

The Efficacy and Safety of Endoscopic Ultrasound-Guided Retroperitoneal Fluid Collection Drainage with Novel Electrocautery-Enhanced Lumen-Apposing Metal Stents (with Video)

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Background/Aims: Various lumen-apposing metal stents (LAMS) have been used for the endoscopic ultrasound-guided transmural drainage (EUS-TD) of postoperative pancreatic fluid collections (POPFC) and peripancreatic fluid collections (PFC). In this study, we aimed to assess the efficacy and safety of novel electrocautery-enhanced LAMSs (Hot-Plumber with Z-EUS IT) with different inter-flange lengths (13 to 33 mm) for managing POPFC and PFC.

Methods: We reviewed the interventional EUS database of Asan Medical Center to identify consecutive patients with POPFC or PFC who underwent EUS-TD with the novel LAMSs between April 2023 and December 2023. Technical success, clinical success, and adverse events were evaluated.

Results: Ten patients (5 with POPFCs and 5 with PFCs) were included in the analysis. The technical and clinical success rates were 100% and 90%, respectively. The LAMS was placed using either the freehand technique (n=5) or the over-the-guide wire technique (n=5). One patient successfully underwent endoscopic necrosectomy for walled-off necrosis through a novel LAMS. Two patients experienced adverse events (one stent migration and one infection). The LAMS was removed in 7 out of 10 patients after resolution of the fluid collection at a median of 61 days (interquartile range, 31 to 69 days) post-LAMS placement.

Conclusions: EUS-TD using the novel LAMS for POPFC and PFC demonstrated high efficacy and an acceptable safety profile. This novel LAMS represents a viable option when selecting stents for EUS-guided drainage of the POPFC and PFC. (*Gut Liver*, 2025;19:454-461)

Key Words: Endosonography; Pancreatic pseudocyst; Stents; Drainage

INTRODUCTION

Endoscopic ultrasound-guided transmural drainage (EUS-TD) has become the preferred first-line therapeutic approach for managing symptomatic postoperative pancreatic fluid collections (POPFC) and peripancreatic fluid collections (PFC) including walled-off necrosis (WON) and pancreatic pseudocyst (PP).^{1,2}

Lumen-apposing metal stents (LAMS) are designed to provide stable anchorage across non-adherent luminal structures in apposition, potentially reducing the risk of stent-related adverse events such as spontaneous stent mi-

gration and fluid leakage into the peritoneum. In cases of WON, the large diameter of the LAMS is particularly advantageous, facilitating effective drainage of necrotic debris and allowing access for direct endoscopic necrosectomy. Since their introduction, LAMS have been widely used in EUS-TD for POPFC and PFC over the past decade.³⁻⁹

An electrocautery-enhanced delivery system with LAMS enables one-step placement of a stent without the need for tract dilation and guidewire (GW) exchanges. To date, two types of electrocautery-enhanced LAMS—namely Hot-AXIOS (AXIOS; Boston Scientific Medical Co., Marlborough, MA, USA) and Hot-SPAXUS (Niti-

S SPAXUS; Taewoong Medical Co., Goyang, Korea)—are commercially available and have demonstrated technical feasibility and high efficacy in managing POPFC and PFC.^{10–14} Recently, a novel electrocautery-enhanced LAMS, Hot-Plumber (HANAROSTENT Hot-Plumber with Z-EUS IT; MI Tech Co., Seoul, Korea), featuring various inter-flange lengths (13 to 33 mm), was developed. Its feasibility has been evaluated in previous studies, although these were limited to an animal experiment and a single case report.^{15,16} The relatively long inter-flange length and the availability of 12 different stent size specifications suggest that this LAMS may be particularly useful for draining fluid collections located more than 1 cm away from the gastrointestinal (GI) wall.

In this study, we aimed to evaluate the efficacy and safety of this novel electrocautery-enhanced LAMS for managing POPFC and PFC.

