

# A novel lumen-apposing metal stent for endoscopic drainage of symptomatic pancreatic fluid collections: a retrospective study

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## ABSTRACT

**Background and Objectives:** Previous studies showed that lumen-apposing metal stent (LAMS) provides a feasible route to perform direct endoscopic necrosectomy. However, the high risk of bleeding and migration induced by the placement of LAMS attracted attention. The aim of this study was to evaluate the safety and effectiveness of a novel LAMS.

**Methods:** In this retrospective study, we enrolled patients with symptomatic pancreatic fluid collections (PFCs) to perform EUS-guided drainage with a LAMS in our hospital. Evaluation variables included technical success rate, clinical success rate, and adverse events.

**Results:** Thirty-two patients with a mean age of  $41.38 \pm 10.72$  years (53.1% males) were included in our study, and the mean size of PFC was  $10.06 \pm 3.03$  cm. Technical success rate and clinical success rate reached 96.9% and 93.8%, respectively. Stent migration occurred in 1 patient (3.1%), and no stent-induced bleeding occurred. The outcomes of using LAMS in 10 patients with pancreatic pseudocyst and 22 patients with walled-off necrosis were comparable. Compared with pancreatic pseudocyst, walled-off necrosis needed more direct endoscopic necrosectomy times to achieve resolution ( $P = 0.024$ ).

**Conclusions:** Our study showed that the novel LAMS is effective and safe for endoscopic drainage of PFCs with a relatively low rate of adverse events. Further large-scale multicenter studies are needed to confirm the present findings.

**Key words:** Pancreatic fluid collections; Pseudocyst; Walled-off necrosis; Lumen-apposing metal stents; Direct endoscopic necrosectomy

## INTRODUCTION

According to the 2012 Atlanta classification of acute pancreatitis, pancreatic fluid collections (PFCs) are a frequent complication of pancreatitis, which can be subdivided into pancreatic pseudocysts (PPCs) and walled-off necrosis (WON).<sup>[1]</sup> They are local complications that usually occur >4 weeks after the initial of pancreatitis and need medical intervention if symptomatic.<sup>[2]</sup> In the past decade, the treatment of PFC has undergone a huge change from surgical approach with high morbidity and mortality to the minimally invasive methods like endoscopic drainage.<sup>[3,4]</sup> EUS-guided transluminal drainage now is recommend to be the first-line therapy for the drainage of PFC in special tertiary centers.<sup>[5,6]</sup>

Conventional endoscopic drainage for PFCs including the use of plastic stents and fully covered self-expandable metal stents has been accepted by endoscopists. However, the stent-related complication rate in these 2 stents was high enough to attract attention.<sup>[7,8]</sup> The complication of stent migration or occlusion is reported in many series, which might cause symptomatic recurrence and secondary infection, even the surgery-transferred.<sup>[9]</sup> In 2011, a specially designed lumen-apposing metal stent (LAMS) for drainage of nonadherent extraintestinal fluid collections was first reported by Itoi et al.<sup>[10]</sup> and Binmoeller and Shah.<sup>[11]</sup> The LAMS creates a robust and reliable conduit between nonadherent lumens around the gastrointestinal tract and thus enables the endoscopy to direct observation of the morphological features of the lesions. With higher feasibility and safety compared with plastic stent and fully covered self-expandable metal stents, it gradually alters other methods in drainage of PFC in tertiary centers.<sup>[12]</sup>

However, high migration rates and stent-related bleeding rates during the procedure or hospitalization were reported in previous studies, even beyond 10% in some cohorts.<sup>[13,14]</sup> Thus, we designed a LAMS to facilitate the fixation on the cystic wall, minimizing the risk of migration and providing a large lumen for better drainage of the PFCs and an easier approach for performing direct endoscopic necrosectomy (DEN). However, the data on antimigration effect as well as the efficacy and safety of this device remain unknown.

Therefore, the aims of this study were to evaluate the efficacy, safety, migration rate, and other adverse events of this novel LAMS for symptomatic PFCs drainage in patients.

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**PATIENTS AND METHODS**

*Study design*

This is a retrospective, single-center initial study of PFC patients who underwent EUS-guided transluminal drainage with LAMS between July 2019 and January 2022 from our hospital. Patient data were anonymized and de-identified before received, and were collected from a registered study (No. ChiCTR2000039955). Informed consent was obtained before the intervention. The study was approved by the institutional review boards.

