Analysis of adverse events with lumen apposing metal stents for drainage of pancreatic fluid collections

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ABSTRACT

Background and study aims Innovations in endoscopic management of pancreatic fluid collections (PFCs) using lumen apposing metal stents (LAMS) have rendered it a preferred approach for drainage of PFCs. These advances have not come without concern for adverse events (AEs). We present our experience with LAMS for drainage of PFCs and analyze factors that contribute to LAMS-related AEs.

Patients and methods From November 2015 to October 2021, a retrospective analysis was performed of patients undergoing endoscopic management of PFCs using LAMS. All AEs were classified as either early (<48 hours) or late (>48 hours). Univariate and multivariate analysis were performed using logistic regression to assess the relationship between independent variables and AEs.

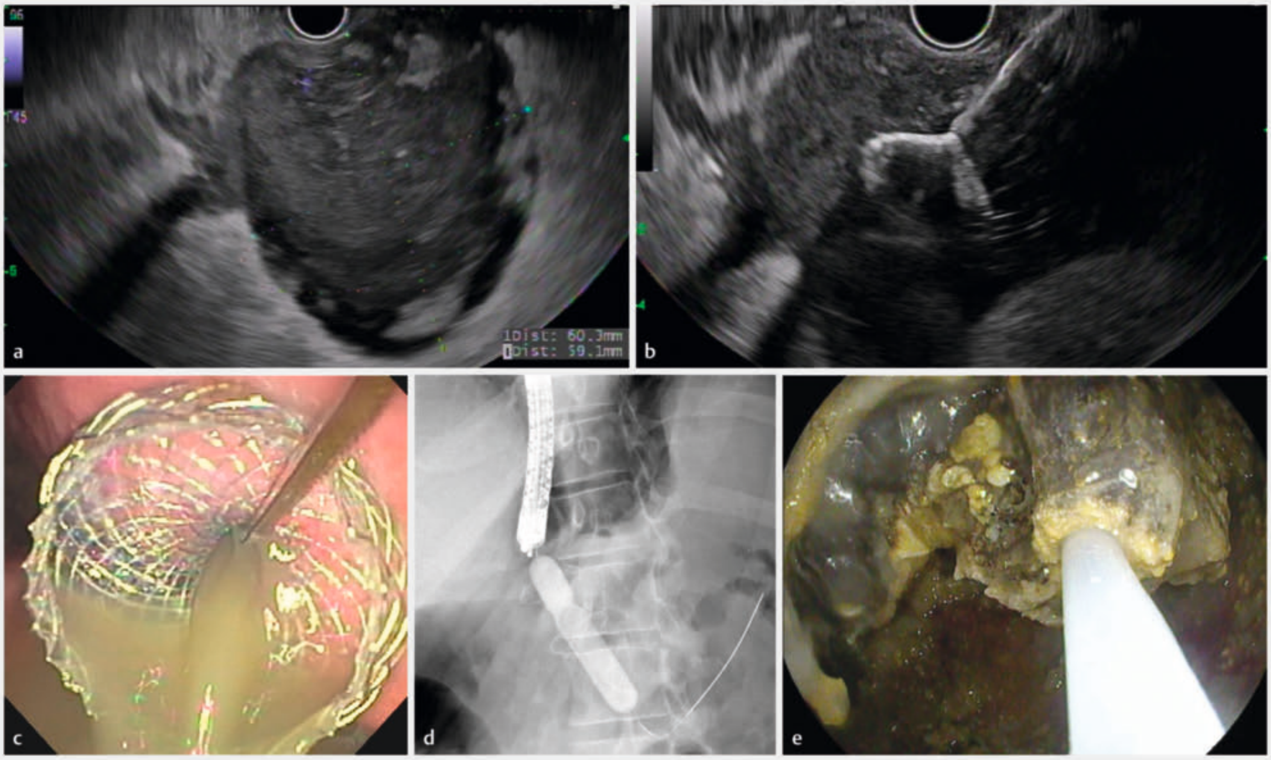
Results A total of 119 patients with symptomatic PFCs underwent endoscopic drainage with LAMS. There were 16 AEs (12.4%). These included systemic inflammatory response syndrome (SIRS) (n = 2), stent occlusion (n = 5), bleeding (n = 7), and stent migration (n = 2). Univariate analysis of risk of AEs showed that no variables approached statistical significance. Of the seven patients who developed bleeding, five had pseudoaneurysms following LAMS placement and underwent angioembolization by an interventional radiologist. The average time to bleeding was 9.3 days (standard deviation 7.3) with all bleeding events occurring within 3 weeks. In a multivariate model, pseudocysts and presence of paracolic gutter extension were associated with an increased risk of bleeding.

