Published in final edited form as:

Clin Gastroenterol Hepatol. 2018 September ; 16(9): 1521–1528. doi:10.1016/j.cgh.2018.02.021.

Increased Incidence of Pseudoaneurysm Bleeding With Lumen-Apposing Metal Stents Compared to Double-Pigtail Plastic Stents in Patients With Peripancreatic Fluid Collections

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Abstract

BACKGROUND & AIMS: There have been few studies that compared the effects of lumen-apposing metal stents (LAMS) and double-pigtail plastic stents (DPS) in patients with peripancreatic fluid collections from pancreatitis. We aimed to compare technical and clinical success and adverse events in patients who received LAMS vs DPS for pancreatic pseudocysts and walled-off necrosis.

METHODS: We performed a retrospective study of endoscopic ultrasound–mediated drainage in 149 patients (65% male; mean age, 47 y) with pancreatic pseudocysts or walled-off necrosis (97 received LAMS and 152 received DPS), from January 2011 through September 2016 at a single center. We collected data on patient characteristics, outcomes, hospitalizations, and imaging findings. Technical success was defined as LAMS insertion or a minimum of 2 DPS. Clinical success was defined as resolution of pancreatic pseudocysts or walled-off necrosis based on imaging results. The primary outcome was resolution of peripancreatic fluid collection with reduced abdominal pain or obstructive signs or symptoms. Secondary outcomes included the identification and management of adverse events, number of additional procedures required to resolve fluid collection, and the recurrence of fluid collection.

RESULTS: Patients who received LAMS had larger peripancreatic fluid collections than patients who received DPS prior to intervention ($P = .001$), and underwent an average 1.7 interventions vs 1.9 interventions for patients who received DPS ($P = .93$). Technical success was achieved for 90 patients with LAMS (92.8%) vs 137 patients with DPS (90.1%) (odds ratio [OR] for success with DPS, 0.82; 95% CI, 0.33–2.0; $P = .67$). Despite larger fluid collections in the LAMS group, there was no significant difference in proportions of patients with clinical success following placement

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Conflicts of interest

These authors disclose the following: Brian Brauer has served as a consultant for Boston Scientific and Medtronic, and received speaking honoraria for Axios; Sachin Wani has served as a consultant for Boston Scientific and Medtronic; Steven Edmundowicz has served as a consultant for Medtronic and Olympus; Mihir Wagh has served as a consultant for Boston Scientific and Medtronic; and Raj J. Shah has served as a consultant for and received grant support from Boston Scientific and Cook Endoscopy. The remaining authors disclose no conflicts.

of LAMS (82 of 84 patients, 97.6%) vs DPS (118 of 122 patients, 96.7%) (OR for clinical success with DPS, 0.73; 95% CI, 0.13–4.0; $P = .71$). Adverse events developed in 24 patients who received LAMS (24.7%) vs 27 patients who received DPS (17.8%) (OR for an adverse event in a patient receiving a DPS, 0.82; 95% CI, 0.33–2.0; $P = .67$). However, patients with LAMS had a higher risk of pseudoaneurysm bleeding than patients with DPS (OR, 10.0; 95% CI, 1.19–84.6; $P = .009$).

CONCLUSIONS: In a retrospective study of patients undergoing drainage of pancreatic pseudocysts or walled-off necrosis, we found LAMS and DPS to have comparable rates of technical and clinical success and adverse events. Drainage of walled-off necrosis or pancreatic pseudocysts using DPS was associated with fewer bleeding events overall, including pseudoaneurysm bleeding, but bleeding risk with LAMS should be weighed against the trend of higher actionable perforation and infection rates with DPS.

Keywords

Pancreas; EUS; Surgery; Treatment

Peripancreatic fluid collections (PFCs) from pancreatitis include pancreatic pseudocysts (PPs) or walled-off necrosis (WON).¹ Although 39% to 60% of PFCs resolve without intervention,^{2–4} they may cause signs or symptoms that prompt drainage including pain, infection, gastric outlet obstruction, and biliary obstruction.^{5,6} If expertise is available, endoscopic drainage of symptomatic PFCs that abut the stomach or duodenum is preferred to percutaneous or surgical approaches.^{7–9} Percutaneous drainage carries the risk of pancreaticocutaneous fistula formation in up to 14% of patients.^{10–12} Surgical approaches have high morbidity (25%) and mortality (5%).^{13,14} Endoscopic ultrasound (EUS)-guided drainage has been shown to have a high technical and clinical success rate, with overall low adverse event rates.^{15–17}