*Patients and follow-up*

Adult patients with PFC (acute pancreatitis >4 weeks) were included if they were symptomatic. The inclusion criteria were as follows: (1) patients between 18 and 75 years old, regardless of sex; (2) patients with PPC or WON diagnosed by enhanced computed tomography (CT); (3) patients with a PFC diameter of more than 6 cm; and (4) the subjects who can understand the purpose of the trial voluntarily participate and sign the informed consent.

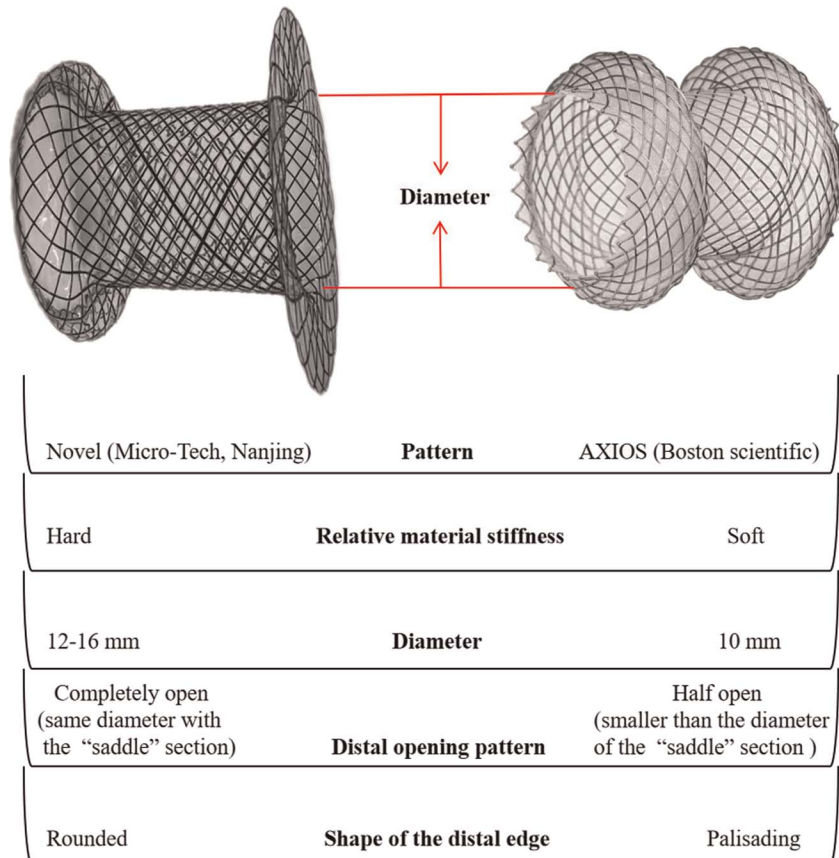
The exclusion criteria were as follows: (1) patients with a poor general condition, who cannot tolerate endoscopy or have contraindications of endoscopic drainage, such as patients with acute inflammation and ulcer of the upper digestive tract after digestive tract reconstruction, upper digestive tract stenosis, and obstruction, and those who cannot pass endoscopy; (2) the patients whose cysts are close to the great vessels, especially those with aneurysms, intracapsular hemorrhage, rupture of cysts, varicose veins of the cardia and gastric

fundus, and suspicious canceration; (3) patients with coagulation dysfunction or bleeding tendency; (4) patients with severe lung or heart disease; (5) patients with allergic history to nitinol; (6) pregnant and lactating women and subjects who are going to be pregnant in the near future; (7) subjects who participated in clinical trials of any drug and/or medical device within 3 months before enrollment; and (8) the researchers believe that there are any other factors that are not suitable for inclusion or affect the subjects' participation in the study.

Follow-up was conducted mainly by CT modality to assess the size of lesions 1 month after endoscopic drainage. Other aspects such as complications with its processing methods were recorded if occurred.

*Device description*

The LAMS (Micro-Tech Co, Ltd, Nanjing, China) evaluated in this study is a nitinol, braided, LAMS fully covered with a silicon membrane. Figure 1 shows the difference between this novel LAMS and AXIOS LAMS. The stent has a fully covered 10- to 16-mm diameter of saddle section and is designed with unilateral flange and unilateral wide flat end to anchor the stomach wall in direct apposition to the cystic wall. The saddle section length is 20 mm. After fully expanded, the available flange diameter ranges from 20 to 26 mm, and the flat end of each stent is 4 mm larger than the flange in diameter. The selection of the stent diameter was mainly based on the contents of the PFC, especially the presence of solid debris identified on EUS. The richer the solid contents, the larger the stent diameter for subsequent necrosectomy and saline irrigation.