Conclusions Endoscopists should be aware of the risk factors for LAMS-related bleeding and tailor their drainage strategy, including utilization of plastic stents for drainage of pseudocysts and adherence to a strict imaging interval and follow-up protocol.

Introduction

Lumen apposing metal stents (LAMS) have been increasingly used for management of pancreatic fluid collections (PFCs). They are biflanged-shaped and have a large stent diameter, better facilitating drainage of necrotic debris compared with smaller plastic stents. In addition, the large diameter of LAMS can serve as a port, allowing for direct endoscopic necrosectomy (DEN), a technique associated with low complication rates and high clinical success [1]. Although the advantages of LAMS are well documented, adverse events (AEs) have been reported with their use. These include bleeding, stent migration, stent occlusion, and buried stent syndrome [2].

Several studies have elucidated predictive factors for the development of AEs associated with LAMS usage. In a study by Bang et al, increased incidence of AEs was associated with a



▶ **Fig. 1** Endoscopic ultrasound-guided drainage of walled-off necrosis with lumen apposing metal stent. **a** Endoscopic ultrasound image of walled-off necrosis. **b** Deployment of proximal flange of lumen apposing metal stent under EUS guidance, **c** Endoscopic image showing fluid draining from the cyst cavity following LAMS placement. **d** Fluoroscopic image showing balloon dilation of LAMS. e Endoscopic image showing direct endoscopic necrosectomy using a snare.

LAMS dwell time >3 weeks [3]. However, other studies have found conflicting results where the timing of LAMS removal was not associated with increased incidence of delayed AEs [4, 5]. Furthermore, other studies have found a lower rate of AEs with improved institutional experience and a higher rate of AEs in patients with pancreatic duct disruption, perigastric varices, pseudoaneurysms, and collections requiring percutaneous drainage [6, 7, 8]. We present our experience with LAMS for management of PFCs at a single tertiary center and analyze factors contributing to LAMS-related AEs.

Patients and methods

Patients admitted with acute pancreatitis who were found to have symptomatic PFCs requiring endoscopic drainage with LAMS from November 2015 to October 2021 were recruited and added to a prospectively maintained database. Following Institutional review board approval, informed consent was obtained from all subjects prior to endoscopic intervention. All patients underwent cross-sectional imaging with either contrast-enhanced computed tomography or magnetic resonance cholangiopancreatography to characterize the collections. Each case was reviewed with a multidisciplinary team (two abdominal radiologists, a hepatobiliary surgeon, and an advanced endoscopist) to plan the optimal endoscopic approach. Inclusion criteria consisted of patients with mature PFCs per the Atlanta classification with a follow-up duration of ≥6 months from the index procedure [9]. Exclusion criteria consisted of patients <age 18 years, patients with concern for malignancy, postoperative fluid collections, platelet count <50,000, and international normalized ratio >1.5. Data including patient demographics, procedure details, collection characteristics, AEs, and clinical outcomes were retrospectively reviewed and analyzed.

All patients with symptomatic PFCs underwent endoscopic ultrasound-guided drainage using a therapeutic linear echoendoscope (Olympus, Tokyo, Japan). A 15 mm×10 mm LAMS (Boston Scientific, Marlborough, Massachusetts, United States) was used for patients with wall-off necrosis (WON) and a 10 mm×10 mm LAMS was used for PC drainage. Following deployment of LAMS, the stent was dilated to its diameter (▶ **Fig. 1**). Patients with WON underwent debridement of necrotic material with rat tooth forceps, snares, and baskets. All patients with WON underwent lavage with 100 cc of 0.3% hydrogen peroxide at the end of the procedure. Coaxial double-pigtail plastic stents were not placed in any patients. The interval for serial imaging after endoscopic drainage was determined based on the type of collection. Patients with PFCs were imaged 1 and 3 weeks after initial drainage. For patients with WON, serial imaging was obtained at 1, 3, and 6 weeks after initial drainage as well as 1 week after each necrosectomy. If the collection size was noted to be <2 cm in largest diameter, the LAMS was scheduled to be removed. Double-pigtail stents were placed following LAMS removal in patients with disconnected duct syndrome.

