▪ Transgastric	20 (87.0)	22 (95.7)		18 (85.7)	24 (96.0)	
▪ Transduodenal	3 (13.0)	1 (4.3)		3 (14.3)	1 (4.0)	
Multigate drainage	3 (13.0)	3 (13.0)	>0.99	3 (14.3)	3 (12.0)	>0.99
Status of pancreatic duct, n (%)			0.25			0.21
▪ Intact MPD	19 (82.6)	21 (91.3)		17 (81.0)	23 (92.0)	
▪ PD leak	0 (0.0)	1 (4.3)		0 (0.0)	1 (4.0)	
▪ DPDS	1 (4.3)	1 (4.3)		1 (4.8)	1 (4.0)	
▪ Unknown	3 (13.0)	0 (0.0)		3 (14.3)	0 (0.0)	
Total procedure time, median (IQR), minutes	8.5 (7.8–9.9)	6.8 (4.5–10.7)	0.30	8.8 (7.8–11.6)	7.0 (5.0–10.0)	0.30
Additional procedure, n (%)						
▪ Plastic stent insertion through LAMS	0 (0.0)	2 (8.7)	0.88	0 (0.0)	2 (8.0)	0.55
▪ ERCP with transpapillary drainage	11 (47.8)	5 (21.7)	0.12	9 (42.9)	7 (28.0)	0.46
▪ Additional stent insertion	4 (17.4)	1 (4.3)	0.34	4 (19.0)	1 (4.0)	0.25
▪ PCD	8 (34.8)	2 (8.7)	0.07	7 (33.3)	3 (12.0)	0.17
▪ Surgical intervention (e. g. VARD)	1 (4.3)	0 (0.0)	0.35	0 (0.0)	1 (4.0)	0.42
Technical success, n (%)	22 (95.7)	23 (100)	>0.99	20 (95.2)	25 (100)	0.39

DPDS, disconnected pancreatic duct syndrome; ERCP, endoscopic retrograde cholangiopancreatography; IQR, interquartile range; ITT, intention-to-treat; LAMS, lumen-apposing metal stent; MPD, main pancreatic duct; PD, pancreatic duct; PCD, percutaneous catheter drainage; VARD, video-assisted retroperitoneal debridement; WON, walled-off necrosis.

Discussion

Our findings indicate that the novel electrocautery-enhanced LAMS system did not significantly reduce the total number of DEN procedures, although it did result in a higher clinical success rate at 8 weeks compared with plastic stents. Notably, 91.3% of patients in the plastic stent group eventually achieved clinical success, indicating comparable therapeutic efficacy between the two stents. Therefore, while LAMS achieves faster therapeutic efficacy for infected WON than plastic stents, both stents exhibit high technical and clinical success rates.

Although plastic stents are commonly the first choice for endoscopic drainage of PFCs, including pseudocysts, their performance may be suboptimal for patients with WON, as the reported clinical success rates range from 63% to 70% [26]. Unplanned revision procedures or necrosectomies are required in up to 27% of patients with WON treated with plastic stents in order to achieve a successful resolution [1]. Siddiqui et al. reported that more frequent procedures were required to resolve WON when plastic stents were used than when tubular metal stents or LAMS were used (3.6 vs. 3.0 vs. 2.2 procedures within

▶ **Table 3** Clinical outcomes.

