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Comparison of three different stents for endoscopic ultrasound-guided drainage of pancreatic fluid collection: A large retrospective study

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Key words
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Abstract

Background and Aim: Endoscopic transmural drainage has been recognized as the first-line treatment for pancreatic fluid collection (PFC). Currently, three different types of stents have been extensively applied, including double pigtail plastic stent (PS), fully covered self-expanding metal stent (FCSEMS), and novel lumen-apposing metal stent (LAMS). Nonetheless, limited data are available about the comparison among them in terms of their clinical outcomes and safety for endoscopic ultrasound-guided drainage of PFC.

Methods: The current retrospective study was carried on 160 PFC patients undergoing endoscopic ultrasound-guided drainage from 2010 to 2018 at a single tertiary care center. Patients were divided into three groups based on different drainage ways: drainage using PS, FCSEMS, or LAMS.

Results: A total of 160 PFC patients (104 male and 56 female) were analyzed in this retrospective study, including 62 patients drained with PS, 28 with FCSEMS, and 70 with LAMS. Typically, the technical success (93.5% *vs* 96.4% *vs* 94.3%, $P = 1.000$) and treatment success rates (84.6% *vs* 85.2% *vs* 89.2%, $P = 0.763$) were similar between PS, FCSEMS, and LAMS. With regard to major adverse events, four patients (FCSEMS: $n = 2$ and LAMS: $n = 2$) with pseudoaneurysms developed severe bleeding; among them, 75% (3/4) of patients were observed within 2 weeks after intervention, and two patients in LAMS group died.

Conclusions: There are no significant differences in the clinical outcomes of PFC patients treated with PS, FCSEMS, or LAMS. Nonetheless, severe (or even fatal) bleeding may occur at the early stage after metal stent placement, which should be paid particular attention to.

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Introduction

According to the 2012 revision of the Atlanta Classification, pancreatic fluid collection (PFC) can be generally classified into four categories based on their content and wall maturity, including acute peri-pancreatic fluid collection, acute necrotic collection, pancreatic pseudocysts (PP), and walled-off pancreatic necrosis (WON).[1] Generally, acute peri-pancreatic fluid collection and

acute necrotic collection are primarily treated conservatively, which can be ascribed to the evolutionary pancreatitis and immature wall of collection.[2] After approximately 4 weeks, PFC becomes mature with a well-defined inflammatory wall (PP and WON), and it is appropriate to perform endoscopic intervention when mature PFC continues to grow in size or become symptomatic.[3] Endoscopic ultrasonography (EUS)-guided transmural drainage has been proven to be effective and less invasive compared with surgical interventions[4–6] with the great advancement in endoscopic and imaging techniques, which has been gradually accepted as the first-line treatment for PFC.[7,8]

Currently, options of transmural placed stents for drainage mainly include plastic stent (PS), fully covered self-expanding metal stent (FCSEMS), and newly emerging lumen-apposing metal stent (LAMS). There are limited data comparing clinical efficacy and safety among these three types of stents, and the results of current studies seemed to be confusing. Therefore, this single-center largest retrospective study of China was conducted to provide more evidence for endoscopic management of PFC and explore potential strategies to monitor and manage these patients.

Materials and methods

Patients. The current retrospective study had consecutively enrolled 160 patients undergoing endoscopic EUS-guided transmural drainage of PFC using three different stents (PS, FCSEMS, or LAMS) between August 2009 and March 2018. All patients were identified from the endoscopic database in Shanghai Changhai Hospital. In this study, "PFC" referred to PP and WON. The drainage inclusion criteria were as follows[3]: (i) $\geq$ 6 cm in size, (ii) symptomatic or causing compression of critical structures (especially for bile duct, gastrointestinal tract, or vessel), (iii) PFC locating adjacent to the stomach or duodenum ($\leq$ 1 cm), and/or (iv) infected PFC.