Conventionally, endoscopists have used double-pigtail plastic stents (DPS) for transmural drainage and, if necessary, followed with endoscopic debridement or in combination with percutaneous flushing.¹⁸ Selfexpanding metal stents (SEMS) have increasingly been used owing to their larger inner diameter and potential for improved drainage, with the ability to allow direct endoscopic necrosectomy on a repeated basis through the internal portion of the stent.¹⁹ It also has been noted anecdotally that lumen-apposing metal stent (LAMS) are technically simpler and faster to place than historical experience with dual DPS. Itoi et al²⁰ reported novel dumbbell-shaped LAMS for PFC and the multicenter study by Shah et al¹⁴ showed the efficacy of PP resolution of 93% and led to the Food and Drug Administration approval of LAMS for PFC that contained less than 30% necrosis, with other studies showing comparable efficacy.^{21,22}

However, there are little comparative data for DPS and LAMS.¹⁷ Although similar efficacy has been suggested with higher bleeding rates with the use of a variety of types of SEMS, the number of included DPS patients was greater than the LAMS patients in these studies. Our study's primary objective was to determine if the technical and clinical success of endoscopic drainage of PFC using DPS or LAMS was similar. The secondary objectives were to determine if there were higher procedure, disease-specific, or device-related adverse events (AEs) in patients receiving LAMS.

Methods

This study was a retrospective, single-center review inclusive of when LAMS became available. We compared DPS (Cook Medical, Winston-Salem, NC) and LAMS (Axios; Boston Scientific, Marlborough, MA) for PP and WON from January 2011 to September 2016. Our endoscopy database (Provation; Provation Medical, Minneapolis, MN) was searched for EUS and “stent” and “pancreas” with identification of 1530 procedures. The electronic medical record (Epic, Verona, WI) then was searched for demographics, prior drainage attempts, indications, imaging and endoscopic findings, the presence and extent of necrosis determined by EUS/cross-sectional imaging review, procedure technique including use of nasocystic drain, number of interventions, and outcomes. All patients had either computed tomography or magnetic resonance imaging performed before endoscopic intervention to assess candidacy and exclude the presence of a pseudoaneurysm (Figure 1).

Procedure

All patients underwent endoscopy with a therapeutic linear array echoendoscope (Olympus America, Center Valley, PA) and general endotracheal anesthesia. Patients received broad-spectrum intravenous antibiotics preprocedure and oral antibiotics for 5 to 14 days after the procedure, depending on the presence of infection and/or significant necrotic debris. The technique of DPS and LAMS placement has been described previously.^{14,22–26} Briefly, for DPS, a 19G needle (Cook Endoscopy, Winston Salem, NC) was used to puncture into a PFC and then a 0.035-inch guidewire (Jagwire; Boston Scientific, Inc) was coiled within the PFC with subsequent dilation of the tract and cystgastrostomy formation and placement of two 7F or 10F stents. If LAMS (inner diameter, 10 or 15-mm) without electrocautery enhancement was used, the earlier-described technique was used. If the electrocautery-enhanced system was used, either direct diathermic puncture (ERBE USA, Inc, Marietta, GA) or predeployment wire placement was performed, followed by distal flange deployment of LAMS under EUS guidance and proximal flange deployment by EUS or endoscopic view. The choice of stent and the decision to perform direct endoscopic necrosectomy (DEN) was based on endoscopist preference.

Patient Follow-Up Evaluation

Electronic medical record review for AEs, repeat hospitalizations, imaging, and clinical follow-up evaluation was performed. For incomplete data, patient contact by telephone was attempted. Three separate telephone attempts were made. Questions were standardized related to current symptoms, pain improvement by more than 50% after endoscopic intervention, any PFC recurrence requiring repeat intervention, or outside imaging. If patients still were not able to be contacted after telephone attempts, then obituaries were examined according to the city and state that patients listed at their initial endoscopic intervention.