Technical success was defined as successful placement of the LAMS into the PFC and complete endoscopic clearance of necrotic material from the cyst cavity in patients with WON. Clinical success was defined as resolution of patient symptoms and a collection size ≤ 2 cm on cross-sectional abdominal imaging at 6-month follow-up. Follow-up duration was measured from the time of index procedure to the last clinic visit with a member of the multidisciplinary team. LAMS-related AEs including bleeding, stent migration, stent occlusion, and infection were classified based on their timing (≤48 hours post-procedure) and severity as determined by American Society of Gastrointestinal Endoscopy (ASGE) lexicon criteria [10]. Bleeding was defined as a drop in hemoglobin in the setting of overt gastrointestinal bleeding. Any change in stent position as observed on endoscopy or interval imaging was recorded as stent migration. If the lumen of the LAMS was obstructed by necrotic debris or food material requiring endoscopic clearance, it was considered stent occlusion. Systemic inflammatory response syndrome (SIRS) was defined as patients with two of the following criteria: body temperature >38°C or <36°C, heart rate >90 bpm, respiratory rate >20 breaths/min, leukocytosis >12,000, or leukopenia <4,000.

Descriptive statistics were used to analyze continuous (mean, standard deviation, median, and interquartile range) and categorical variables (frequency and proportion). Univariate and multivariate analysis with logistic regression was performed to identify risk factors for overall AEs and bleeding in patients undergoing endoscopic management of PFCs using LAMS. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated for each variable. Univariate effects with $P \leq 0.12$ were used to create a multivariate model to assess independent predictors of AEs. A cumulative proportion of AEs over time following LAMS placement was assessed using a linear regression model.

Results

There were 5,277 patients diagnosed with acute pancreatitis at our institution during the study period. Of these, 119 patients with PFCs were identified and deemed amenable to endoscopic drainage on cross-sectional imaging. All patient demographic information including age, body mass index (BMI), Charlson comorbidity index, etiology, presence of infection, collection characteristics, and clinical outcomes are summarized in ▶**Table 1** and ▶**Table 2** [11]. Of the 119 patients undergoing endoscopic drainage, 85 had WON and 34 had symptomatic pseudocysts. Technical success was achieved in all patients (n = 119, 100%). The average procedure time was 40.9 minutes. The median post-procedure length of stay was 3 days. Of the 85 patients with WON, 80 underwent endoscopic necrosectomy. The median number of necrosectomies was two. In five patients with WON, no necrosectomy was performed as the necrosis was <10%. Clinical success was achieved in 112 patients (94.1%).

▶**Table 1** Baseline patient characteristics of patients undergoing drainage of pancreatic fluid collections.

Patient characteristics (n = 119)	
Age (years), mean, SD	53.5, 14.3
Female gender, n, %	44, 37.0%
BMI (kg/m^2), mean, SD	28.1, 7.1
Charlson Comorbidity index, mean, SD	3.0, 2.3
Etiology of pancreatitis	
▪ Alcohol, n, %	48, 40.3%
▪ Biliary, n, %	42, 35.3%
▪ Idiopathic, n, %	21, 17.6%
▪ Hypertriglyceridemia, n, %	4, 3.4%
▪ Drug induced, n, %	4, 3.4%
WON, n, %	85, 71.4%
Infected collection, n, %	41, 34.5%
Area of collection (cm^2), mean, SD	109.4, 88.4
Presence of DPDS, n, %	63, 52.9%

SD, standard deviation; BMI, body mass index; WON, walled-off necrosis; DPDS, disconnected pancreatic duct syndrome.

▶**Table 2** Clinical outcomes of patients undergoing endoscopic drainage of pancreatic fluid collections.

