Accepted Manuscript

Submission Date: 2023-12-24
Accepted Date: 2024-06-07
Accepted Manuscript online: 2024-06-10

Endoscopy

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

Jong Ho Moon, Se Woo Park, Yun Nah Lee, Sang Hyub Lee, Seong-Hun Kim, Dong Wook Lee, Chang Min Cho, Sung Bum Kim, Chan Hyuk Park.

Affiliations below.

DOI: 10.1055/a-2342-1140

Please cite this article as: Moon J, Park S, Lee Y et al. A comparison of novel electrocautery-enhanced lumen-apposing metal stents and plastic stents in EUS-guided drainage of infected walled-off necrosis: A multicenter randomized study. Endoscopy 2024. doi: 10.1055/a-2342-1140

Conflict of Interest: Professor Jong Ho Moon, he is a developer of the novel EC-LAMS (Niti-S HOT SPAXUS Stent™, Taewoong Medical, Goyang, Korea). The other authors have no potential conflicts of interest. All authors alone are responsible for the content and writing of the paper.

This study was supported by SoonChunHyang University Research Fund , J.H.M.

Trial registration: KCT0004087, Clinical Research Information Service, Republic of Korea (https://cris.nih.go.kr), Prospective, Randomized, Multi-Center Study

Abstract:

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

Patients and methods: Patients who underwent endoscopic ultrasound-guided WON drainage were randomly assigned to the LAMS or PS groups. The primary outcome was the total number of direct endoscopic necrosectomy (DEN) procedures required to achieve clinical success. The secondary outcomes included technical success, clinical success, and adverse event occurrence.

Results: Forty-six patients were divided into the LAMS or PS groups (n=23 each). The total number of DEN procedures did not differ significantly between the PS (four procedures, interquartile range [IQR] 2.5–5.0) and LAMS groups (nine procedures, IQR: 8.0–9.0) (P=0.07). The LAMS group demonstrated a significantly higher clinical success rate than the PS group based on intention-to-treat analysis (100% vs. 73.9%, P=0.03) at 8 weeks but not at 4 weeks. No significant bleeding events were reported in the LAMS group, and one was reported in the PS group.

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

Corresponding Author:

M.D. & Ph.D. Se Woo Park, Hallym University Dongtan Sacred Heart Hospital, Department of Internal Medicine, Hwaseong, Korea (the Republic of), britnepak@outlook.com, britnepak@naver.com

Affiliations:
Jong Ho Moon, Soonchunhyang University Hospital Bucheon, Digestive Disease Center and Research Institute, Department of Internal Medicine, Bucheon, Korea (the Republic of)
Se Woo Park, Hallym University Dongtan Sacred Heart Hospital, Department of Internal Medicine, Hwaseong, Korea (the Republic of)
Yun Nah Lee, Soonchunhyang University Hospital Bucheon, Department of Internal Medicine, Bucheon, Korea (the Republic of)
[...]
Chan Hyuk Park, Hanyang University College of Medicine, Department of Internal Medicine, Guri, Korea (the Republic of)

Supplemental material

Authors' names: Se Woo Park et al.

Title of paper: Clinical efficacy and safety of a novel electrocautery-enhanced lumen-apposing metal stent in EUS-guided drainage of infected walled-off necrosis: Multi-center, randomized trial