Study Definitions and Outcome Measures

Imaging studies preceding the endoscopic examination were reviewed using Philips IntelliSpace PACS (version 4.4.5430; Philips Healthcare Informatics, Inc, Foster City, CA) by a board-certified body imaging radiologist with 4 years of subspecialty experience. This

radiologist, blinded to the outcomes, evaluated each study to determine whether the percentage of necrosis of the pancreatic parenchyma was in 1 of 5 categories: no data available for review, 0%, 1% to 30%, 31% to 50%, or 51% or greater.²⁷ Any presence of necrosis was categorized as WON. Technical success was defined as the successful placement of the number of planned stent(s), with at least 2 DPS stents placed. Adverse events were defined according to standard American Society for Gastrointestinal Endoscopy criteria that have been outlined previously.²⁸ The primary outcome of the study was to examine resolution of PFC associated with improvement of abdominal pain or obstructive signs or symptoms. PFC resolution was defined as a lack of residual fluid collection or one that was smaller than 3 cm in maximal diameter on follow-up imaging.^{14,22} Secondary outcomes included the identification and management of AEs, the number of additional procedures required to resolve PFC, and the recurrence of PFC during the available follow-up period.

Data Analysis

DPS and LAMS data were analyzed in relation to the primary end points of technical and clinical success as well as secondary end points of adverse events and follow-up procedures. By intention-to-treat analysis, an inability to obtain sufficient follow-up evaluation to determine clinical response was deemed a failure. Subgroups of patients also were analyzed based on pancreatitis etiology, PFC location, presence of necrosis, and nasocystic tube placement. When comparing means, an independent *t* test was used and took into account unequal variance determined by Levene's test for equal variance. For binomial variables, a chi-squared test with the Pearson chi-squared *P* value and likelihood ratio *P* value were calculated.

Results

Baseline Characteristics

We evaluated a total of 249 patients who had stent placement from January 2011 to September 2016 for PP and WON (Figure 2). Ninety-seven (39%) patients underwent LAMS placement and 152 (61%) patients underwent DPS placement. There was no difference between the 2 groups with regard to age, sex, percentage of patients with WON, prior attempt at drainage, pancreatitis etiology, and use of a nasocystic drain. The most common etiology of pancreatitis in both groups for DPS and LAMS was alcohol (28.3% vs 34%, respectively; *P* = .95) followed by biliary stone passage (22.4% vs 32%, respectively; *P* = .55). The primary indication for drainage in both LAMS and DPS patients was abdominal pain (81.4% vs 95.4%, respectively). Other indications for drainage in LAMS and DPS patients included gastric outlet obstruction (10.3% vs 2%), infectious symptoms (6.2% vs 1.3%), vascular compression (2% vs 0%), and cholestatic liver function tests (0% vs 1.3%), respectively. The DPS group was more likely to have chronic pancreatitis than the LAMS group (38.8% vs 20.6%, respectively; *P* = .03). The LAMS group was more likely to have a larger fluid collection than the DPS group (80.1 vs 69.8 mm, respectively; *P* = .001). LAMS were more likely to be used in PFCs containing the most necrosis (56.7% vs 36.2%, respectively; *P* = .038) (Table 1).

For drainage, a transgastric approach was used in 145 DPS patients (95.4%) vs 94 LAMS patients (96.9%). The size of the LAMS placed was 15 mm in 82 (84.5%) patients and 18 (18.6%) LAMS placements were performed with the electrocautery-enhanced system. Nasocystic drains were inserted in 13 of 97 (13.4%) LAMS and in 33 of 152 (21.7%) DPS cases. There were 2 patients in each group who underwent transpapillary stenting in addition to either DPS or LAMS placement. The location of PFC collection in DPS patients was as follows: head (26; 14.9%), genu (10; 5.7%), neck (1; 0.57%), uncinate process (1; 0.57%), body (107; 61.1%), tail (28; 16%), and peripancreatic (1; 0.57%). In comparison, location of fluid collections in LAMS patients were as follows: head (8; 6.7%), genu (7; 5.9%), neck (5; 4.2%), uncinate process (1; 0.8%), body (71; 59.7%), tail (18; 15.1%), peripancreatic (8; 6.7%), and left lobe of liver (1; 0.8%). These percentages total more than 100% because some PFCs spanned multiple anatomic locations.

DPS patients had a median number of 2 stents placed (minimum, 1; maximum, 4). All LAMS patients had placement of 1 stent except for 1 patient who received 2 LAMS during the index procedure for a large fluid collection. Eight LAMS patients had a DPS placed through the LAMS.