Clinical data and details of patients were reviewed from the hospital records. Informed consents were obtained from all patients prior to procedures. This article received an institutional approval waiver by the ethics committee of Shanghai Changhai Hospital due to its retrospective nature of outcome report.

Procedures. All procedures were performed by endoscopists with over 5 years of experience in endosonography under general anesthesia or monitored anesthesia care. The linear therapeutic echo-endoscope (Olympus or Fuji) was used in combination with fluoroscopy.

First, the presence and location of vessels were assessed through color Doppler ultrasonography to determine the optimal transmural puncture (gastric or duodenal) site of the cyst. Afterwards, a 19-gauge access needle (Cook Medical, Limerick, Ireland) was used to puncture PFC under the guidance of real-time EUS and fluoroscopy, a long 0.035-in. guidewire was then introduced and coiled into the cyst cavity through fluoroscopy, and the needle was subsequently removed. Then, the cyst-gastrostomy tract was dilated to facilitate stent insertion using one or more of the following devices: (i) dilating catheter (6F-10F Soehendra dilator, Cook Medical), (ii) balloon dilator (QBD-6 × 3,Cook Medical), (iii) needle-knife catheter (HPC-3, Cook Medical), and (iv) electrocautery catheter (10F Cystotome, Cook Medical). Double pigtail PS (7F or 10F, Cook Medical) or FCSEMS (10 × 40 mm, WallFlex, Boston Scientific) or LAMS (16 mm in inner diameter, 20 mm in length, Micro-Tech, Nanjing, China) was then inserted over the guidewire into the cyst cavity following dilation.

Additional interventions including (i) placement of one or more double pigtail PS (7 or 10F) coaxial with the FCSEMS to prevent stent migration,[9,10] and (ii) placement of a short-term nasocystic tube (7F, ENBD-7-LIGUORY-C, Cook Medical) for lavage. After the initial procedure, the endoscopists would determine whether direct endoscopic necrosectomy (DEN) was required based on conditions of patients.

According to our experience, transmural drainage was preferred over transpapillary pancreatic duct stenting due to the high technical and treatment success rates, even though the communication between pancreatic duct and PFC had been identified through imaging examination. Therefore, endoscopic retrograde cholangiopancreatography was not performed routinely before transmural drainage. Results of recent meta-analysis also supported the notion that endoscopic retrograde cholangiopancreatography provided no additional clinical benefit for transmural drainage of PFC.[11]

Patient follow-up. All patients were given intravenous injection of a broad spectrum antibiotic before and after the procedures. PFC resolution was assessed with computed tomography (CT) at 3 to 8 weeks after initial stent placement in outpatient clinic or local hospitals. The stents were subsequently removed using standard endoscopic snares or rat-tooth forceps. Thereafter, the patients were further followed up by telephone or outpatient contact until September 2018 (initiation of manuscript compiling). All patients, except the dead or lost-to-follow-up cases, were followed for at least 6 months.

Outcome measures and definitions. Technical success was defined as successful transmural stent placement. Treatment success was defined as significant improvement in patient symptoms and complete resolution of PFC or incomplete resolution of PFC 20 mm (or smaller) in size on the follow-up cross-sectional imaging. Adverse events (AEs) were defined based on the standard American Society for Gastrointestinal Endoscopy criteria.[12] Typically, early or late AEs were defined as the procedure-related AEs that occurred within or longer than 2 weeks after stent placement. Major AEs indicated AEs that required surgery, interventional treatment (such as endoscopic, percutaneous, and vascular treatment), and transfusion or those inducing death. Length of hospital stay was defined as the duration from initial stent placement to hospital discharge. Re-intervention was defined as the need of repeat endoscopic intervention for AEs or insufficient drainage (including planned DEN). Notably, planned stent change and stent removal were not counted as re-intervention. Recurrence was defined as the presence of PFC $>$ 3 cm in size discovered on follow-up imaging after the initial successful treatment and stent removal.