Table S1. Main clinical outcomes according to the institutions

	A hospital (n=16)	B hospital (n=5)	C hospital (n=6)	D hospital (n=10)	E hospital (n=5)	F hospital (n=4)	P
LAMS, n (%)	8 (50%)	2 (40%)	3 (50%)	5 (50%)	3 (60%)	2 (50%)	
PS, n (%)	8 (50%)	3 (60%)	3 (50%)	5 (50%)	2 (40%)	2 (50%)	
Total procedure time (min), mean (SD)	6.8 ± 2.8	10.7 ± 5.1	7.5 ± 4.8	8.2 ± 4.1	13.4 ± 6.8	10.2 ± 4.2	0.062
Technical success, n (%)	16 (100.0%)	5 (100.0%)	5 (83.3%)	10 (100.0%)	5 (100.0%)	3 (75.0%)	0.160
Multigate drainage, n (%)	2 (12.5%)	1 (20.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	2 (50.0%)	0.239
Additional procedure, n (%)							
PS insertion through LAMS	0 (0.0%)	1 (20.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0.401
ERCP with transpapillary drainage	5 (31.2%)	2 (40.0%)	1 (16.7%)	5 (50.0%)	2 (40.0%)	1 (25.0%)	0.811
Additional stent insertion	2 (12.5%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (20.0%)	1 (25.0%)	0.648
PCD	1 (6.2%)	2 (40.0%)	3 (50.0%)	2 (20.0%)	1 (20.0%)	1 (25.0%)	0.296
Surgical intervention (e.g. VARD)	1 (6.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	0.366
Total no. of DEN, median (IQR)	7.5 [5.0-10.5]	-	5.0 [5.0-5.0]	8.5 [8.0-9.0]	1.0 [1.0-1.0]	-	0.357
Clinical success at 4 weeks, n (%)	4 (25.0%)	3 (60.0%)	3 (50.0%)	6 (60.0%)	2 (40.0%)	2 (50.0%)	0.537
Clinical success at 8 weeks, n (%)	12 (75.0%)	5 (100.0%)	6 (100.0%)	9 (90.0%)	5 (100.0%)	3 (75.0%)	0.416
Overall clinical success regardless period, n (%)	16 (100.0%)	5 (100.0%)	6 (100.0%)	9 (90.0%)	5 (100.0%)	3 (75.0%)	0.276
Successful stent removal, n (%)	16 (100.0%)	5 (100.0%)	6 (100.0%)	9 (90.0%)	5 (100.0%)	3 (100.0%)	0.611
Adverse events: n (%)							
Bleeding	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.235
Spontaneous migration	0 (0.0%)	0 (0.0%)	1 (16.7%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0.298
Stent dislodgement during DEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	>0.999
Stent occlusion leading to infection	4 (25.0%)	3 (60.0%)	3 (50.0%)	4 (40.0%)	2 (40.0%)	2 (50.0%)	0.737
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (25.0%)	0.276
Others	1 (6.2%)	2 (40.0%)	1 (16.7%)	1 (10.0%)	0 (0.0%)	1 (25.0%)	0.385
Stent dysfunction, n (%)	4 (25.0%)	3 (60.0%)	3 (50.0%)	4 (40.0%)	2 (40.0%)	2 (66.7%)	0.628

SD, standard deviation; PS, plastic stent; LAMS, lumen-apposing metal stent; ERCP, endoscopic retrograde cholangiopancreatography; PCD, percutaneous catheter drainage; VARD, Video-assisted retroperitoneal debridement; DEN, direct endoscopic necrosectomy; IQR, interquartile range

A comparison of novel electrocautery-enhanced lumen-apposing metal stents and plastic stents in EUS-guided drainage of infected walled-off necrosis: A multi-center randomized study

Running head: EUS-guided drainage for infected walled-off necrosis

Authors:

Jong Ho Moon M.D. & Ph.D.[1], Se Woo Park M.D. & Ph.D.[2], Yun Na Lee M.D. & Ph.D.[1], Sang Hyup Lee M.D. & Ph.D.[3], Seong-Hun Kim M.D. & Ph.D.[4], Dong Wook Lee M.D. & Ph.D.[5], Chang Min Cho M.D. & Ph.D.[5], Sung Bum Kim M.D. & Ph.D.[6], Chan Hyuk Park, M.D. & Ph.D.[7]

Departmental and institutional affiliations:

[1] Division of Gastroenterology, Department of Internal Medicine, SoonChunHyang University College of Medicine, Bucheon, South Korea