MATERIALS AND METHODS

1. Patients

We reviewed the interventional EUS database at Asan Medical Center to identify consecutive patients with POPFC or PFC with a maximum diameter greater than 6 cm, who underwent EUS-TD using a novel LAMS between April 2023 and December 2023. The inclusion criteria were: (1) infected POPFC or PFC, or (2) symptomatic POPFC or PFC, causing organ compression-related symptoms such as abdominal pain, early satiety, or jaundice. The exclusion criteria were as follows: (1) age <20 years, (2) pregnancy, (3) previous placement of other stents, or (4) absence of follow-up computed tomography (CT) imaging for evaluating clinical success. This single-center, retrospective pilot study was approved by the Institutional

Review Board of Asan Medical Center (IRB number: 2024-0821). Written informed consent was waived. PFC was categorized as either PP or WON according to the revised Atlanta classification.¹⁷ POPFC was defined as a clinically relevant postoperative pancreatic fistula-associated fluid collection following pancreatectomy.¹⁸

2. Stent and delivery system

1) Lumen-apposing metal stents

The novel LAMS, Hot-Plumber (HANAROSTENT Hot-Plumber; MI Tech Co.), is made of nitinol wire and is fully covered with a silicone membrane. The stent has anti-migration bi-flanges at both ends (Fig. 1A). A lasso string is attached to one flange for easy stent removal (Fig. 1B). The novel LAMS comes in diameters of 10, 12, 14, and 16 mm, with available inter-flange lengths of 13 mm (total length 20 mm), 23 mm (total length 30 mm), and 33 mm (total length 40 mm). With four diameters and three inter-flange lengths, 12 different stent sizes are available. The operator can select the stent size that best fits the lesion.

2) Delivery system

The novel LAMS is incorporated into an electrocautery-enhanced delivery system (Z-EUS IT; MI Tech Co.), which can be Luer-locked to the inlet port of the EUS scope working channel, enabling a single endoscopist to perform one-handed deployment. The electrode at the distal tip allows advancement of the delivery system into fluid collection, eliminating the need for tract dilation and GW exchanges. To prevent unintended deployment, the system employs a dual safety-locking mechanism that requires locking and unlocking at each step, including advancing or retracting the sheath and deploying the bi-flanges (Fig. 1C).

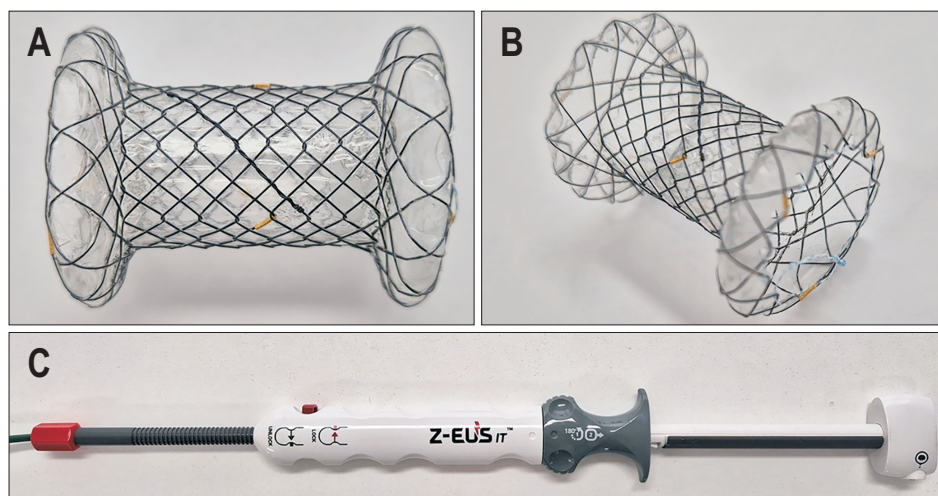


Fig. 1. Designs of the stent and delivery system. (A, B) Lumen-apposing metal stents. (C) Electrocautery-enhanced delivery system.

3. Procedure

Two experienced endoscopists (T.J.S. and D.O.) performed all procedures. EUS-TD was performed using a linear array echoendoscope (GF-UCT 260; Olympus Optical, Tokyo, Japan) under fluoroscopic guidance. All patients received intravenous midazolam and meperidine for conscious sedation, along with prophylactic antibiotics. The gastric or duodenal wall was chosen as the puncture site to access fluid collection, while intervening vessels were avoided using Doppler imaging. The choice of stent size was at the discretion of the attending endoscopist, based on the distance between the GI wall and fluid collection measured on the EUS image.

The delivery system was advanced into the fluid collection using either the freehand (FH) technique or the over the GW technique.¹⁹ In the FH technique, the electrocautery-enhanced distal tip of the delivery system punctured the fluid collection directly. The system was advanced into fluid collection, while the electrocautery tip was activated with a brief burst of pure cutting current. Once the distal tip was confirmed to be within the fluid collection under EUS guidance, the distal flange was deployed (Fig. 2A). The delivery sheath was then pulled back toward the GI tract and the distal flange was anchored to the fluid collection wall. Finally, the proximal flange was deployed using an intra-scope channel stent release technique to prevent stent migration toward the peritoneum (Fig. 2B).^{20,21} The detailed technique is shown in Supplementary Video.