Variable	ITT analysis			As treated analysis		
	Plastic stent (N = 23)	LAMS (N = 23)	*P* value	Plastic stent (N = 21)	LAMS (N = 25)	*P* value
Patients requiring DEN, n (%)	3 (13.0)	5 (21.7)	0.70	2 (9.5)	6 (24.0)	0.37
▪ Total DEN procedures, median (IQR)	4.0 (2.5–5.0)	9.0 (8.0–9.0)	0.07	3.0 (1.0–5.0)	8.5 (6.0–9.0]	0.13
Stent dysfunction, n (%)	12 (52.2)	6 (26.1)	0.10	10 (47.6)	8 (32.0)	0.36
▪ Duration of stent placement, median (95%CI), days	51.0 (30.1–71.9)	33.0 (29.2–36.8)	0.22	47.0 (27.2–66.7)	33.0 (29.2–36.8)	0.93
▪ Duration to 1st stent dysfunction, median (95%CI), days	7.0 (3.6–10.4)	7.0 (5.9–8.1)	0.46	7.0 (3.9–10.1)	7.0 (5.7–8.3)	0.56
Successful stent removal, n (%)	21 (91.3)	23 (100)	0.47	20 (95.2)	24 (96.0)	>0.99
Clinical success, n (%)						
▪ 4 weeks	7 (30.4)	13 (56.5)	0.14	7 (33.3)	13 (52.0)	0.33
▪ 8 weeks	17 (73.9)	23 (100)	0.03	17 (81.0)	23 (92.0)	0.50
Adverse events, n (%)[1]						
▪ Bleeding	1 (4.3)	0 (0.0)	>0.99	1 (4.8)	0 (0.0)	0.93
▪ Grade IIIa	1 (4.3)	0 (0.0)	>0.99	1 (4.8)	0 (0.0)	0.93
▪ Spontaneous migration	1 (4.3)	2 (8.7)	0.49	2 (9.5)	1 (4.0)	0.88
▪ Grade I	1 (4.3)	1 (4.3)	0.60	1 (4.8)	1 (4.0)	0.54
▪ Grade IIIa	0 (0.0)	1 (4.3)		1 (4.8)	0 (0.0)	
▪ Stent dislodgment during DEN	0 (0)	0 (0)	>0.99	0 (0)	0 (0)	>0.99
▪ Stent occlusion leading to infection	12 (52.2)	6 (26.1)	0.13	10 (47.6)	8 (32.0)	0.44
▪ Grade II	9 (39.1)	4 (17.4)	0.24	7 (33.3)	6 (24.0)	0.39
▪ Grade IIIa	2 (8.7)	2 (8.7)		3 (14.3)	1 (4.0)	
▪ Grade IIIb	1 (4.3)	0 (0.0)		0 (0.0)	1 (4.0)	
▪ Others	3 (13.0)	3 (13.0)	>0.99	3 (14.3)	3 (12.0)	>0.99
▪ Grade II	1 (4.3)	2 (8.7)	0.72	1 (4.8)	2 (8.0)	0.33
▪ Grade IIIa	1 (4.3)	1 (4.3)		2 (9.5)	0 (0.0)	
▪ Grade IIIa	1 (4.3)	0 (0.0)		0 (0.0)	1 (4.0)	
Death, n (%)	2 (8.7)	0 (0.0)	0.47	1 (4.8)	1 (4.0)	>0.99

DEN, direct endoscopic necrosectomy; IQR, interquartile range; ITT, intention-to-treat; LAMS, lumen-apposing metal stent.
[1]The assessment and severity grading of all adverse events were documented using a novel classification system called Adverse Events in GI Endoscopy (AGREE), ensuring a standardized and reproducible approach [23].

6 months, respectively; $P = 0.04$) [1]. Additionally, use of plastic stents was identified as the only negative predictor of successful resolution of WON in the multivariate analysis [1]. In contrast, LAMS provided higher technical success and better long-term outcomes in a previous study [8], particularly in the context of EUS-guided drainage of pseudocysts. A subsequent larger study [6], including 11 patients with WON and 22 with pseudocysts who underwent PFC drainage, further supported the advantages of using LAMS, as LAMS led to resolution in 93% of patients. LAMSs with larger diameters allow for DEN without the need for stent removal [11]. Furthermore, the anchoring flanges of LAMS are critical in preventing stent dislodgment during DEN, making LAMS an attractive and valuable option for clinicians in such cases [27].

Contrary to the initial and primary hypotheses that the number of DEN procedures would be lower, more DENs were performed in the LAMS group in the current study. This unexpected result may be attributed to selection bias, indicating that

certain factors or patient characteristics in the LAMS group may have influenced the requirement for more DEN procedures. In our study, we deliberately selected patients with WON characterized by a minimum of 30% solid components. Our findings revealed that the median proportion of solid components was 70% and 80% in the plastic stent and LAMS groups, respectively. Considering the characteristics of WON, the proportion of patients undergoing DEN procedures in the LAMS group was notably greater than that in the plastic stent group. This trend was evident in the intention-to-treat analysis (five patients/21.7% in the LAMS group vs. three patients/13.0% in the plastic stent group) and the as-treated analysis (six patients/24.0% in the LAMS group vs. two patients/9.5% in the plastic stent group). Additionally, the total number of DEN procedures required for clinical success was higher in the LAMS group than in the plastic stent group (intention-to-treat analysis 9.0 [8.0–9.0] vs. 4.0 [2.5–5.0]; as-treated analysis 8.5 [6.0–9.0] vs. 3.0 [1.0–5.0]). This suggests that clinical success was attained more rapidly in the LAMS group, likely due to active and more frequent DEN intervention compared with the plastic stent group, where DEN procedures were performed less frequently, if at all, whenever possible. From this perspective, comparing the number of DEN procedures between groups may not adequately establish superiority as the primary outcome. Other factors, such as the speed and efficacy of achieving clinical success along with the overall management approach, should be considered.