[2] Division of Gastroenterology, Department of Internal Medicine, Hallym University Dongtan Sacred Heart Hospital, Hallym University College of Medicine, Hwaseong, South Korea

[3] Division of Gastroenterology, Department of Internal Medicine, Seoul National University College of Medicine, Seoul, South Korea

[4] Department of Internal Medicine, Research Institute of Clinical Medicine of Jeonbuk National University-Biomedical Research Institute of Jeonbuk National University Hospital, South Korea

[5] Division of Gastroenterology, Department of Internal Medicine, School of Medicine, Kyungpook National University, Daegu, South Korea

[6] Division of Gastroenterology, Department of Internal Medicine, Yeungnam University College of Medicine, Daegu, South Korea

[7] Department of Internal Medicine, Hanyang University Guri Hospital, Hanyang University College of Medicine, Guri, Republic of Korea

Correspondence to:

Professor Se Woo Park M.D. & Ph.D.

Division of Gastroenterology, Department of Internal Medicine, Hallym University Dongtan Sacred Heart Hospital, Hallym University College of Medicine, 7, Keunjaebong-gil, Hwaseong-si, Gyeonggi-do, 18450, Korea

Tel: +82-31-8086-2858, Fax: +82-31-8086-2029, E-mail: mdsewoopark@gmail.com

Word Count: 3,439

Author Contributions

Guarantor of the article: Se Woo Park

Specific author contributions:

Conception and design of the study: Se Woo Park and Jong Ho Moon

Generation, collection, assembly, analysis and/or interpretation of data: Se Woo Park, Jong Ho Moon, Yun Na Lee, Sang Hyup Lee, Seong-Hun Kim, Chang Min Cho, Sung Bum Kim, and Chan Hyuk Park

Drafting or revision of the manuscript: Se Woo Park and Jong Ho Moon

Approval of the final version of the manuscript: Se Woo Park and Jong Ho Moon

ABSTRACT

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

Patients and methods: Patients who underwent endoscopic ultrasound-guided WON drainage were randomly assigned to the LAMS or PS groups. The primary outcome was the total number of direct endoscopic necrosectomy (DEN) procedures required to achieve clinical success. The secondary outcomes included technical success, clinical success, and adverse event occurrence.

Results: Forty-six patients were divided into the LAMS or PS groups (n=23 each). The total number of DEN procedures did not differ significantly between the PS (four procedures, interquartile range [IQR] 2.5–5.0) and LAMS groups (nine procedures, IQR: 8.0–9.0) (*P*=0.07). The LAMS group demonstrated a significantly higher clinical success rate than the PS group based on intention-to-treat analysis (100% vs. 73.9%, *P*=0.03) at 8 weeks but not at 4 weeks. No significant bleeding events were reported in the LAMS group, and one was reported in the PS group.

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

Trial registration number: The International Clinical Trials Registry Platform (https://cris.nih.go.kr; number KCT0004087).

Keywords: Endoscopic ultrasound; lumen-apposing metal stent; plastic stents; walled-off necrosis; direct endoscopic necrosectomy

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 due 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 (PS) 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 lumen-apposing metal stents (LAMSs) for WON drainage has increased recently. A significant benefit of LAMSs is their 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 dislodgement 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 (RCT) comparing LAMS to PS reported no significant difference in clinical outcomes between the two stents and recommended removal of LAMSs within 3 weeks due to

stent-related adverse events (AEs), including bleeding.[12] However, no RCTs have specifically compared the efficacy and safety of novel electrocautery-enhanced LAMSs (EC-LAMSs) with those of PSs for treating infected WON. Therefore, this study evaluated whether EC-LAMSs were more effective than PSs for treating infected WON and assessed whether EC-LAMSs 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.

PATIENTS AND 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 defined according to the 2012 revised Atlanta classification[13] as a mature encapsulation of pancreatic or peripancreatic necrotic tissue contained within an enhancing wall of reactive 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/cmm^3) were excluded from this 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 excluded.