In the GW technique, a 19-gauge needle (EUSN-19-T; Cook Endoscopy, Winston-Salem, NC, USA) punctured the fluid collection, and cystic fluid was aspirated for microbial culture if an infection was suspected. A 0.025-inch GW (Optimo; Taewoong Medical Co.) was passed through the needle and coiled within the fluid collection. After the needle was carefully removed, the electrocautery-enhanced delivery system was advanced into the fluid collection over the GW, followed by LAMS deployment in the same manner as in the FH technique.

4. Follow-up

Follow-up abdominal CT imaging was performed 3 to 4 weeks after LAMS placement to evaluate clinical success (Fig. 2C and D). If the CT scan indicated clinical success, a scheduled LAMS removal was performed. During the stent indwelling period, early abdominal CT imaging or endoscopic examination was performed if symptoms or signs of adverse events were observed.

5. Definition of outcomes

The main outcomes of this study were technical success, clinical success, early and late adverse events, and stent removal success. Technical success was defined as the successful placement of the LAMS across the GI tract into the POPFC or PFC, with adequate fluid flow through the LAMS, as determined by the endoscopist during the procedure. Clinical success was defined as the complete

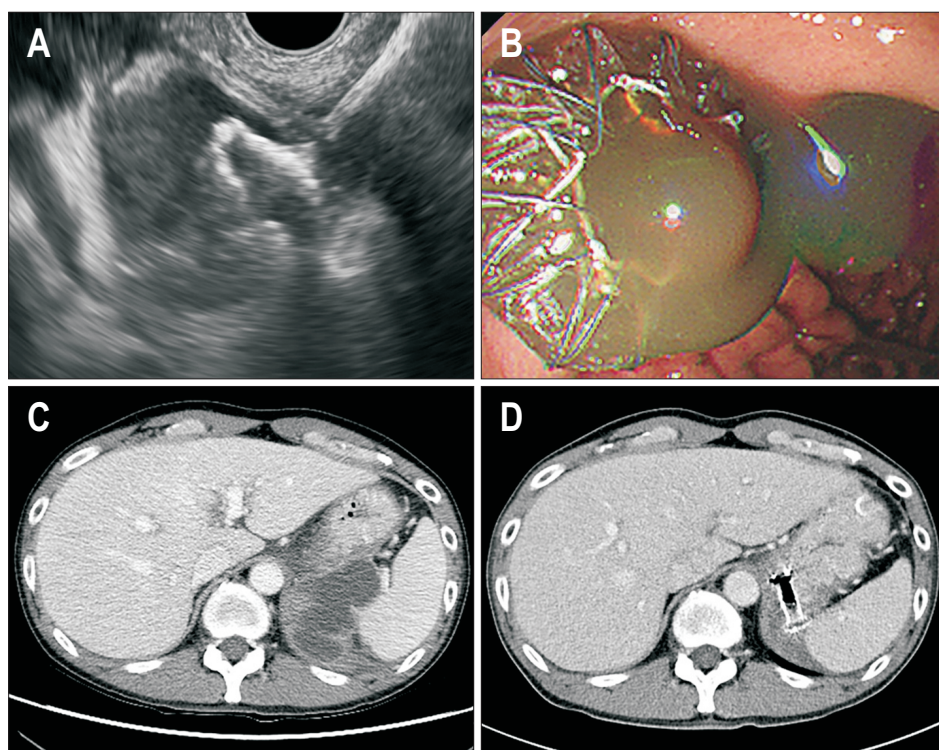


Fig. 2. Endoscopic ultrasound-guided transmurial drainage (EUS-TD) for walled-off necrosis (WON). (A) EUS image showing the deployment of the distal flap of a novel lumen-apposing metal stent (LAMS) in the WON. (B) Endoscopic view showing the successful placement of the novel LAMS, with fluid gushing out through the LAMS. (C, D) Follow-up computed tomography images showing resolution of the WON following novel LAMS placement.

resolution of the POPFC or PFC on follow-up CT imaging at 3 to 4 weeks, along with the resolution of POPFC or PFC-related symptoms. Adverse events were defined and graded according to the American Society of Gastrointestinal Endoscopy Lexicon for endoscopic adverse events.²² Early adverse events were defined as any procedure-related adverse events occurring within 2 weeks, while late adverse events were those occurring after 2 weeks.