Technical and Clinical Success

Technical success was similar between DPS and LAMS patients (90.1% vs 92.8%; $P = .67$). Technical failure in the LAMS group ($n = 7$) included maldeployment caused by incomplete distal flange expansion ($n = 3$), or deployment was entirely within the PFC ($n = 1$) or entirely within the stomach ($n = 3$). Failures were treated successfully with additional LAMS ($n = 2$) or DPS placement ($n = 5$). For the DPS failures ($n = 15$), 6 were treated with additional DPS placement at different puncture sites, 4 had only 1 DPS placed, 3 were managed conservatively after an inability to drain the PFC, and 2 had unknown outcomes after an initial attempt at endoscopic drainage.

Follow-up evaluation was obtained in 93.8% of LAMS and 94.1% of DPS patients. Clinical success was similar between DPS and LAMS patients (90.1% vs 91.8%; $P = .54$). The majority of failures were patients who were lost to follow-up evaluation (6 in the LAMS arm, and 9 in the DPS arm) in an intention-to-treat analysis. The average number of endoscopic necrosectomies were similar between the DPS and LAMS group, respectively (1.9; range, 1–19; vs 1.7; range, 1–11; $P = .93$). Stent duration on average for DPS patients was 59.8 days (range, 9–388 d) vs 51.5 days (range, 4–195 d) for LAMS patients ($P = .26$). There was no statistical difference between stent duration in the 2 groups, 16 patients in the DPS arm had stents in place for more than 90 days for a variety of reasons, but primarily for disconnected pancreatic duct syndrome in comparison with the LAMS arm, in which 5 patients had stents in for more than 90 days. The longest stent duration in the DPS group was 388 days, and in the LAMS arm was 158 days. In patients with evaluable follow-up evaluation, the overall recurrence of PFC was similar between DPS and LAMS patients (4.6% vs 6.2%; $P = .57$). This is despite the fact that patients who have chronic pancreatitis usually have a higher recurrence rate of PFC and there was a higher proportion of chronic pancreatitis patients in the DPS arm (Table 2). Based on subset statistical analysis, the location of the fluid collection, etiology of pancreatitis, overall presence of necrosis, or the

use of a nasocystic drain were not significant factors contributing to technical or clinical success or adverse event occurrence (data not shown).

All nasocystic drains were placed in individuals with WON with the exception of 2 in the LAMS group and 2 in the DPS group. In the LAMS group 13 total nasocystic drains were placed, 11 of the 81 patients with WON (13.6%). In the DPS group 33 total nasocystic drains were placed, 31 of 116 patients with WON (26.7%). There were a total of 4 percutaneous drains used, 2 in the LAMS and 2 in the DPS group, each in WON patients for flushing of PFC. There was 1 patient in each group who required surgical necrosectomy after an attempt at endoscopic drainage.

Adverse Events

Overall adverse events were similar between the 2 groups (Table 3). There were 27 (17.8%) events in the DPS group and 24 (24.7%) in the LAMS group ($P = .67$). There were 15 bleeding events in the LAMS group vs 5 in the DPS group ($P = .0005$). There was a statistically significant higher rate of pseudoaneurysm bleeding in the LAMS group vs the DPS group (8.2% vs 0.7%; $P = .009$). There were 5 interventional radiology angiography proven and 3 presumed pseudoaneurysm bleeding events in the LAMS group, and patients received a median of 3 units of blood (range, 0–10 units) (Figure 3). The presumed cases were because of arterial bleeding seen coming from the PFC and/or arterial irregularities found on computed tomography angiogram. Five of these bleeding events occurred in the first 14 days after the index procedure, but the overall average time to bleeding event was 18.5 days. The 5 confirmed cases of pseudoaneurysm bleeding underwent coil embolization of the gastroduodenal and pancreaticoduodenal cascade arteries ($n = 2$), splenic artery ($n = 2$), and gastroduodenal artery ($n = 1$). All LAMS were indwelling at the time of pseudoaneurysm bleeding. One individual in the DPS group had embolization of a splenic artery pseudoaneurysm bleed on day 53 after the removal of original DPS and required 6 units of blood. Nonpseudoaneurysm bleeding events that required transfusion and/or endoscopic intervention occurred in 2.6% of DPS patients and in 7.2% of LAMS patients ($P = .09$).