The enrolled patients were randomly assigned to either the LAMS or PS 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. This trial was registered in the International Clinical Trials Registry Platform (https://cris.nih.go.kr; number KCT0004087).

Endoscopic procedures

All procedures were conducted using a linear array echoendoscope by experienced endoscopists using a well-established technique.[16] 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, Korea) was advanced into the WON, coiled under fluoroscopic guidance, and the needle was removed.

Placement of the lumen-apposing metal stents

The EC-LAMS (Niti-S HOT SPAXUS Stent, Taewoong Medical, Goyang, Korea; **Figure 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 using 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 was 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 an electrosurgical unit (ESU) set to AutoCut mode (80–120 Watts, 400–500 Vp), the delivery catheter was advanced into the WON through the guidewire. The stent deployment hub was released to deploy the distal flange of the stent after positioning the catheter within the WON through the guidewire. Subsequently, the echoendoscopist carefully and gently released the proximal flanges 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, Goyang, Korea) was used to dilate the cystostomy tract using an ESU 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, Natick, Massachusetts, USA). Following dilation, one or more 7-Fr PSs with a double-pigtail configuration were placed in the cyst cavity over the guidewire using endoscopy and fluoroscopy (**Video 2**).

Direct endoscopic necrosectomy

We implemented a DEN based on the step-up approach policy, which involves initial EUS-guided drainage followed by monitoring for 72–96 h. Further, drainage-based intervention was considered if insufficient improvement was observed.[17] These interventions may include stent replacement or addition, EUS-guided drainage (multigateway technique), and/or percutaneous drainage (multimodality technique). DEN may be considered if indicated after two rounds of drainage-based step-up interventions.[18] LAMS allows direct insertion of the endoscope through the stent for easier implementation of DEN (**Figures 2A** and **B**). In contrast, PS requires tract dilatation to facilitate endoscope passage and the cumbersome process of reinserting the stent to prevent tract closure

(**Figures 2C** and **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 are captured using instruments originally designed for different 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.[19-21] The debris was released into the stomach or duodenum (**Video 3**). Although no definitive indication is available regarding when to stop DEN, regardless of stent type, the decision is typically made by the endoscopist based on various factors, including clinical improvement, completion of necrosectomy, procedure-related AEs, inadequate access or visualization, and deterioration of the patient's condition.[17]

Outcome measurements and definitions

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

Technical success was defined as the successful placement of the LAMS or PS within the WON. Clinical success is 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 to the initial size, accompanied by the complete resolution of clinical symptoms. Clinical failure was defined as the absence of achieving 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.[22] Significant bleeding was defined as the requirement for transfusion, hospitalization, endoscopic hemostasis, or radiological intervention. As observed on 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.[23]

Statistical analysis

The sample size was determined based on a recent study[24] that focused on the total number of DEN procedures required for treatment success using LAMSs and PSs. The mean number of DENs required was 2.74 ± 1.48 in the PS 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, whereas continuous variables were presented as medians and interquartile ranges (IQR). 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 <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). Statistical significance was set at $P < 0.05$.

RESULTS

Study population and baseline characteristics

A total of 125 patients who underwent EUS-guided drainage for PFCs were initially considered for this study (**Figure 3)**. From this cohort, 79 patients were excluded based on the following criteria: pure pseudocyst or WON with a solid component <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 PS group were transitioned to the LAMS group due to poor clinical response, and one patient initially assigned to the LAMS group was crossed over to the PS group due to technical failure.

The median patient age was 49 and 56 years in the PS 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 PS and LAMS groups.