Clinical outcomes (n = 119)	
Procedure time (min), mean, SD	40.9, 22.5
Length of hospitalization (days), median, IQR	3 (1, 9)
Surgical intervention, n, %	6, 5.0%
Duration of LAMS placement (days), mean, SD	46.2, 34.7
Technical success, n, %	119, 100%
Clinical success, n, %	112, 94.1%
Length of follow-up (days), mean, SD	488, 492

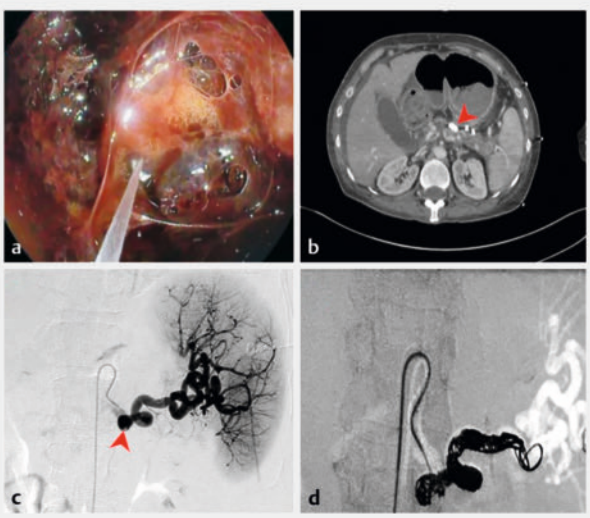
SD, standard deviation; IQR, interquartile range; LAMS, lumen apposing metal stent.

A total of 16 AEs were seen in the study group (▶**Table 3**). These were classified as mild (n = 3, 18.8%), moderate (n = 12, 75%), and severe (n = 1, 6.3%) according to the ASGE lexicon criteria. Six AEs occurred in PFCs and 10 in WON. Early AEs (<48 hours) were seen in three patients (18.7%). Two of these patients developed SIRS after endoscopic necrosectomy requiring overnight intensive care unit admission and one patient presented with bleeding following pseudocyst drainage requiring interventional radiation embolization of the splenic artery (▶**Fig. 2**). Late AEs (>48 hours) were seen in 13 patients (81.3%). This included stent migration (n = 2), stent occlusion (n = 5), and bleeding (n = 6). Of the patients with stent migra-

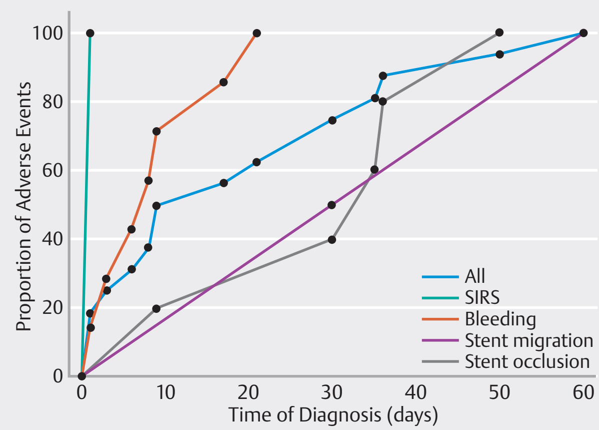
▶ **Table 3** Adverse events in patients undergoing endoscopic drainage.

Adverse events, n, %			16, 13.4%
▪ Pseudocyst			6/34 (17.6%)
▪ Walled-off necrosis			10/85 (11.8%)
Adverse events (n = 16)	PS (n = 34)	WON (n = 85)	
Adverse events (<48 hours), n, %			3, 18.7%
▪ SIRS, n	0	2	2
▪ Bleeding, n	1	0	1
Adverse events (≥48 hours), n, %			13, 81.3%
▪ Bleeding	4	2	6
▪ Stent occlusion	0	5	5
▪ Stent migration	1	1	2

PS, pseudocyst; WON, walled-off necrosis; SIRS, systemic inflammatory response syndrome.