There were 5 (2%) symptomatic, actionable perforations in the DPS group vs 0 in the LAMS group ($P = .22$). One perforation was found when crepitus was noted immediately postprocedurally and a malpositioned stent was removed and the patient required care in the intensive care unit for 1 day. The second perforation occurred from guidewire placement for a second stent with air under that liver, which was managed conservatively but required a 3-day hospitalization. A third perforation occurred during stent placement for initial DPS with deployment of an entire stent within the PFC that was managed conservatively with DPS retrieved from inside of the PFC at later date. The fourth perforation occurred during a subsequent DEN with a small abscess collection that required interventional radiology drainage and antibiotics. Finally, the fifth perforation occurred when both DPS stents were positioned in the mesentery and not PFC, with significant hemoperitoneum that required surgical intervention. Infection rates between the DPS and LAMS groups were similar (3.9% vs 2%, respectively; $P = .28$). Other adverse events in the DPS group included 2 patients with abdominal pain requiring admission, 1 patient with acute renal failure, 1 gastric ulcer, 1

episode of pancreatitis, and 1 death related to underlying illness. Other adverse events in the LAMS group included 2 patients with abdominal pain requiring admission, 1 patient with an atrial flutter, 1 patient with a myocardial infarction, 1 seizure, and 1 death related to underlying illness.

Discussion

The wide availability of LAMS has simplified the drainage of PFC and can permit DEN through the existing stent, but the metal stents are more expensive than plastic stents. This higher initial cost may be offset by shorter procedure times, but direct studies comparing LAMS and DPS overall costs for PFC are limited.^{16,29}

We report a similar rate (range, 90%–92%) of technical and clinical success between DPS and LAMS, as well as a similar overall rate of adverse events (range, 18%–25%). The high success rate is despite larger PFCs in the LAMS v DPS groups (80.1 vs 69.8 mm, respectively; $P = .001$) and a high percentage of patients in both arms with WON (range, 76%–84%), which often require more intensive endotherapy and are associated with higher complications.²⁶ It is important to note that there were more LAMS vs DPS patients with more than 50% necrosis at the time of the index procedure (56.7% vs 36.2%, respectively; $P = .038$), and considering the overall comparable efficacy with DPS, this more complex subgroup of patients potentially may benefit with LAMS use, which can ease DEN as well. Furthermore, the similar success rates and total number of interventions may be attributable to the careful identification and intervention for underlying necrotic debris.

The theoretical advantage to LAMS is the large internal diameter and the ability to perform direct endoscopic necrosectomies through the stent in comparison with DPS, which requires additional tract dilation, stent removal, followed by direct access. Lang et al³⁰ reported a single-center experience with 84 DPS and 19 LAMS patients that included both PP and WON with similar clinical success between the 2 groups ($P = .78$). Fourteen of 84 (16.7%) DPS patients and 9 of 19 (47.3%) LAMS patients were classified as WON. WON was defined in this study as mature encapsulation of pancreatic or peripancreatic necrotic tissue contained within an enhancing wall of reactive tissue. There was a higher incidence of bleeding in the LAMS group than in the DPS group (19% vs 1%, respectively; $P = .0003$). They reported 4 episodes of bleeding in LAMS patients; 2 with splenic artery pseudoaneurysms, 1 with a collateral vessel bleed, and 1 with an intracavitary variceal bleed in comparison with 1 bleed in the DPS group from stent erosion into the gastric wall. The bleeding was hypothesized to be from rapid collapse of the PFC with LAMS placement and possible exposure to gastric acid.³⁰ A dual-center retrospective study of various SEMS and DPS to treat WON patients included 106 DPS, 121 fully covered SEMS (FCSEMS), and 86 LAMS. They found that technical success was similar between the groups ($P = .37$), but clinical success was superior for FCSEMS and LAMS compared with DPS arms (95% vs 90% vs 81%, respectively; $P = .001$). The mean number of interventions for DPS vs FCSEMS vs LAMS (3.6, 3, and 2.2, respectively; $P = .04$) was in favor of LAMS, but there was a higher rate of overall adverse events in the LAMS group (DPS, 7.5%; FCSEMS, 1.6%; and LAMS, 9.5%; $P = .01$). When examining early adverse events, there were more bleeding events in the LAMS group vs DPS vs FCSEMS groups (6 vs 2 vs 0, respectively; P

= .006). Other early AEs including abdominal pain, aspiration, hypotension, self-limited pneumoperitoneum, and hemorrhage secondary to puncture of an artery were more significant in the DPS group in comparison with the FCSEMS and LAMS groups, respectively (6 vs 0 vs 1, respectively; $P = .011$). The late adverse event that was significant was stent occlusion, which was seen more frequently in FCSEMS and DPS in comparison with LAMS, respectively (26 vs 23 vs 3, respectively; $P = .0006$).¹⁷