Walled-off necrosis characteristics and procedure-related findings

The distribution of WON locations did not differ significantly between the PS and LAMS groups (**Table 2**). The degree of necrosis, calculated based on the solid portion within the WON, was 70% (IQR: 60.0–80.0%) in the PS group and 80% (IQR: 70.0–80.0%) in the LAMS group. The largest diameter of the WON was similar between the groups (PS: 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 PS (87.0%) and LAMS (95.7%) groups. The main pancreatic duct (PD) was intact in 82.6% of the patients in the PS group and in 91.3% of the patients in the LAMS group. The total procedure time was not significantly different between the PS (8.5 min [IQR: 7.8–9.9 min]) and LAMS (6.8 min [IQR: 4.5–10.7 min]) groups. Additional procedures, including percutaneous catheter drainage, additional stent placement, and transpapillary PD drainage via endoscopic retrograde

cholangiopancreatography, were more frequently performed in the PS group than in the LAMS group, although the difference was not significant.

Clinical outcomes and adverse events

The technical success rates were 95.7% and 100% in the PS and LAMS groups were 95.7% and 100 %, respectively (**Table 2**). At 8 weeks, the LAMS group had a significantly higher clinical success rate than the PS 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 54.5% of patients in the PS 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 PS group and 33 days (IQR: 29.2–36.8 days) in the LAMS group.

The occurrence of DEN did not differ between the PS and LAMS groups (13% vs. 21.7%, respectively; *P*=0.70), nor did the total number of DEN procedures required to achieve clinical success (PS: 4 procedures [IQR: 2.5–5.0 procedures]; LAMS: 9 procedures; [IQR: 8.0–9.0]; *P*=0.07). Overall, the rates of AEs were not significantly different between the groups. The incidence of stent occlusion did not show a statistically significant difference between the PS 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 S1 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.

DISCUSSION

Our findings indicate that the novel EC-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 than PS. Notably, 91.3% of the patients in the PS group eventually achieved clinical success, indicating comparable therapeutic efficacy between the two stents. Therefore, while LAMS achieves faster therapeutic efficacy for infected WON than PS, both stents exhibit high technical and clinical success rates.

Although PSs are commonly the first choice for endoscopic drainage of PFC, including pseudocysts, their performance may be suboptimal for patients with WON, as the reported clinical success rates range from 63% to 70%.[25] Unplanned revision procedures or necrosectomies are required in up to 27% of patients with WON treated with PSs to achieve a successful resolution.[1] Siddiqui et al. reported that more frequent procedures were required to resolve WON when PSs were used than when tubular structure metal stents or LAMS were used (81% vs. 95% vs. 90%, respectively; all P <0.001).[1] Additionally, PS was identified as the only negative predictor of successful resolution of WON in a multivariate analysis. In contrast, LAMSs 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 needing 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.[26]

Contrary to the initial and primary hypotheses that the number of DEN procedures would be lower, more studies were conducted in the LAMS group in this 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 participants 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 PS and LAMS groups, respectively. Considering the characteristics of WON, the proportion of DEN procedures performed in the LAMS group was notably greater than that in the PS group. This trend was evident in the intention-to-treat (ITT) analysis (five cases/21.7% in the LAMS group vs. three cases/13.0% in the PS group) and the as-treated analysis (six cases/24.0% in the LAMS group vs. two cases/9.5% in the PS group). Additionally, the total number of DEN procedures required for clinical success was higher in the LAMS group than in the PS group (ITT 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 to the PS 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 PS, which requires tract dilatation 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 AEs associated with balloon dilatation, such as bleeding or repeated stent reinsertion, may be reduced with LAMS, making it a more suitable option for some patients.[27]

The rates of AEs 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 PS group, which differs from previously reported results.[12] This difference may be attributed to geographic 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.[28] 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, LAMSs may be a reasonable option, providing flexibility in the management of PFC drainage and allowing for treatment tailored to individual patients. In addition, no occurrences of buried LAMS syndrome were reported in this study, suggesting that a dedicated folded back design may provide a more controlled apposing force, preventing excessive tissue embedding.

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 PS 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. Hence, our findings may be underpowered to adequately assess AEs and other outcomes due to the small size of the study population. Third, the decision to place a PS 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 PS for infected WON. We observed a variation in the median duration of stent indwelling, with LAMS typically removed around 30 days and PS 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 AEs, such as bleeding or buried LAMS syndrome, underscoring the safety of EC-LAMS for extended treatment durations.