▶ **Fig. 2** LAMS-associated bleeding secondary to splenic artery pseudoaneurysm managed with angioembolization. **a** Endoscopic image of bleeding within the cyst cavity following LAMS placement. **b** CT angiogram showing splenic artery pseudoaneurysm (red arrowhead). **c** Angiogram showing splenic artery pseudoaneurysm (red arrowhead). **d** Coils packing the pseudoaneurysm and splenic artery.



▶ **Fig. 3** Cumulative proportion of AEs over time following LAMS placement.

tion, one stent migrated out of the cavity at 1 month and passed spontaneously without complication. This patient did not require further intervention because the collection had resolved. In the second patient, endoscopy was performed to retrieve the stent from within the cavity at 2 months followed by placement of two 10F double-pigtail plastic stents. All five patients with stent occlusion required endoscopic intervention for stent clearance. Of the six patients who presented with bleeding, four were found to have a pseudoaneurysm (superior pancreaticoduodenal artery, gastroduodenal artery, left gastric artery, and splenic artery) and underwent angioembolization. The remaining two patients had bleeding due to cyst wall trauma while on anticoagulation, which was managed conservatively.

AEs were diagnosed an average of 19.8 days following LAMS placement (SD 18.5). Stent occlusion occurred after a mean of 32 days (standard deviation [SD] 14.8). The average time to bleeding was 9.3 days (SD 7.3) with all bleeding events occurring within 3 weeks of LAMS placement (▶ **Fig. 3**).

Among patients with AEs, the average age was 52.9 years (SD 11.1), and three patients were female (18.8%). The average BMI was 27.9 (kg/m^2) (SD 6.0). There were six pseudocysts (37.5%) and 10 WONs (62.5%), of which seven were infected (43.8%). Etiology of collections included alcohol (n = 5, 31.3%), gallstone (n = 8, 50%), hypertriglyceridemia (n = 1, 6.3%), and idiopathic (n = 2, 12.5%). The average area of collection was 101.2 cm^2 (SD 83.4). Ten collections (62.5%) were located in the body of the pancreas, four (25%) in the head, and two (12.5%) in the tail. Six collections (37.5%) extended into the

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▶ **Table 4** Risk of adverse events: univariate analysis.

Variable	Odds ratio	95% CI	*P* value
Age (per 5-year increase)	0.98	0.82–1.18	0.86
Gender (F/M)	0.35	0.09–1.30	0.12
BMI (kg/m^2) (per 1-unit increase)	0.996	0.92–1.08	0.93
Etiology of pancreatitis			0.63
▪ Alcohol	0.66	0.21–2.04	0.47
▪ Gallstone	2.03	0.70–5.87	0.19
▪ Idiopathic	0.63	0.13–3.02	0.56
▪ Other	0.79	0.09–6.79	0.83
Type (PS vs WON)	1.61	0.53–4.83	0.40
Area (cm^2) (per 10-unit increase)	0.99	0.92–1.05	0.69
PFC location			0.43
▪ Body vs head	0.45	0.12–1.63	0.21
▪ Body vs tail	1.16	0.23–5.81	0.50
Infection (Y/N)	1.58	0.54–4.61	0.40
Drainage approach (transgastric vs other)	0.80	0.20–3.12	0.74
Extension into paracolic gutter (Y vs N)	3.04	0.97–9.47	0.056
Concomitant IR drainage (Y vs N)	2.15	0.52–8.83	0.29
Length of hospitalization (per 1 additional day)	1.02	0.99–1.04	0.14
Procedure time (per 10-min increase)	1.17	0.95–1.44	0.15

CI, confidence interval; BMI, body mass index; PS, pseudocyst; WON, walled-off necrosis; PFS, pancreatic fluid collection; IR, interventional radiation.

paracolic gutters and three collections required concomitant interventional radiology drainage (18.8%). Thirteen collections (81.3%) were drained with a transgastric approach and three (18.8%) with a transduodenal approach. The median hospital length of stay was 4 days (IQR 2.3, 18.5).