An interim analysis of a prospective randomized study has reported adverse events in 6 of 12 LAMS patients vs 0 of 9 DPS patients ($P = .019$), including 3 pseudoaneurysm bleeds in the LAMS group and 2 buried LAMS. This has led to a change in study protocol and earlier cross-sectional imaging completed at 3 weeks with removal of the stent if PFC is resolved.³¹

There appears to be a higher rate of bleeding in the use of metal stents to treat PFC. In our series specifically comparing DPS and LAMS, the number of bleeding events in the LAMS group, and in particular serious pseudoaneurysm bleeding, was higher than previously reported data.^{17,22,30} Furthermore, our bleeding events seem to occur within the first 3 weeks of placement, prompting some to consider removal within 4 weeks or earlier if imaging shows resolution. A possible explanation for the bleeding includes rapid collapse of the PFC with LAMS placement, which may cause the distal flange to irritate the back wall of the PFC, promoting pseudoaneurysm formation and subsequent bleeding. An additional hypothesis is that some PFCs are so large that, despite predrainage cross-sectional imaging, vessels may be missed owing to compression by the PFC.¹⁷ PFC size has not necessarily increased from the pre-LAMS era, with previous sizes ranging in large studies up to 27.5 cm addressed with DPS, again raising concern for something unique to LAMS and the increase in bleeding.^{8,15,32} Although symptomatic, actionable perforation was not statistically different, there were more perforations in the DPS group than in the LAMS group, which some providers attributed to the fact that dual DPS are technically more difficult to place than LAMS, which could lead to this adverse event. An advantage of LAMS over DPS is the technical ease of placement.

We generally do not keep LAMS for PFC indwelling for longer than 2 months because of concerns for delayed bleeding. Thus, one perceived potential advantage to DPS stents is their ability to be left in place for a longer period of time or indefinitely to allow for tract (fistula) formation between the stomach/duodenum and pancreas for those individuals with disrupted pancreatic duct or distal obstruction. Overall, stent duration was similar between our 2 arms, but we did have 16 patients in the DPS group with stents left in place for more than 90 days (range, 95–358 d) in comparison with 5 in the LAMS group (range, 96–158 d). It should be noted that LAMS have Food and Drug Administration approval to be in place for no longer than 60 days. One concern for leaving LAMS in place longer is the risk of bleeding that has been shown.

There were inherent limitations in our retrospective design. We had a heterogeneous patient population, as is true in clinical practice, including acute and chronic pancreatitis, different degrees of WON, and so forth, and the technical considerations and indications for drainage might be different in these 2 groups. Although the number of patients lost to follow-up evaluation was low in each arm, there is the potential for not capturing all AEs. There also

was heterogeneity in image quality for patients outside of our system, which may lead to missed pseudoaneurysm detection before performance of the procedure. In addition, the decision to place a DPS or LAMS was at the discretion of the endoscopist and the rationale for choosing one stent vs another could not be determined retrospectively. This could lead to a selection and/or treatment bias.

In conclusion, despite the limitations described earlier, this was a large study comparing DPS and LAMS in drainage of both PP and WON. Drainage of PFC using DPS appears to remain a valid option given lower pseudoaneurysm bleeding events with similar technical and clinical success and with a similar number of total procedures to achieve resolution. However, larger inner-diameter lumens with LAMS do simplify access during DEN and may reduce procedure times, but this was not specifically assessed in our study. Our noted high rate of bleeding, especially pseudoaneurysm bleeding, should influence discussion with patients regarding risks and to consider use of DPS for simple PP and in patients with minimal necrosis within the cavity. All of these factors may influence the favorability of one stent choice vs another. Prospective randomized studies that include an assessment of long-term systemic events from underlying necrotizing pancreatitis, cost of overall intervention, time of intervention, and quality-of-life assessments are necessary to help further define patient characteristics and choice of stent to drain PFCs.

Abbreviations used in this paper:

AE	adverse event
DEN	direct endoscopic necrosectomy
DPS	double-pigtail plastic stent
EUS	endoscopic ultrasound
FCSEMS	fully covered self-expanding metal stents
LAMS	lumen-apposing metal stents
PFC	peripancreatic fluid collections
PP	pancreatic pseudocyst
SEMS	self-expanding metal stents
WON	walled-off necrosis

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Figure 1. CT imaging of DPS (A) before and (B) after (arrow) the procedure and LAMS (C) before and (D) after (arrow) the procedure fluid collections.