Statistical analysis. Continuous data were summarized as means with standard deviation and compared between groups using a one-way analysis of variance, and when necessary, two-by-two comparisons were made using least significant difference (LSD) method. Categorical data were summarized as frequencies with percentages and were compared using the chi-square or the

Fisher's exact test as indicated. *P* values 0.05 or lower were considered significant. All statistical analysis was performed using SPSS version 21.0 for Windows.

Results

Baseline characteristics. A total of 160 PFC patients (104 male and 56 female) undergoing related treatment were analyzed, including 62 with PS, 28 with FCSEMS, and 70 with LAMS. The average age of patients was 46.6 ± 14.4 years, and 65% of them were male. The etiology of pancreatitis included gallstones (53.1%), alcohol (13.1%), trauma (6.9%), idiopathic (20.6%), and others (6.3%). One hundred twenty-nine PFC were classified as PP, while the remaining was classified as WON based on the Atlanta Classification. PFC was located in the head/uncinated (11.9%) and body/tail (88.1%) of the pancreas with the mean size of 10.5 ± 3.4 cm in long axis. The characteristics of the study population were matched among the three groups and summarized in Table 1.

Besides, the median number of PS placed was 2 (range 1–3). By contrast, one stent was placed in each patient in metal stent (FCSEMS and LAMS), except for three patients with huge cysts who received two LAMS in index procedure. Additionally, one patient in LAMS group and six in PS group were lost to follow-up after hospital discharge, and they were thus excluded from outcome statistics, except for technical success and length of hospital stay.

Technical and treatment success. Technical success was similar among PS, FCSEMS, and LAMS (93.5% *vs* 96.4% *vs* 94.3%, *P* = 1.000). Meanwhile, technical failure occurred in nine patients, which could be attributed to failure to identify an appropriate puncture point due to abundant regional vasculature (PS: *n* = 1, FCSEMS: *n* = 1, and LAMS: *n* = 1), failure to enter PFC as a result of calcification in puncture route (PS: *n* = 1), or failure to insert stent after dilation of cyst-gastrostomy tract (LAMS: *n* = 1 and PS: *n* = 1) or hemorrhage that recognized immediately during procedure (PS: *n* = 1). Besides, stent placement planned to be

Table 1 Patient characteristics of all PFC drained with three types of stents

Parameters	PFC drained with PS (*n* = 62)	PFC drained with FCSEMS (*n* = 28)	PFC drained with LAMS (*n* = 70)	*P* value
Mean age (SD), years	46.6 (15.9)	49.7 (9.9)	45.4 (14.4)	0.433
Sex, male/female	36/26	16/12	52/18	0.103
Etiology, *n* (%)				0.932
Gallstone	31 (50.0)	14 (50.0)	40 (57.1)	
Alcohol	7 (11.3)	4 (14.3)	10 (14.3)	
Trauma	5 (8.1)	3 (10.7)	3 (4.3)	
Idiopathic	15 (24.2)	5 (17.9)	13 (18.6)	
Others	4 (6.5)	2 (7.1)	4 (5.7)	
Type of PFC, *n* (%)				0.390
PP	52 (83.9)	24 (85.7)	53 (75.7)	
WON	10 (16.1)	4 (14.3)	17 (24.3)	
Location, *n* (%)				0.810
Head/uncinate	8 (12.9)	4 (14.3)	7 (10.0)	
Body/tail	54 (87.1)	24 (85.7)	63 (90.0)	
Mean size† of PFC (SD), cm	10.3 (3.3)	10.2 (3.2)	10.9 (3.7)	0.535
Combined with CP, *n* (%)	13(21.0)	2 (7.4)	13 (18.6)	0.290

†Size of PFC was measured in long axis.

CP, chronic pancreatitis; FCSEMS, fully covered self-expanding metal stent; LAMS, lumen-apposing metal stent; PFC, pancreatic fluid collection; PP, pancreatic pseudocysts; PS, plastic stent; WON, walled-off pancreatic necrosis.