In a univariable model, analyzing the association of AEs with age, gender, BMI, etiology, type of collection, area of collection, PFC location, drainage approach, paracolic gutter extension, concomitant interventional radiology drainage, length of hospitalization, and procedure time, no significant differences were seen between the cases (patients with AEs) and controls (patients without AEs). However, compared with control subjects, cases were more likely to have extension into the paracolic gutter ($P = 0.056$) (▶ **Table 4**). A univariate analysis of the risk of bleeding is summarized in ▶ **Table 5**. Patients with bleeding secondary to LAMS were more likely to have pseudocysts (OR 7.16, 95%CI 1.32–38.9; $P = 0.023$) with collections located in the body (OR 5.71, 95%CI 1.05–31.2; $P = 0.075$) and extending into the paracolic gutter (OR 3.45, 95%CI 0.72–16.6; $P = 0.12$). Univariate effects with $P \leq 0.12$ was used to create a multivariate model to assess odds of bleeding. On a multivariable analysis, pseudocysts (OR 23.9, 95%CI 2.1- 271; $P = 0.010$) and collections extending into the paracolic gutter (OR 15.9, 95%CI 1.4–175; $P = 0.024$) were statistically significant.

Discussion

Over the past several years, LAMS have largely replaced double-pigtail plastic stents and have increasingly been used for drainage of PFCs. The biflanged design of LAMS, large diameter, short saddle length, and ease of deployment make them ideal to appose two lumens and perform endoscopic necrosectomy. These features have allowed for improved outcomes for PFCs that were previously managed surgically, with high morbidity and mortality [12]. These successes have enabled rapid dissemination of LAMS in the community; however, their prolific impact on the management of PFCs has not come without concern because AE rates have been reported in excess of 30% [3]. Our study closely examined the safety profile of LAMS and identified two critical risk factors for LAMS-associated bleeding.

The rate of AEs associated with LAMS usage in our study cohort was 13.4%. This risk of AEs is lower than what has been reported in other studies, likely due to the rigorous protocolized management strategy with serial imaging at regular intervals and close follow-up [13, 14, 15]. Factors including demographic correlates, collection characteristics, etiology of pancreatitis, and procedure details were not associated with an increased likelihood of the development of AEs, although paracolic gutter extension approached statistical significance. Despite the lack of significant variables impacting AEs, when specifically analyz-

▶ **Table 5** Risk of bleeding: univariate analysis.

Variable	Odds ratio	95% CI	*P* value
Age (per 5-year increase)	0.95	0.73–1.23	0.70
BMI (kg/m^2) (per 1-unit increase)	0.92	0.80–1.04	0.19
Etiology of pancreatitis			
▪ Alcohol	2.14	0.46–10	0.33
▪ Gallstone	1.40	0.30–6.59	0.67
Type (PS vs WON)	7.16	1.32–38.9	0.023
Area (cm^2) (per 10-unit increase)	0.86	0.71–1.05	0.14
PFC location			0.12
▪ Body vs head	5.71	1.05–31.2	0.075
▪ Body vs tail	0.68	0.07–6.87	0.21
Infection (Y/ N)	0.30	0.03–2.57	0.27
Drainage approach (transgastric vs other)	0.45	0.08–2.50	0.36
Extension into paracolic gutter (Y/ N)	3.45	0.72–16.6	0.12
Concomitant IR Drainage (Y/ N)	0.49	0.03–9.10	0.99
Length of hospitalization (per 1 additional day)	1.00	0.96–1.04	0.96
Procedure time (per 10-min increase)	1.07	0.79–1.46	0.65

CI, confidence interval; BMI, body mass index; PS, pseudocyst; WON, walled-off necrosis; PFC< pancreatic fluid collection.

ing the risk of bleeding, type of collection and presence of paracolic gutter extension were concerning as factors promoting post-procedure bleeding-related complications.

The cumulative risk of bleeding in patients undergoing LAMS placement is 6.9% at 12 months [16]. In a study by Abdallah et al, 39 of the 607 patients diagnosed with necrotizing pancreatitis had pseudoaneurysms [17]. Of these, 17 patients (43.6%) had a LAMS placed prior to the pseudoaneurysm formation. Of the 39 patients with pseudoaneurysms, 74.3% presented with gastrointestinal bleeding and hemorrhagic shock was seen in 30%. These findings were particularly concerning because bleeding from pseudoaneurysms resulting from LAMS-induced erosion was associated with significant morbidity and mortality. Furthermore, in a retrospective study of 149 patients with PFCs, the authors found that patients undergoing drainage with LAMS had a high rate of pseudoaneurysm-associated bleeding when compared with patients undergoing drainage with double-pigtail stents [8]. The aforementioned studies underscore the risk of LAMS-related bleeding and show that while LAMS are useful stents for drainage of PFCs, prudent evaluation of their necessity and close examination of risk factors for the development of AEs should be considered prior to their deployment.