ACKNOWLEDGEMENTS

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).

COMPETING INTERESTS

Professor Jong Ho Moon is a developer of the EC-LAMS (Niti-S HOT SPAXUS Stent, Taewoong Medical, Goyang, Korea). The other authors have no potential conflicts of interest. All authors are responsible for the content and writing of the paper.

References

1. Siddiqui, A.A., et al., *Fully covered self-expanding metal stents versus lumen-apposing fully covered self-expanding metal stent versus plastic stents for endoscopic drainage of pancreatic walled-off necrosis: clinical outcomes and success.* Gastrointest Endosc, 2017. **85**(4): p. 758-765.
2. Lang, G.D., et al., *EUS-guided drainage of peripancreatic fluid collections with lumen-apposing metal stents and plastic double-pigtail stents: comparison of efficacy and adverse event rates.* Gastrointest Endosc, 2018. **87**(1): p. 150-157.
3. Varadarajulu, S., et al., *Endoscopic transmural drainage of peripancreatic fluid collections: outcomes and predictors of treatment success in 211 consecutive patients.* J Gastrointest Surg, 2011. **15**(11): p. 2080-8.
4. Baron, T.H., et al., *Outcome differences after endoscopic drainage of pancreatic necrosis, acute pancreatic pseudocysts, and chronic pancreatic pseudocysts.* Gastrointest Endosc, 2002. **56**(1): p. 7-17.
5. Penn, D.E., et al., *Prospective evaluation of the use of fully covered self-expanding metal stents for EUS-guided transmural drainage of pancreatic pseudocysts.* Gastrointest Endosc, 2012. **76**(3): p. 679-84.
6. Shah, R.J., et al., *Safety and efficacy of endoscopic ultrasound-guided drainage of pancreatic fluid collections with lumen-apposing covered self-expanding metal stents.* Clin Gastroenterol Hepatol, 2015. **13**(4): p. 747-52.
7. Siddiqui, A.A., et al., *EUS-guided drainage of peripancreatic fluid collections and necrosis by using a novel lumen-apposing stent: a large retrospective, multicenter U.S. experience (with videos).* Gastrointest Endosc, 2016. **83**(4): p. 699-707.
8. Itoi, T., et al., *Clinical evaluation of a novel lumen-apposing metal stent for endosonography-guided pancreatic pseudocyst and gallbladder drainage (with videos).* Gastrointest Endosc, 2012. **75**(4): p. 870-6.

9. Sharaiha, R.Z., et al., *Endoscopic Therapy With Lumen-apposing Metal Stents Is Safe and Effective for Patients With Pancreatic Walled-off Necrosis.* Clin Gastroenterol Hepatol, 2016. **14**(12): p. 1797-1803.

10. Yoo, J., et al., *Feasibility, safety, and outcomes of a single-step endoscopic ultrasonography-guided drainage of pancreatic fluid collections without fluoroscopy using a novel electrocautery-enhanced lumen-apposing, self-expanding metal stent.* Endosc Ultrasound, 2017. **6**(2): p. 131-135.

11. Rinninella, E., et al., *EUS-guided drainage of pancreatic fluid collections using a novel lumen-apposing metal stent on an electrocautery-enhanced delivery system: a large retrospective study (with video).* Gastrointest Endosc, 2015. **82**(6): p. 1039-46.

12. Bang, J.Y., et al., *Non-superiority of lumen-apposing metal stents over plastic stents for drainage of walled-off necrosis in a randomised trial.* Gut, 2019. **68**(7): p. 1200-1209.

13. Banks, P.A., et al., *Classification of acute pancreatitis--2012: revision of the Atlanta classification and definitions by international consensus.* Gut, 2013. **62**(1): p. 102-11.

14. Zhang, H., et al., *Ultrasonic/CT image fusion guidance facilitating percutaneous catheter drainage in treatment of acute pancreatitis complicated with infected walled-off necrosis.* Pancreatology, 2018. **18**(6): p. 635-641.