Table 2 Clinical outcomes

Parameters	PFC drained with PS (*n* = 62)	PFC drained with FCSEMS (*n* = 28)	PFC drained with LAMS (*n* = 70)	*P* value
Technical success, *n* (%)	58 (93.5)	27 (96.4)	66 (94.3)	1.000
Treatment success,† *n* (%)	44 (84.6)	23 (85.2)	58 (89.2)	0.763
Length of hospital stay (SD), days	7.8 (8.2)	7.0 (8.0)	6.5 (7.8)	0.646
Re-intervention, *n* (%)	7 (13.5)	7 (25.9)	18 (27.7)	0.161
Recurrence, *n* (%)	6 (13.6)	5 (21.7)	5 (8.6)	0.236
Stent removal time (SD), days	94.0 (49.8)	60.5 (33.0)	58.0 (28.0)	0.000
LAMS *vs* FCSEMS	—	60.5 (33.0)	58.0 (28.0)	0.784
LAMS *vs* PS	94.0 (49.8)	—	58.0 (28.0)	0.000
FCSEMS *vs* PS	94.0 (49.8)	60.5 (33.0)	—	0.001

†Only patients with successful stent placement were measured and those who lost to follow-up (PS: *n* = 6, FCSEMS: *n* = 0, and LAMS: *n* = 1) were excluded (intention-to-treat analysis: *P* values = 0.253).

FCSEMS, fully covered self-expanding metal stent; LAMS, lumen-apposing metal stent; PFC, pancreatic fluid collection; PS, plastic stent.

approached from cardia in two cases of LAMS group was given up, due to the high risk of occlusion and infection.

No statistically significant difference was observed in treatment success among patients achieving successful stent placement (84.6% *vs* 85.2% *vs* 89.2%, $P = 0.763$). A total of 19 patients failed to respond well to stent placement and required alternative treatments; among them, (i) 2 died in LAMS group and another 1 in FCSEMS group was transferred to surgery due to bleeding; (ii) 2 with repeated cyst infection in PS group finally received surgery due to the poor response to endoscopic therapy; (iii) the remaining 14 (LAMS: $n = 5$, FCSEMS: $n = 3$, and PS: $n = 6$) presented with incomplete resolution of PFC > 20 mm in size at the time of stent removal, regardless of the markedly improved symptoms.

There were no statistically significant differences in the mean length of hospital stay (7.8 *vs* 7.0 *vs* 6.5 days, $P = 0.646$) and re-intervention rate (13.5% *vs* 25.9% *vs* 27.7%, $P = 0.161$). Typically, the mean time of stent removal was significantly longer in patients drained with PS than those with LAMS and FCSEMS (94.0 *vs* 58.0 *vs* 60.5 days, $P = 0.000$). Among 125 PFC patients with successful resolution, 16 experienced recurrence during follow-up, and difference in the recurrence rate was not statistically significant (13.6% *vs* 21.7% *vs* 8.6%, $P = 0.236$).

Clinical outcomes were summarized in Table 2.

Table 3 Adverse events

AEs	PFC drained with PS ($n = 52$)†	PFC drained with FCSEMS ($n = 27$)†	PFC drained with LAMS ($n = 65$)†	*P* value
Early AEs, *n*				
Occlusion/infection	9	5	12	1.000
Bleeding	4	2	3	0.734
Migration	0	3	1	0.021
Other‡	4	1	1	0.242
Late AEs, *n*				
Occlusion/infection	3	0	1	0.402
Bleeding	0	1	1	0.470
Migration	10	3	1	0.003
Other†	1	0	1	1.000
Patients with AEs, *n*	28	13	20	0.030
Major AEs	15	11	16	0.289
Death	0	0	2	0.672
Bleeding	4	3	4	0.655

†Other late AEs: PS (one peritonitis) and LAMS (one difficult removal of stent).

‡Other early AEs: PS (one perforation, one severe acute pancreatitis, one peritonitis, and one aspiration pneumonia combined with acute left heart failure), FCSEMS (one peritonitis), and LAMS (one peritonitis).