Figure 2.
Identification of patients.

Figure 3. Distal splenic artery pseudoaneurysm with extravasation (*dashed arrows*) in relation to LAMS (*solid arrows*), which subsequently was coiled.

Table 1.

Patient Characteristics

	LAMS (n = 97)	DPS (n = 152)	P value
Male, <i>n</i> (%)	65 (67)	98 (64.5)	.58
Age, <i>y</i>	47 (11–74)	48 (1–87)	.78
Size, <i>mm</i>	80.1 (35–170)	69.8 (10–170)	.001
Any WON, <i>n</i> (%)	81 (83.5)	116 (76.3)	.52
WON categories, <i>n</i> (%)	No data: 9 (9.3)	No data: 37 (33.6)	.0028
	No necrosis: 7 (7.2)	No necrosis: 11 (7.2)	.68
	30%, 9 (9.3)	30%, 33 (21.1)	.00037
	>30% to 50%, 17 (17.5)	>30% to 50%, 17 (11.2)	.39
	>50%, 55 (56.7)	>50%, 55 (36.2)	.038
Prior failed drainage attempt, <i>n</i> (%)	12 (12.2)	19 (12.5)	.41
Pancreatitis etiology, <i>n</i> (%)	Alcohol, 33 (34)	Alcohol, 43 (28.3)	.95
	Biliary, 31 (32)	Biliary, 34 (22.4)	.55
	Idiopathic, 15 (15.5)	Idiopathic, 32 (21.1)	.71
	Other, 18 (18.6)	Other, 43 (28.3)	.36
Chronic pancreatitis, <i>n</i> (%)	20 (20.6)	60 (38.8)	.03
Nasocystic drain, <i>n</i> (%)	13 (13.4)	33 (21.7)	.39

DPS, double-pigtail plastic stent; LAMS, lumen-apposing metal stents; WON, walled-off necrosis.

Table 2.

Primary and Secondary Outcomes

	LAMS (n = 97)	DPS (n = 152)	P value
Technical success, <i>n</i> (%)	90 (92.8)	137 (90.1)	.67
Clinical success, <i>n</i> (%) Intention to treat	89 (91.8)	137 (90.1)	.54
Stent duration, <i>d</i>	51.5 (4–195)	59.8 (9–388)	.26
Interventions/DEN	1.7 (1–11)	1.9 (1–19)	.93
Recurrence, <i>n</i> (%)	6 (6.2)	7 (4.6)	.57

DEN, direct endoscopic necrosectomy; DPS, double-pigtail plastic stent; LAMS, lumen-apposing metal stents.

Table 3.

Adverse Events

	LAMS (n = 97)	DPS (n = 152)	P value
Total adverse event rate, <i>n</i> (%)	24 (24.7)	27 (17.8)	.67
Total bleeding events, <i>n</i> (%)	15 (15.5)	5 (3.3)	.0005
Presumed	8 (8.2)	1 (0.7)	.009
pseudoaneurysm bleed, <i>n</i> (%)	6 (6.2) IR embolization 1 (1.0) stent removal 1 (1) conservative therapy	1 (0.7) IR embolization	
Other bleeding requiring transfusion and/or endoscopic intervention and/or IR, <i>n</i> (%)	7 (7.2)	4 (2.6)	.09
Perforation, <i>n</i> (%)	0	5 (2) 2 (1.3) endoscopic repair 1 (0.7) surgical repair 1 (0.7) IR drainage 1 (0.7) conservative therapy	.22
Infection, <i>n</i> (%)	2 (2.0)	6 (3.9)	.28
Other, <i>n</i> (%)	6 (6.2) 2 (2.1) abdominal pain 1 (1.0) atrial flutter 1 (1.0) NSTEMI 1 (1.0) seizure 1 (1.0) death	6 (3.9) 2 (1.3) abdominal pain 1 (0.7) renal failure 1 (0.7) gastric ulcer 1 (0.7) pancreatitis 1 (0.7) death	

DPS, double-pigtail plastic stent; IR, interventional radiology; LAMS, lumen-apposing metal stents; NSTEMI, non-ST segment myocardial infarction.