**Figure 1.** Comparison between novel lumen-apposing metal stent (LAMS) and typical LAMS.

**Procedure**

According to the outcome of laboratory assays, electrocardiograms, and basic characteristics, patients' physical situation was assessed and graded by an anesthesiologist before endoscopic intervention. All endoscopic procedures [Figure 2] were performed under general anesthesia and on the left-side position of patients. Linear EUS (GF-UCT260; Olympus, Tokyo, Japan) was performed by experienced endosonographers to locate the PFC. Then endosonographers assessed the size and the fluid or solid contents of the PFC as well as the surrounding vessels.

EUS-guided cyst gastrostomy was conducted by using an endoscopic knife (CST-10, Cook, Ireland). A guidewire was coiled into the PFCs. The LAMS was then deployed between the stomach and the PFC's cavity over the guidewire. The distal flat of the LAMS was first released. After the position against the inner cystic wall was verified on EUS, the proximal flange was deployed onto the stomach wall under direct visualization. Further balloon dilation (4- or 6-mm Hurricane; Boston Scientific, Natick, MA) was performed at the discretion of the endoscopists. Endoscopic intervention, including the irrigation of saline or DEN, was dictated by the clinical course of the patient.

**Definitions**

The study end points included effectiveness and safety. Effectiveness consists of the following parts: technical success was defined as drainage of the PFC after placement of the LAMS and removal

of it using a standard endoscopic snare; clinical success was defined as a resolution at least a 50% decrease in PFC size on imaging, without the need for additional endoscopic or surgical drainage. Safety was defined as the number of procedure-related and stent-induced complications. The major complications include stent migration, bleeding, fever, PFC infection, and perforation, which required admission or extraendoscopic or surgical intervention. In particular, stent migration was defined as an adverse event that needed additional interventions to retrieve the stent from the cyst or the other cavities.

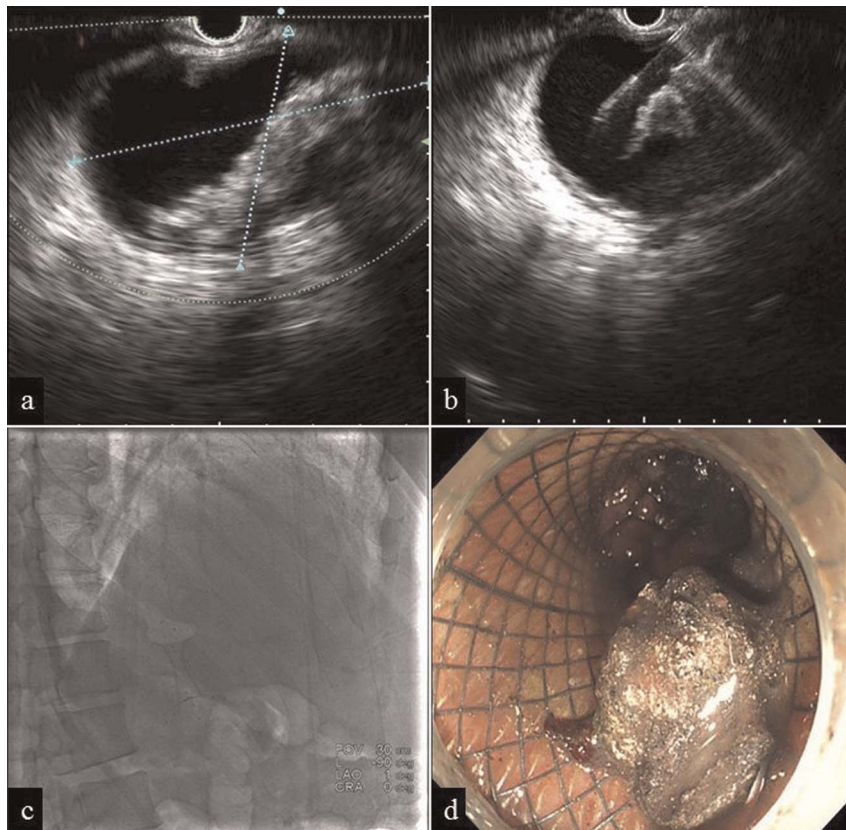
**Statistical analysis**

SPSS 26.0 (IBM, Armonk, NY) software was used for data analysis. Continuous data were reported using means (SD) and medians (interquartile range), as appropriate. They were compared with the Student *t* test or Mann-Whitney *U* test. Categorical data are presented as counts and proportions. Categorical data were compared with Fisher exact test. All tests were 2-sided, and *P* values <0.05 were considered statistically significant.