AEs, adverse events; FCSEMS, fully covered self-expanding metal stent; LAMS, lumen-apposing metal stent; PFC, pancreatic fluid collection; PS, plastic stent.

Adverse events. As shown in Table 3, a total of 67 AEs occurred among 61 patients. Among AEs, 12 patients (PS: $n = 9$, FCSEMS: $n = 2$, and LAMS: $n = 1$) had already achieved treatment success when stent migration was found on follow-up imaging or during the procedure of planned stent removal. Thus, these were not counted as major AEs. In addition, seven patients (PS: $n = 3$, FCSEMS: $n = 1$, and LAMS: $n = 3$) with infection who received intravenous antibiotics and one patient (PS: $n = 1$) with perforation who underwent conservative therapy were not counted as major AEs, either. Thus, patients with major AEs accounted for 28.5% (41/144) of cases achieving successful stent placement.

Among 23 major AEs of stent occlusion or infection, 1 in PS group was transferred to surgical treatment, and the rest were successfully managed through endoscopic intervention (DEN, lavage, stent change, or nasocystic tube). Compared with PS and LAMS group, the stent migration rate within 2 weeks was evidently

Table 4 Patient characteristics of 11 patients with significant bleeding after procedure

Sex M/F	Age (years)	Size of PFC (cm)	Type of stent	Type of PFC	Dilation of tract	DEN no.	Days after procedure	Intervention	Outcome
M	41	12.6	LAMS	PP	Hot‡	0	6	Endoscopy	Resolved
M	61	7.8	LAMS	PP	Hot	0	8	Endoscopy	Resolved
M	52	9.0	LAMS	WON	Hot	1	7	Embolization + surgery	Dead
F	57	8.0	LAMS	WON	Hot	4	150	Embolization	Dead
F	53	11.5	FCSEMS	PP	Hot	0	63	—	Resolved
F	56	6.3	FCSEMS	PP	Hot	0	13	Endoscopy + embolization + surgery	Resolved
M	66	8.0	FCSEMS	WON	Hot	0	1	Embolization	Resolved
M	12	8.0	PS	PP	Cold†	0	1	—	Resolved
F	55	7.9	PS	PP	Cold	0	1	Endoscopy	Resolved
F	59	16.0	PS	PP	Cold	0	1	—	Resolved
M	55	16.7	PS	PP	Cold	1	13	Endoscopy	Resolved

†"Cold" technique: Needle-knife catheter, dilating catheter, and/or balloon dilator.

‡"Hot" technique: Electrocautery catheter (Cystotome).

DEN, direct endoscopic necrosectomy; FCSEMS, fully covered self-expanding metal stent; LAMS, lumen-apposing metal stent; PFC, pancreatic fluid collection; PP, pancreatic pseudocysts; WON, walled-off pancreatic necrosis.

higher in FCSEMS group ($P = 0.021$). And the stent migration rate after 2 weeks was notably higher in PS group ($P = 0.003$).

Significant bleeding (bleeding that required surgery, interventional treatment, and transfusion or death) after successful stent placement were shown in Table 4 and Figure 1. Among 11 patients with significant bleeding, 3 (PS: $n = 2$ and FCSEMS: $n = 1$) presented as self-limited bleeding but received blood transfusion. Emergent gastroscopy was performed in four patients with intracavitary variceal bleeding, two of them were managed by lavage with ice normal saline (containing noradrenaline), and no active bleeding was observed in the other two patients. The remaining four patients (FCSEMS: $n = 2$ and LAMS: $n = 2$) presented with severe bleeding that confirmed as pseudoaneurysms through following angiograms; among them, one patient in FCSEMS group underwent emergent gastroscopy at first but found impossible to manage the massive bleeding. Then, all the four patients turned to interventional radiology-guided coil embolization and/or surgery. However, only two of them were successfully managed, while the other two died. As regard to the occurring time of bleeding, 81.8% (9/11) were observed within 2 weeks after procedure. Among the four patients with severe bleeding, 75% (3/4) were observed within 2 weeks after procedure.