Furthermore, the step-up approach with LAMS placement allows for easier implementation of DEN in patients who do not achieve adequate clinical success. In contrast to plastic stents, which require tract dilation to facilitate endoscope passage and the cumbersome process of reinserting the stent to prevent tract closure, LAMS allows for DEN without the need for stent removal, leading to a more efficient and streamlined procedure [8, 10] Furthermore, the risk of adverse events associated with balloon dilation, such as bleeding, or repeated stent reinsertion may be reduced with LAMS, making it a more suitable option for some patients [28].

The rates of adverse events were not significantly different between the groups in the current study. No bleeding events were reported in the LAMS group, whereas one case of bleeding was reported in the plastic stent group, which differs from previously reported results [12]. This difference may be attributed to design differences in the bilateral stent edges between the stents used in each study. The conventional LAMS has a tubular-shaped cylindrical mesh at both ends of the stent, whereas the novel LAMS has folded back anchoring flanges, reducing the risk of mechanical irritation caused by the stent edges, potentially leading to a lower risk of bleeding [29]. The hypothesis regarding the lower risk of bleeding with LAMS was based on the specific design features of the stent. Although the stent was in place for >4 weeks, the risk of bleeding was not significantly increased in the LAMS group, indicating that prolonged indwelling times may not be a concern for bleeding associated with the stent. The traditionally recommended indwelling period for LAMS is approximately 3 weeks [12]. However, in patients in whom it is necessary to keep the stent in place for a longer duration to manage the WON effectively, LAMS may be a reasonable option, providing flexibility in the management of PFC drainage and allowing for treatment tailored to individual patients. In addition, no buried LAMS syndrome was reported in this study, suggesting that a dedicated folded-back design may provide a more controlled apposing force, preventing excessive tissue embedment.

Various limitations and key points should be considered when interpreting the results of this study. First, although the sample size was calculated based on the assumption of a higher number of DEN procedures in the plastic stent group, the actual number of DEN procedures in the LAMS group was higher than expected, which may have influenced the conclusions of the study. Second, the study population included a relatively small and heterogeneous group of patients with different proportions of solid components and pancreatitis etiology. Thus, our findings may be underpowered to adequately assess adverse events and other outcomes owing to the small size of the study population. Third, the decision to place a plastic stent through the LAMS for laterally extended WON was not standardized among endoscopists.

In conclusion, our study identified no significant differences in clinical outcomes, including the total number of DEN procedures, between patients treated with LAMS or plastic stents for infected WON. We observed a variation in the median duration of stent indwelling, with LAMS typically removed around 30 days and plastic stent often retained for longer. This variation may contribute to the differences in clinical success noted at 8 weeks, although such conclusions require cautious interpretation. Importantly, there were no significant adverse events, such as bleeding or buried LAMS syndrome, underscoring the safety of electrocautery-enhanced LAMS for extended treatment durations.

Acknowledgement

This study was supported in part by the SoonChunHyang University Research Fund (J.H.M.) and by the free offer for use allowance of the EC-LAMS (Niti-S HOT SPAXUS Stent; Taewoong Medical, Goyang, Korea).

Conflict of Interest

J.H. Moon is a developer of the EC-LAMS (Niti-S HOT SPAXUS Stent; Taewoong Medical, Goyang, Korea). S.W. Park, Y.N. Lee, S.H. Lee, S. H. Kim, D.W. Lee, C.M. Cho, S.B. Kim, and C.H. Park declare that they have no conflict of interest.

Funding Information

SoonChunHyang University Research Fund J.H.M.

Clinical Trial

Trial Registration: Clinical Research Information Service, Republic of Korea (https://cris.nih.go.kr) | Registration number (trial ID): KCT0004087 | Type of study: Prospective, Randomized, Multi-Center Study

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