15. Park, C.H., et al., *Efficacy and safety of etomidate-based sedation compared with propofol-based sedation during ERCP in low-risk patients: a double-blind, randomized, noninferiority trial.* Gastrointest Endosc, 2018. **87**(1): p. 174-184.

16. Irisawa, A., et al., *Basic technique of FNA.* Gastrointest Endosc, 2009. **69**(2 Suppl): p. S125-9.

17. Rerknimitr, R., *Endoscopic Transmural Necrosectomy: Timing, Indications, and Methods.* Clin Endosc, 2020. **53**(1): p. 49-53.

18. Chandrasekhara, V., et al., *Predicting the Need for Step-Up Therapy After EUS-Guided Drainage of Pancreatic Fluid Collections With Lumen-Apposing Metal Stents.* Clin

Gastroenterol Hepatol, 2021. **19**(10): p. 2192-2198.

19. Arvanitakis, M., et al., *Endoscopic management of acute necrotizing pancreatitis: European Society of Gastrointestinal Endoscopy (ESGE) evidence-based multidisciplinary guidelines.* Endoscopy, 2018. **50**(5): p. 524-546.
20. Seifert, H., et al., *Transluminal endoscopic necrosectomy after acute pancreatitis: a multicentre study with long-term follow-up (the GEPARD Study).* Gut, 2009. **58**(9): p. 1260-6.
21. Abu Dayyeh, B.K., et al., *Large-caliber metal stents versus plastic stents for the management of pancreatic walled-off necrosis.* Gastrointest Endosc, 2018. **87**(1): p. 141-149.
22. Nass, K.J., et al., *Novel classification for adverse events in GI endoscopy: the AGREE classification.* Gastrointest Endosc, 2022. **95**(6): p. 1078-1085 e8.
23. de Jong, D.M., et al., *Impact of long-term transmural plastic stents on recurrence after endoscopic treatment of walled-off pancreatic necrosis.* Endoscopy, 2024.
24. Bapaye, A., et al., *Endoscopic ultrasonography-guided transmural drainage of walled-off pancreatic necrosis: Comparison between a specially designed fully covered bi-flanged metal stent and multiple plastic stents.* Dig Endosc, 2017. **29**(1): p. 104-110.
25. Sharaiha, R.Z., et al., *Metal versus plastic for pancreatic pseudocyst drainage: clinical outcomes and success.* Gastrointest Endosc, 2015. **82**(5): p. 822-7.
26. Bang, J.Y., et al., *Lumen-apposing metal stents for drainage of pancreatic fluid collections: When and for whom?* Dig Endosc, 2017. **29**(1): p. 83-90.
27. Gardner, T.B., et al., *Direct endoscopic necrosectomy for the treatment of walled-off pancreatic necrosis: results from a multicenter U.S. series.* Gastrointest Endosc, 2011. **73**(4): p. 718-26.
28. Lee, K.J., et al., *Placement of Plastic Stents after Direct Endoscopic Necrosectomy through a Novel Lumen-Apposing Metal Stent for Effective Treatment of Laterally Extended Walled-Off Necrosis: A Pilot Study.* J Clin Med, 2023. **12**(3).

FIGURE LEGENDS

Figure 1. Lumen-apposing metal stent. (A) The lumen-apposing metal stent (LAMS) (Niti-S HOT SPAXUS, Taewoong Medical, Gyeonggi-do, Korea) 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 WON. (D) Bilateral anchor flanges were designed to establish lumen-to-lumen anchoring and diminish stent migration and leakage.

Figure 2. Direct endoscopic necrosectomy using each stent. The lumen-apposing metal stent enables straightforward placement of the endoscope through the stent to simplify direct endoscopic necrosectomy (DEN) implementation (see Figures 2A and B). In contrast, the plastic stent necessitates tract dilatation to ease endoscope passage and involves a cumbersome procedure of stent reintroduction to avoid tract closure after DEN (see Figures 2C and D).