There is no significant difference between plastic (PS) and metal stents (LAMS + FCSEMS) in terms of major AEs, significant bleeding, and severe bleeding (Table S2).

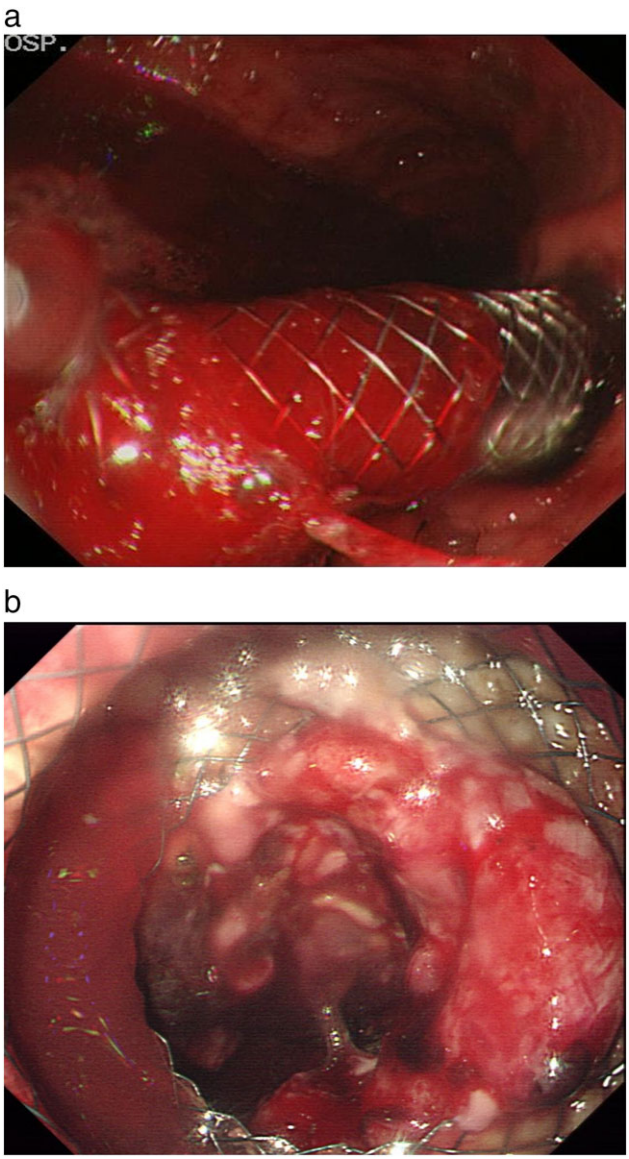

Figure 1 Endoscopic views during emergency gastroscopy showing the following: (a) massive and active bleeding was seen flowing from fully covered self-expanding metal stent in a patient; (b) extensive old blood and blood clots were seen in stomach of a patient with lumen-apposing metal stent. [Color figure can be viewed at wileyonlinelibrary.com]

Discussion

Initially, the transmural tract is maintained with one or more double pigtail PS. However, the small-caliber diameter of PS is limited to 10F, and the placement of multiple PS is time-consuming and technically challenging. Given these problems, FCSEMS was then introduced.[13] Theoretically, the large diameter of FCSEMS facilitates the rapid drainage of PFC. Penn *et al.*[9] demonstrated that EUS-guided drainage with FCSEMS was effective and easily deployed. But the column-shaped structure of FCSEMS will result in high risk of migration. And the coaxially placed double pigtail PS within FCSEMS was reported to prevent migration despite its efficacy need further evidence.[9,10] As a newly invented fully covered metallic braided stent, LAMS with bilateral anchor flanges aimed to reduce migration, and the large diameter even permits endoscopic intervention through the inner lumen.[14] Thus, LAMS triggered a worldwide trend of research and has become increasingly popular in recent years.[15–21]