6. Statistical analysis

Results are presented as numbers with percentages or as medians with interquartile ranges (IQR). Statistical analyses were performed using SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY, USA).

RESULTS

1. Patient characteristics

A total of 11 patients who met the inclusion criteria were identified in our database. One patient was excluded due to the lack of follow-up CT imaging for evaluating clinical success, as this patient died from lung cancer within one month of LAMS placement. Thus, 10 patients (5 with POPFC, 3 with PP, and 2 with WON) were included in the analysis. The baseline characteristics of the patients are presented in Table 1. The median age was 57 years (IQR, 47.0 to 66.8 years), and 60% were male. The median longest diameter of the fluid collection was 90.5 mm (IQR, 80.5 to 111.8 mm). The indications for EUS-TD were suspected infection (n=7) and abdominal pain (n=3). Among the five patients with PFC, the etiologies of pancreatitis included pancreatic duct obstruction due to malignancy (n=2), alcohol (n=2), and unknown etiology (n=1). All five patients with POPFC underwent pancreatectomy (4 distal pancreatectomy and 1 pancreaticoduodenectomy). In six of the 10 patients, the fluid collections were located less than 1 cm from the GI wall on EUS imaging. In the remaining four patients, all of whom had POPFCs, the distances between the fluid collection and the GI wall measured on EUS imaging were 1.1 cm, 1.1 cm, 1.4 cm, and 2.2 cm, respectively.

2. Procedural outcomes

The procedural outcomes are presented in Table 1. EUS-TD using the novel LAMS was successfully performed in all patients (technical success rate=100%) using either the FH technique (n=5) or the GW technique (n=5). In all cases, neither an additional double-pigtail plastic stent nor a nasocystic drainage tube was placed through the LAMS. The puncture site for EUS-TD was the gastric wall in nine

Table 1. Baseline Characteristics and Outcomes of Patients Undergoing EUS-TD

No.	Age, yr/sex	Fluid collection size, mm	Underlying condition	Indication for procedure	Technique	Stent size, mm (diameter×length)	Puncture site	Technical success	Clinical Success	Adverse event	Interval from index EUS-TD to stent removal, day
1	65/M	85	POPFC	Infection	Guidewire	10×33	Stomach	Yes	Yes	None	29
2	69/M	86	POPFC	Infection	Guidewire	10×33	Stomach	Yes	No	Stent migration	NA
3	51/F	132	PP	Abdominal pain	Freehand	10×23	Stomach	Yes	Yes	None	NA
4	23/F	95	POPFC	Infection	Guidewire	10×13	Stomach	Yes	Yes	None	63
5	52/M	171	WON	Abdominal pain	Guidewire	14×23	Stomach	Yes	Yes	Infection*	61
6	75/F	105	POPFC	Infection	Freehand	12×23	Stomach	Yes	Yes	None	31
7	41/M	96	WON	Infection	Guidewire	10×23	Stomach	Yes	Yes	None	66
8	66/M	67	PP	Infection	Freehand	12×23	Duodenum	Yes	Yes	None	69
9	49/F	63	POPFC	Infection	Freehand	10×23	Stomach	Yes	Yes	None	60
10	62/M	86	PP	Abdominal pain	Freehand	10×13	Stomach	Yes	Yes	None	NA

EUS-TD, endoscopic ultrasound-guided transmural drainage; M, male; F, female; POPFC, postoperative pancreatic fluid collection; PP, pseudocyst; WON, walled-off necrosis; NA, not available.

*The infected WON was treated with two sessions of direct endoscopic necrosectomy through a lumen-apposing metal stents.

patients. The duodenal wall was chosen as the puncture site for only one patient, whose PP was located around the pancreatic head. The clinical success rate was 90% (9/10) in the intention-to-treat analysis. In seven of the 10 patients, the LAMS was removed after achieving clinical success at a median of 61 days (IQR, 31 to 66 days) after LAMS placement. In the remaining three patients, the stents were not removed due to advanced malignancy with a short life expectancy (n=1), spontaneous stent migration (n=1), and loss to follow-up (n=1).