**RESULTS**

**Patient characteristics**

Thirty-two patients (mean age, 41.38 ± 10.72; 53.1% males) were enrolled. Patient demographics, characteristics, and etiologies are listed in Table 1.



**Figure 2.** Endoscopic procedure of the PFC drainage. A, EUS showing the PFCs in the tail of pancreas. B, EUS images of a guide wire placement into the PFC through aspiration needle. C, Fluoroscopic image showing fully deployed LAMS. D, Endoscopic image showing rich solid debris draining through the stent. PFC: pancreatic fluid collections; LAMS: lumen-apposing metal stent.

*Technical success rate*

The position of LAMS was assessed by radiological and endoscopic imaging, and successful one-shot LAMS placement was achieved in 31 of 32 patients (98.5%) (Table 2). The stents were placed through the stomach wall in all cases (100%). Only one failure placement was caused by the malpositioning, and the stent dropped into the abdominal cavity. A few days later, endoscopic forceps were used to remove it through the artificial stomach wound. No complications occurred during the following hospitalization.

*Clinical success rate*

The clinical success rate excluding one technical failure in the study cohort was 93.5% (29 of 31) with the resolution of the PFCs on repeat imaging. The size of PFC decreased significantly from baseline 30 days after stent placement. Two patients with failure of PFC drainage were both in the WON group. A repeat CT scan of one patient showed that the size of WON decreased from 12 to 6.8 cm 34 days after stent placement, but the reduction degree did not meet the criteria of clinical success. The size of WON in another patient was virtually unchanged 1 month later. However, clinical symptoms of them have resolved, and they will be followed up for a long time to observe and record changes in their signs and symptoms. The median number of days for resolution of the PFCs after stent placement was 31.5 days, and the median days to remove LAMS was 31 days (Table 2).

**Table 1**  
**Baseline characteristics of patients**

Patient Characteristics	
Sex, n (%)	
Male	17 (53.1)
Female	15 (46.9)
Age, y	
Mean ± SD	41.38 ± 10.72
Range	28–69
ASA classification, n (%)	
I	3 (9.4)
II	28 (87.5)
III	1 (3.1)
PFC size, mean ± SD, cm	10.06 ± 3.03
PFC location, n (%)	
Body	14 (43.8)
Tail	14 (43.8)
Head	4 (12.4)
PFC etiology, n (%)	
Pancreatitis of unknown etiology	5 (15.6)
Gallstone pancreatitis	10 (31.2)
Alcohol-induced pancreatitis	8 (25.0)
Postsurgical pancreatitis	3 (9.4)
Trauma	3 (9.4)
Medication induced	1 (3.1)
Hyperlipidemia	2 (6.3)
Main symptoms, n (%)	
Abdominal pain	20 (62.4)
Nausea	2 (6.3)
Vomiting	2 (6.3)
Distention	8 (25.0)

ASA: American Society of Anesthesiologists; PFC: pancreatic fluid collections.

**Table 2**  
**Clinical outcomes of patients in the present study**

Characteristics	Value (%)
Technical success	
Stent placement	31 (96.9)
Stent removal	32 (100)
Clinical success	
30-d visit	29 (93.5)
Follow-up interval from surgery, median (IQR), d	31.5 (28.2–34.7)
Days to stent removal, median (IQR)	31.0 (28.0–31.0)
PFC size on repeat CT, median (IQR), cm	0.5 (0–3.7)
Site of drainage, n (%)	
Transgastric	32 (100)
Procedure-related adverse events, n (%)	
Fever	3 (9.4)
Stent migration	1 (3.1)
Abdominal pain	1 (3.1)
Bleeding	0 (0)

CT: computed tomography; IQR: interquartile range; PFC: pancreatic fluid collection.

*Adverse events*

Adverse events occurred totally in 5 patients. The main adverse event was fever (9.4%). The baseline temperatures of those 3 patients were in the normal range, and 1 day after the procedure, an unexplained fever occurred. Using antibiotics, their temperature returned to normal within 2 or 3 days. Distal stent migration occurred in 1 patient (3.1%) when the endoscopist performed DEN. After irrigation of saline and DEN were completed, LAMS was retrieved. Unexplained abdominal pain occurred in another patient (3.1%) and gradually faded away after the performance of DEN. No complication of bleeding (0%) occurred neither in the procedural period nor during the follow-up period.