Although LMAS was widely perceived superior to FCSEMS and PS, our study and some other latest studies revealed that efficacy and safety of LAMS might not be substantially improved, as suggested by the treatment outcomes compared with PS[17,22,23] and FCSEMS.[24,25] One possible reason was that metal stents with larger diameter allow the bidirectional movement of contents between the gastrointestinal tract and the cavity. Therefore, when the rapid drainage of PFC (especially for drainage of the WON contents) is facilitated, undigested solid material can also easily enter the cyst cavity and cause stent occlusion or cavity infection.[26] Besides, as described in our recent published paper,[27] there is a fair possibility that the collapsed cyst wall could obstruct the distal flange (internal) of LAMS, as the large diameter of LAMS facilitates the rapid drainage of PFC cavity. Furthermore, PFC treated by LAMS was also reported to have a high rate of stent-related AEs including delayed bleeding, buried stent syndrome, and biliary stricture,[28] which were not common in PS group. These may explain why the specially designed LAMS still presents many AEs, and there was no significant difference in the rate of AEs between PS and LAMS. And AEs (such as fatal bleeding, stent occlusion, and cavity infection) could affect the final treatment effect. It may be one of the reasons why metal stents do not significantly improve treatment outcomes over PS as expected.

Notably, when it comes to stent-related AEs, severe bleeding of LAMS became most concerned because it tended to be fatal and unexpected.[22,28] Bang *et al.*[23,28] had carried out the only randomized controlled trial comparing efficacy and safety between LAMS

and PS and reported a high rate of stent-related AEs during their ongoing trial. Therefore, they had to amend the study protocol to remove the stent if PFC had resolved at 3 weeks. Intriguingly, no severe bleeding occurred in LAMS group later supported their protocol change, which might remind a strategy to reduce and prevent severe bleeding in the late stage. It was hypothesized that, as the cyst collapsed rapidly, LAMS with a bi-flanged design that tended to remain in place could result in friction between the distal flange of LAMS and the vasculature surrounding the cavity, which would thereby cause bleeding. Besides, the wide diameter might also facilitate the exposure of intracavitary vessels to gastric acid and thus promote bleeding.[17] On the other hand, PS was speculated to be associated with less bleeding, because it probably migrated into the gastrointestinal tract when the PFC was resolved.[28] However, bleeding among three groups is not statistically significant in this study. The puncture of vessel and "cold" dilation (mechanically dilated using balloon dilator and/or needle knife) of the tract was suspected to cause this bleeding in PS group (the "hot" technique using Cystotome was not introduced into our center until 2012). Three (75%) patients with bleeding were observed within 24 h after the procedure.

Although it is not statistically significant, bleeding in PS group seemed to be self-limited because all the four severe bleeding (required embolization, surgery, or death) occurred in metal stent (LAMS and FCSEMS) group. It was consistent with previous reports and attracted increasing attention.[22,23] Bang *et al.*[23] recommended that LAMS should be removed at 3 weeks if PFC had resolved to minimize risk of late bleeding. However, 75% (3/4) bleeding cases in LAMS of our study was observed at about 1 week after procedure, indicating that early bleeding might be more frequent than expected. To confirm this finding, studies reporting the time and outcomes of bleeding were systemically retrieved in Table S1 and summarized in Table 5.[17,22,23,25,29–34] Generally, bleeding was reported in 34 patients from eight studies during the first 3 weeks, which was reported in only 16 patients from six studies 3 weeks after intervention. Moreover, all bleeding-related deaths were identified during the first 3 weeks. Taken together, there was probably increasing fatal bleeding at the early stage of LAMS. As a result, more efforts should be made to identify patients with high risk of bleeding and intensively monitor them in the early stage. Intriguingly, pseudoaneurysm was found to be associated with severe bleeding at both early and late stages,[17,22,23] which might thereby serve as a promising predictor of severe bleeding.