Figure 3. Study flow diagram. Abbreviations: EUS, endoscopic ultrasound; WON, walled-off necrosis; LAMS, lumen-apposing metal stent; PS, plastic stent.

Categorical variables were presented as frequencies and proportions using the as-treated analysis.

VIDEO LEGENDS

Video 1. Endoscopic ultrasound-guided drainage using a lumen-apposing metal stent for infected walled-off necrosis. Endoscopic ultrasound (EUS)-guided drainage was performed using a linear array echoendoscope in a patient diagnosed with infected walled-off necrosis (WON). Once the WON was identified in 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 lumen-apposing metal stent (LAMS) (Niti-S HOT SPAXUS; Taewoong Medical, Gyeonggi-do, Korea) featuring an electrocautery-enhanced tip was introduced into the WON with a cutting current and gradually deployed under the guidance of both echo-endoscopy and fluoroscopy. Finally, the stent was fully deployed in the working channel under endoscopic observation.

Video 2. Endoscopic ultrasound-guided drainage using a plastic stent for infected walled-off necrosis. Endoscopic ultrasound (EUS)-guided drainage was performed using a linear array echoendoscope in a patient diagnosed with infected walled-off necrosis (WON). The WON was identified within the stomach and punctured using a standard 19-G 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, Natick, Massachusetts, USA). After dilation, a plastic stent with a double-pigtail configuration was introduced into the WON and was gradually deployed.

Video 3. Direct endoscopic necrosectomy with or without a lumen-apposing metal stent. Direct endoscopic necrosectomy (DEN) with a lumen-apposing metal stent (LAMS) allows the advancement of a standard upper endoscope into walled-off necrosis (WON). 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 track dilation using a 15 mm balloon catheter (CRE balloon catheter, Boston Scientific, Natick, Massachusetts, USA). After the track is dilated, the remaining procedure mirrors that of the LAMS.

TABLE

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

	ITT analysis			As treated analysis		
Variable	PS cohort (N=23)	LAMS cohort (N=23)	*P*-value	PS cohort (N=21)	LAMS cohort (N=25)	*P*-value
Age, years, median (IQR)	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
Sex (Male), n (%)	11 (47.8%)	16 (69.6%)	0.23	9 (42.9%)	18 (72.0%)	0.09
BMI, kg/m^2, median (IQR)	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, /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, /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
γGT, 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

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

Table 2. WON characteristics and procedure-related findings

	ITT analysis			As treated analysis		
Variable	PS cohort (N=23)	LAMS cohort (N=23)	*P*-value	PS cohort (N=21)	LAMS cohort (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, cm), median (IQR)	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 (min), median (IQR)	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 (%)						
PS 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%)	0.39

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

Table 3. Clinical outcomes

	ITT analysis			As treated analysis		
Variable	PS cohort (n=23)	LAMS cohort (n=23)	P-value	PS cohort (n=21)	LAMS cohort (n=25)	P-value
Direct endoscopic necrosectomy	3 (13.0%)	5 (21.7%)	0.70	2 (9.5%)	6 (24.0%)	0.37
Total no. of DEN, 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	12 (54.5%)	6 (26.1%)	0.10	10 (50.0%)	8 (32.0%)	0.36
Duration of stent placement (days), median (95% CI)	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 (days), median (95% CI)	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%)	0.47	20 (100.0%)	24 (96.0%)	>0.99
Clinical success at 4 weeks, n (%)	7 (30.4%)	13 (56.5%)	0.14	7 (33.3%)	13 (52.0%)	0.33
Clinical success at 8 weeks, n (%)	17 (73.9%)	23 (100.0%)	0.03	17 (81.0%)	23 (92.0%)	0.50
Adverse events, n (%) *						
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 dislodgement 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

ITT, intention-to-treat; PS, plastic stent; IQR, interquartile range; DEN, direct endoscopic necrosectomy

* 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.