*Subgroup analysis of patients with PPC versus WON*

There were no differences between the PPC group and the WON group in terms of baseline characteristics, American Society of Anesthesiologists classification, PFC etiology, PFC size, and symptoms, as shown in Table 3. Patients with WON experienced significantly greater times of debridement compared with PPC ( $P = 0.024$ ). No significant difference was detected in terms of adverse events, days to stent removal, and hospitalization time after stent placement. Although the failure of clinical resolution of PFCs all occurred in the WON group, the comparison between the 2 groups was not statistically significant ( $P = 1.000$ ).

**DISCUSSION**

In the present study, we evaluated the outcomes of EUS-guided drainage for PFCs with a novel LAMS (Micro-Tech Co, Ltd). Technical success and clinical success of this LAMS achieved in 96.9% and 93.5% of patients, respectively. Before the advent of this LAMS, 3 main types of stents were reported in the literature. Table 4 shows the outcomes of 3 frequently used LAMS in previous studies. Among them, the technical success and the clinical success of EUS-guided drainage for PFCs with an AXIOS LAMS (Boston Scientific) were relatively higher than the else stents, which ranged from 96% to 100% and 89% to 96%, respectively. The NAGI pseudocyst stent was specifically designed to act as a temporary cystogastrostomy and achieved high technical success to 99% in 205 patients and 98.1%



**Table 3**

**Subgroup analysis comparing pseudocyst versus walled-off pancreatic necrosis**

	PPC (n = 10)	WON (n = 22)	P
Sex (male), n (%)	4 (40.0)	13 (59.1)	0.450
Age, mean (SD), y	40.30 (9.73)	41.86 (11.33)	0.709
AP biliary etiology, n (%)	3 (30.0)	7 (31.8)	
AP other etiologies, n (%)	7 (70.0)	15 (68.2)	
ASA classification, n (%)			0.354
I	0 (0)	3 (13.6)	
II	10 (100)	18 (81.8)	
III	0 (0)	1 (4.5)	
Size at CT scan, mean (SD), cm	9.43 (1.94)	10.34 (3.42)	0.441
Debridement times, median (IQR)	1 (0.75–1)	2 (1–3)	0.024
Technical success, n (%)	10 (100)	21 (95.5)	1.000
Clinical success, n (%)	10 (100)	19 (90.5)	1.000
Adverse events (overall), n (%)	2 (20.0)	3 (13.6)	0.572
Migration rate	0 (0)	1 (4.5)	
Abdominal pain	0 (0)	1 (4.5)	
Fever	2 (20.0)	1 (4.5)	
Days to stent removal, median (IQR), d	32.0 (26.0–34.5)	30.5 (27.7–32.2)	0.316
Hospitalization time after stent placement, mean (SD), d	9.1 (5.7)	10.7 (5.4)	0.444

AP: acute pancreatitis; ASA: American Society of Anesthesiologists; CT: computed tomography; IQR: interquartile range; PPC: pancreatic pseudocyst; WON: walled-off necrosis.

in 54 patients. However, the reported clinical success of NAGI stent fluctuated between 76.6% and 96.5%. SPAXUS, a novel fully covered with silicone membrane stent, achieved 87.2% technical success and 90.2% clinical success in 47 patients. The successful insertion of the LAMS reported in our study was in line with the aforementioned studies. In terms of clinical success, our novel LAMS was comparable to AXIOS stent and slightly higher than SPAXUS stent and NAGI stent. However, larger-scale controlled studies were required to confirm the outcomes observed so far.

The most intriguing innovation of previous LAMS was the fully covered metallic prosthesis in the shape of a dumbbell with anchoring flanges on 2 sides of a saddle. The diameter of the lumen was larger than the normal gastrointestinal endoscope, which allowed the introduction of an endoscope into the cyst to conduct irrigation or DEN. However, some reported literature demonstrated that the main adverse events, including stent migration rate and bleeding rate, reached 18.5% and 4%, respectively, which was high enough to raise attention.<sup>[24]</sup> In case of stent migration, extrainterventions like open surgery were required to remove the stent.<sup>[25]</sup> Bleeding also needed to be stopped by drugs or endoscopic interventions.