3. Adverse events

During a median follow-up of 229.5 days (IQR, 114.8 to 305.0 days), two early adverse events occurred, including stent migration and infection, while no late adverse events, such as buried LAMS syndrome or delayed bleeding, were observed. In one patient with POPFC who had undergone pancreaticoduodenectomy, a 10×33 mm LAMS was selected for placement because the distance between the gastric wall and the POPFC located at the pancreaticojejunal anastomosis was 22 mm. The LAMS was successfully placed without intraprocedural adverse events. However, the patient developed a mild fever 5 days after the procedure, and a follow-up CT scan at 7 days showed a decrease in the POPFC, but the LAMS was absent from the CT scanning field, suggesting spontaneous LAMS migration. This patient improved with conservative management, and additional intervention was not required. The other patient presenting with abdominal pain underwent EUS-TD using a 14×33 mm LAMS for drainage of symptomatic WON. The patient developed fever and abnormal laboratory results, including leukocytosis and elevated inflammatory markers, 1 day after the procedure. Two sessions of direct endoscopic necrosectomy were performed through the novel LAMS to manage suspected infected WON at 3 days and 5 days after LAMS placement. During these sessions, additional balloon dilatation of the LAMS lumen was not required, and no stent-related adverse events, such as migration, were observed. The LAMS was removed 61 days after placement following confirmation of WON resolution on an abdominal CT performed 1 month after LAMS placement.

DISCUSSION

In this retrospective pilot study, various types of retroperitoneal fluid collections, including POPFC, WON, and PP were treated with EUS-TD using stents of different sizes. We found that EUS-TD using a novel electrocautery-enhanced LAMS demonstrated high technical (100%) and

clinical success rates (90%) with an acceptable safety profile in the management of POPFC and PFC. The feasibility of direct endoscopic necrosectomy through the novel LAMS was also evaluated in one case. These findings are consistent with previous studies on electrocautery-enhanced LAMS for the drainage of PFC, which reported technical success rates of 93% to 99%, clinical success rates of 90% to 97%, and adverse event rates of 5% to 24%.¹⁰⁻¹⁴

Unlike previous studies on LAMS, which primarily included patients with PFC, our study included both PFC and POPFC as candidates for EUS-TD of retroperitoneal fluid collection. POPFC, induced by pancreatic fistula after pancreatectomy, is a significant cause of postoperative morbidity.¹⁸ Percutaneous drainage of POPFCs entails the risk of a permanent pancreatic-percutaneous fistula.²³ Therefore, EUS-TD can be considered the first therapeutic modality for the drainage of POPFC. Our previous study also reported the high effectiveness of EUS-TD using LAMS for POPFC.⁹ Unlike PFC, POPFC is often located at the resection margin of a pancreatectomy and lacks direct apposition to the GI wall.²⁴ This can make the placement of LAMS with an inter-flange length of 1 cm challenging in some cases of POPFC. The availability of new LAMS with variable lengths may be beneficial for the drainage of POPFC, as reflected in the fact that in four of five POPFC patients in the present study, EUS-TD was successfully performed using longer LAMS with inter-flange lengths of 13, 23, and 33 mm.

Three types of electrocautery-enhanced LAMS, namely Hot-AXIOS, Hot-SPAXUS, and Hot-Plumber, are currently available for EUS-TD. Each of these stents has distinct characteristics. Hot-AXIOS, the first developed and widely used LAMS, features an enhanced delivery system that allows single-endoscopist deployment. Hot-AXIOS has a high lumen-apposing force, enabling its use in various interventional EUS procedures, including EUS-guided biliary drainage, gallbladder drainage, and gastroenterostomy.²⁵⁻²⁷ However, the high lumen-apposing force of AXIOS, with its 1 cm inter-flange length, entails a risk of delayed bleeding due to adjacent vessel injury and buried LAMS syndrome, although it theoretically minimizes fluid leakage and stent migration.^{1,28,29} Hot-SPAXUS offers the advantage of both flanges being folded back to hold the two luminal walls in apposition, allowing for adjustable apposition regardless of wall thickness. Although the total length of the stent is 20 mm, the inter-flange length can be shortened to 7 mm after deployment. This unique design is expected to minimize the risk of late adverse events caused by high lumen-apposing force.⁷ However, the electrocautery-enhanced delivery system of this stent is a 10-F conventional system that is not locked to the inlet port of