Thus, we recommended that CT angiography or EUS examination should be performed in all patients to detect pseudoaneurysm (or assess the vessels) around PFC at about 1 week after intervention; it might provide important reference for adjusting treatment, such as stent change, stent removal, or treatment of pseudoaneurysm. What's more, there was a hypothesis that vessels might be missed due to compression during predrainage cross-sectional imaging by some huge PFC.[35] Besides, necrosectomy might also be correlated with early severe bleeding, because complete mechanical cleaning of the necrotic cavity may remove the final buffer between vessel and distal end of LAMS. Therefore, the way of removing the necrotic debris (how complete and the timing) should be further investigated. Given the aforementioned discussion, we agreed with Stecher that exchanging LAMS for plastic pigtail stents before hospital discharge might be feasible for certain patients.[29]

Although most of stent occlusion and infection could be managed by endoscopic intervention in our study, it is recommended that coaxially placed PS through LAMS could minimize the risk of infection.[26]

Table 5 Systemic review of studies reporting time and outcomes of significant bleeding after procedure

No.	First author	*N*	Bleeding ≤ 3 weeks				Bleeding > 3 weeks			
			n (%)	Pseudoaneurysm	Death, *n*/*N*	Description	*n* (%)	Pseudoaneurysm	Death, *n*/*N*	Description
1	Stecher[†29]	46	7 (15)	—	3/7	5 bleeding ≤ 2 weeks	1 (2)	—	0	—
2	Zeissig[30]	260	4 (2)	—	0	3 severe bleeding	1 (0.3)	—	0	—
3	Bang[23]	31	0	—	0	—	3 (10)	3/3	0	2 bleeding > 5 weeks
4	Brimhall[22]	97	15 (15)	8/15	0	5 bleeding < 2 weeks	0	—	0	—
5	Vazquez-Sequeiros[†25]	72	1 (1)	—	0	Bleeding < 2 weeks	6 (8)	—	0	—
6	Lang[17]	19	3 (16)	2/3	1/3	—	0	—	0	—
7	Venkatachalapathy[31]	116	1 (1)	—	0	Bleeding < 1 weeks	0	—	0	—
8	Bapaye[†32]	72	0	—	0	—	2 (3)	—	0	Bleeding > 12 weeks
9	Garcia-Alonso[33]	124	2 (2)	—	0	Bleeding < 2 weeks	3 (2)	—	0	Bleeding > 2 weeks
10	Sahar[34]	25	1 (4)	—	0	Bleeding = 3 days	0	—	0	—

[†]Including non-lumen-apposing metal stent mental stents.

In this study, biliary obstruction secondary to mechanical compression by stent was not observed, which might be probably because only one patient underwent stent placement through the duodenal bulb. Buried LAMS was not seen; however, one patient receiving LAMS had difficulty in stent removal due to tissue ingrowth, and we had to remove the steel wires of stent one by one with forceps.[36]

The study is inevitably associated with some limitations. The primary limitation lies in its retrospective and non-randomized control nature. Another limitation is the lack of standard methods for drainage. For instance, "hot" technique (Cystotome) was not introduced until 2012, and procedures such as coaxially placed PS and nasocystic tube were carried out at the discretion of the endoscopists. Third, double pigtail PS was the only choice before 2013, whereas FCSEMS and LAMS were introduced to our institution in 2013 and 2015, respectively. Thus, the size of each group is not homogenous and imbalance in the case distribution might affect the results of the statistical comparisons. Considering the small size of subgroups and limited power of test, which would decrease the credibility of results, statistical analysis of subgroups (WON and PP) was not conducted.

In conclusion, our study suggests no significant differences in technical success, treatment success, and major AEs among PFC patients drained with PS, FCSEMS, or LAMS. The unique design of LAMS does not appear to substantially improve the clinical effect and safety. Moreover, monitoring, for example, CT angiography, should be conducted to assess the risk of fatal bleeding at the early stage after stent placement, especially for LAMS, while further large randomized controlled trials were needed to confirm this finding and explore the optimal timing of stent removal.

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Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Published large studies about treatment of PFC using LAMS (No. LAMS≥25).
Table S2. Comparisons of adverse events between plastic and metal stent.