The overall adverse event rate of the new-designed LAMS reported in our study was 15.6%, which was relatively lower than some studies of other LAMS (Table 4). Stent migration rate was even occurred more than 10% of patients by using double-flange stents. In addition, the complication of stent-related bleeding reported in a study of AXIOS stent was present in 16.2% patients. Theoretically, device-related bleeding can be induced when a stent tip scrapes the cystic wall, especially in the period of rapid shrinkage of a PFC.<sup>[26]</sup> The distal end of the novel stent designed to be flat facilitated the fixation on the cystic wall and prevented migration of the stent. Using this novel stent, migration occurred only in 1 patient (3.1%). That is to say, this special design of the stent minimized the risk of migration. Furthermore, designed with a distal flat end and rounded tips, the novel stent minimized the mechanical irritation of the adjacent vessels, which explained why bleeding did not occur in our study.

Subgroup analysis of PPC and WON showed comparable outcomes both in technical success and clinical success, demonstrating that this novel LAMS achieved similar effectiveness in draining both types of lesions. Moreover, we found that, compared with PPC, WON needed more times of interventions to conduct drainage of the contents, which was in line with the previous literature.<sup>[27]</sup> From the

**Table 4**

**Effectiveness and main adverse events of recent studies on evaluating drainage of pancreatic fluid collections with different type of lumen-apposing metal stents**

Study	Patients (n)	Stent Type	Technical Success	Clinical Success	Overall Adverse Events	Stent Migration	Bleeding
Shamah et al. <sup>[15]</sup>	68	AXIOS	100%	94%	28%	11%	9%
Oh et al. <sup>[16]</sup>	47	SPAXUS	87.2%	90.2%	12.8%	4.3%	0.0%
Khan et al. <sup>[17]</sup>	202	AXIOS	97.1%	88.8%	19.3%	7.4%	2.0%
Schawkat et al. <sup>[18]</sup>	28	AXIOS	96%	96%	36%	11%	7%
Kayal et al. <sup>[19]</sup>	27	AXIOS	100%	96.3%	7.4%	0.0%	3.7%
Anderloni et al. <sup>[20]</sup>	105	AXIOS	100%	93.6%	12.2%	5.1%	4.1%
Kumta et al. <sup>[21]</sup>	192	AXIOS	98.4%	92.6%	7.8%	5.6%	5.7%
Adler et al. <sup>[22]</sup>	80	AXIOS	98.7%	90.0%	23.7%	1.3%	16.2%
Lakhtakia et al. <sup>[23]</sup>	205	NAGI	99.0%	96.5%	13.6%	9.7%	2.9%
Chandran et al. <sup>[6]</sup>	54	NAGI	98.1%	76.6%	26.0%	11.1%	4.7%

viewpoint of the content compositions, WON with more or less solid debris, theoretically required more endoscopic interventions including irrigation of saline and DEN, to speed up the removal of contents.

This study had several strengths and limitations. First, the outcomes of technical success, clinical success, and major adverse events of 3 common LAMS were listed and reviewed in our study. Second, we evaluated the effect on the use of a novel LAMS for PPCs and WON separately to confirm that the drainage outcomes were comparable in those 2 lesions. One limitation of this study is that it was a retrospective study and the number of patients was relatively small. However, the data were collected prospectively, which might reduce the selection bias. In addition, because of the maximum length of the LAMS used in our study was 20 mm, the cases included in our study have a short distance between PFC and the luminal wall of <10 mm. Thus, a longer length of the stents will be designed to match the cases with a long distance (>10 mm) in the future.

In conclusion, using novel LAMS for PFC drainage had high effectiveness and safety, which showed a comparable result to other available LAMSs, and had an extremely low stent migration rate. An equal drainage effect was achieved in PPC and WON. Furthermore, a prospective controlled study is warranted to confirm the safety and effectiveness of this novel LAMS, and whether novel LAMS is superior to other LAMSs for PFC drainage would need more randomized controlled trials.

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### Conflict of Interest

Enqiang Linghu is an Associate Editor of the journal. This article was subject to the journal's standard procedures, with peer review handled independently of the editor and his research group.

### Ethical Approval and Informed Consent

Informed consent was obtained before the intervention. The study was approved by the institutional review boards.

### Author Contributions

All Ning Xu and Longsong Li contributed equally to this manuscript; Ningli Chai and Ning Xu contributed to manuscript drafting; Ning Xu and Longsong Li wrote the manuscript; Song Su, Danqi Zhao, Jingyuan Xiang, Pengju Wang, Yaxuan Cheng were responsible for the revision of the manuscript for significant content; Chai NL and Linghu EQ were the patient's endoscopists and reviewed the literature; all authors issued final approval for the version to be submitted.

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