In our study, seven patients (5.9%) developed gastrointestinal bleeding secondary to LAMS. Of these, five collections were pseudocysts and two were WONs. Five of the seven patients who bled had pseudoaneurysms detected after LAMS placement and required angioembolization. In the remaining two patients, bleeding was associated with cyst wall trauma secondary to LAMS placement. All patients with bleeding presented within 3 weeks of LAMS placement and the average duration of bleeding was 9.3 days (SD 7.3). We found that patients with pseudocysts and collections extending into the paracolic gutter were at a significantly higher risk of LAMS-associated bleeding. We hypothesize that rapid collapse of the cyst cavity following deployment of LAMS with resultant cyst wall trauma due to friction with the metal stent promotes the formation of pseudoaneurysms and bleeding. In addition, patients with paracolic gutter extension have extensive inflammation, which can lead to erosion of retroperitoneal blood vessels, thereby leading to pseudoaneurysm formation and bleeding secondary to trauma following LAMS placement. Given that pseudocysts do not contain necrotic material, one can presume that these collections can safely be drained with plastic stents, thereby decreasing the risk of bleeding. Furthermore, evaluation for the presence of paracolic gutter extension on cross-sectional imaging prior to drainage should be performed to facilitate shorter-interval hemoglobin checks and prompt LAMS removal in this subset of patients.

Other AEs that have been associated with LAMS are stent migration and occlusion. The biflanged shape of LAMS was designed to minimize the risk of stent migration. In a study by Garcia-Alonzo et al, LAMS migration in patients undergoing PFC drainage was 21% [16]. A strategy that has been reported in the literature to decrease the risk of stent migration is placing a double-pigtail stent within the LAMS to help anchor the stent [18, 19]. Shamah et al in a retrospective analysis of 68 patients comparing 35 patients with LAMS and DPS versus 33 patients with LAMS alone found no significant difference in AEs or clinical outcomes between the two groups [20]. In a recent randomized controlled trial by Vanek et al comparing 67 patients with WON drained with LAMS alone or LAMS with DPS, it was seen that the addition of coaxial DPS within a LAMS was associated with lower rates of AE and stent occlusion [21]. However, this study was not blinded and because stent occlusion is a subjective diagnosis, observer bias impacts the validity of these findings. Our study cohort had a stent migration rate of 1.7% (2 patients) and a stent occlusion rate of 4.2% (5 patients). None of the patients in our study had DPS placed within the LAMS. The reason for the low incidence of stent migration and occlusion in our study was a protocolized management strategy with prompt direct endoscopic necrosectomy and interval follow-up imaging. Further studies are needed to clarify the utility of using DPS within LAMS to decrease the incidence of AEs.

The strengths of this study include the value of a multidisciplinary team made up of an interventional endoscopist, a hepatobiliary surgeon, and abdominal radiologists. All cases were reviewed closely by the team to plan the most appropriate management strategy. In addition, an established standardized procedural protocol was followed in all patients at the same institution. The limitations of this study include its retrospective design, which created the possibility of observer bias. Furthermore, the procedures were performed by skilled endoscopists at a large tertiary care center; therefore, generalizability may not always be possible.

Conclusions

In conclusion, we have demonstrated that the use of LAMS for PFCs is safe and effective and associated with a low risk of AEs. Drainage strategy should be adjusted to mitigate AEs including reevaluation of pseudocyst drainage with plastic double-pigtail stents instead of LAMS. Shorter-interval hemoglobin checks and imaging should be performed in patients with paracolic gutter extension to minimize the complications associated with LAMS. Further prospective and randomized trials are needed to confirm these findings.

Conflict of Interest

Rishi Pawa is a consultant for Boston Scientific and Cook Medical. The remaining authors have no conflict of interest to declare.

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