the EUS scope channel, making single-operator deployment unfeasible. Hot-Plumber is available in four different diameters and three different lengths, providing a total of 12 different-size options. This variety may offer endoscopists more flexibility in selecting the appropriate stent size based on the characteristics of the target lesion. Hot-Plumber has relatively longer lengths (13, 23, and 33 mm) compared to other LAMS such as AXIOS and SPAXUS. The reduced lumen-apposing force due to the longer inter-flange lengths may lower the risk of late adverse events, such as delayed bleeding and buried LAMS syndrome. In this study, no life-threatening or late adverse events were observed during the follow-up period. POPFC or PFC located more than 1 cm away from the GI wall could be candidates for EUS-TD using the Hot-Plumber with lengths of 13, 23, and 33 mm. However, theoretically, LAMS with less lumen-apposing force carries the risk of fluid leakage and stent migration. In our study, one patient with POPFC experienced spontaneous migration of a 10×33 mm LAMS. The longest available stent (33 mm) was used for this patient because the distance between the two lumens was measured as 22 mm on the EUS image. The plausible explanation for the spontaneous stent migration is the reduced lumen-apposing force provided by the longer LAMS and the increasing distance between the two lumens as the fluid collection rapidly collapsed, contributing to the stent migration. Further studies are needed to evaluate the relationship between procedural outcomes and LAMS size.

Despite the feasibility of the FH technique in EUS-TD using Hot-Plumber, the delivery system was advanced into the fluid collection using the GW technique in five patients in this study. The FH technique offers advantages over the GW technique, such as faster and technically easier stent placement without the need for an additional 19-gauge needle puncture followed by GW advancement into the fluid collection. Meanwhile, the GW technique allows for fluid aspiration for microbial culture before stent deployment and enables the placement of a coaxial plastic stent through the deployed LAMS over the GW. The GW technique is particularly useful for stabilizing the advancing delivery system, especially when the EUS scope is acutely angulated, or the targeted fluid collection is located far from the GI tract and not directly attached to it. In the present study, the GW technique was used due to the fluid collection being more than 1 cm from the GI tract (n=3), acute angulation of the scope (n=1), and aspiration for microbial culture before deployment (n=1). Repeated puncture can lead to cystic fluid leakage and entails unnecessary risk of adverse events due to prolonged procedure time. Therefore, the choice between FH and GW techniques for electrocautery-enhanced LAMS placement was made

based on clinical circumstances.

The multi-length LAMS allowed for successful placement even when the distance between the GI wall and the fluid collection was greater than 1 cm. However, the use of the longest LAMS carries potential risks, including fluid leakage and stent migration. In our study, one case of stent migration was observed, which may be attributed to the reduced lumen-apposing force resulting from the longer inter-flange length, as well as the rapid collapse of the fluid collection following stent placement. To reduce these risks, several strategies could be considered. First, careful selection of the appropriate stent size based on the distance between the GI wall and the fluid collection is important, ensuring that the stent is not excessively long relative to the actual distance. Second, particularly in high-risk cases, such as those with large or distally located fluid collections, placing additional coaxial double-pigtail plastic stents through the LAMS may help prevent stent migration.

Our study has several limitations, primarily due to its retrospective design. First, this was a retrospective pilot study with inherent selection bias limitations. Second, all procedures were performed by two experienced endoscopists in a high-volume tertiary center. The different stent sizes were also chosen at the discretion of the attending endoscopists based on the fluid collection characteristics. Therefore, procedural outcomes may vary in other centers with different levels of experience. Third, only a small number of patients were included in this pilot study. However, various types of retroperitoneal fluid collections, such as POPFC, PP, and WON, were treated in this study using different-sized stents, even though the number of cases was limited.

In conclusion, EUS-TD using the novel electrocautery-enhanced long LAMS demonstrated high efficacy and an acceptable safety profile in the management of retroperitoneal fluid collections. This novel stent may be a suitable LAMS option, especially for fluid collections located relatively far (>1 cm) from the GI tract. Further prospective studies are warranted to expand the indications of EUS-TD using the novel LAMS to include procedures such as biliary drainage, gallbladder drainage, and gastroenterostomy.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

AUTHORS CONTRIBUTION

Study concept and design: T.J.S. Data acquisition; Data analysis and interpretation: S.H.C., T.J.S., Y.L., D.O., D.W.S. Drafting of the manuscript: S.H.C. Critical revision of the manuscript for important intellectual content: T.J.S. Statistical analysis: S.H.C. Study supervision: T.J.S. Approval of final manuscript: all authors.

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SUPPLEMENTARY MATERIALS

Supplementary materials can be accessed at <https://doi.org/10.5009/gnl240452>.

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