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Safety and efficacy of early versus late removal of LAMS for pancreatic fluid collections

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ABSTRACT

Background and study aims Optimal timing for removal of lumen-apposing metal stents (LAMS) for effective drainage of pancreatic fluid collections (PFC) while minimizing adverse events (AE) is unknown. Outcomes of early (≤ 4 weeks) or delayed (> 4 weeks) LAMS removal on both clinical efficacy and the incidence of AE were assessed.

Patients and methods This was a retrospective analysis of a prospectively maintained registry of PFC drainage between November 2016 and September 2021. Clinical success was defined as a 75% decrease in fluid collection volume with no need for reintervention at 6 months. AE were defined using the American Society for Gastrointestinal Endoscopy lexicon. Multiple logistic regression analysis was performed to determine variables associated with clinical success and AE.

Results A total of 108 consecutive PFCs were included. LAMS deployment was technically successful in 103 of 108 cases (95.4%). Failure was associated with collection diameter ≤ 4 cm (odds ratio [OR] 24.0, $P = 0.005$) and presence of more than 50% necrotic material (OR 20.1, $P = 0.01$). Stents were left in place for a median of 48 days. Patients with early stent removal (< 4 weeks) had clinical success in 70.0% of cases, which was significantly less than in the group with delayed stent removal (96.4%, $P = 0.03$). On multiple regression analysis, clinical failure was associated with early stent removal (OR 25.5, $P = 0.003$). AEs occurred in 8.7% of cases (9/103). There were no predictors of AE. Notably, delayed stent removal did not predict the occurrence of AE.

Conclusions Early LAMS removal (< 4 weeks) did not prevent AEs but did lead to increased clinical failure.

Introduction

Pancreatic fluid collections (PFC) are a common complication of acute pancreatitis [1]. Chronic collections (> 4 weeks from pancreatitis onset) are classified as pseudocysts or walled-off necrosis (WON) depending on the presence or absence of solid necrotic debris [2]. Both can require intervention if they become symptomatic. There have been several studies comparing endoscopic management to either surgical or percutaneous drainage, with most concluding in the superiority of endoscopic management in terms of efficacy and safety [3, 4, 5, 6, 7, 8].

The management of PFC has been revolutionized in the past 5 years with the arrival of lumen-apposing metal stents (LAMS) [7]. These large diameter stents not only allow for spontaneous drainage, but also provide an easy access for endoscopic necrosectomy when needed [9, 10, 11, 12]. LAMS have proven to have both high technical and clinical success rates for PFC treat-

ment [13]. They are also easy to use and have the advantage of shorter procedure time when compared with plastic stents [14].

However, major adverse events (AEs) such as erosion of surrounding arteries by LAMS and stent migration have been reported [15]. A retrospective review of 180 cases of LAMS for PFC by Bang et al. was the first to suggest that stent removal more than 4 weeks after insertion was associated with an increased risk of AEs [10]. Recent guidelines favor removal of LAMS 3 to 5 weeks after insertion, to avoid vascular impingement and delayed bleeding after PFC decompression [16]. This recommendation is based solely on retrospective studies and predictors of AEs remain unclear. A registry study of 1018 patients from multiple centers in the United Kingdom published this year did not show an increase in AEs with delayed stent removal [17]. Moreover, PFC can take more than 4 weeks to resolve, and early stent removal may lead to incomplete drainage, sepsis, and need for further interventions [18]. Therefore, the risk of AEs with delayed stent removal must be put into perspective with the additional clinical benefits.

The aim of this study was to better compare the differences in both clinical efficacy and the incidence of AE in patients in whom LAMS were removed before or after 4 weeks.

Patients and methods

This was a retrospective analysis of cases retrieved from a prospectively maintained endoscopic ultrasound (EUS) database at the Centre Hospitalier de l'Université de Montréal (CHUM), a quaternary center performing approximately 2800 EUS procedures annually. The study was conducted according to the principles of the Declaration of Helsinki (2013) and the study protocol was approved by our local ethical committee (CER number 21.317).

All consecutive patients referred for LAMS insertion for any PFC (pseudocyst or WON) between November 2016 and September 2021 were included. Patients with < 6 months of follow-up after stent insertion were excluded. The endpoints of this study were clinical success, technical success, and the occurrence of AEs. Clinical success was defined by a decrease of at least 75% of the collection's volume on imaging, with no need for further endoscopic, radiological, or surgical drainage procedure in the following 6 months. Technical success was defined as proper stent deployment into the PFC with no immediate procedural AEs. We used the American Society for Gastrointestinal Endoscopy (ASGE) classification [19] for AEs. Stent dislodgement, stent migration, and buried stent, which is internal migration of the LAMS into the gastric wall which could not be retrieved using only endoscopic forceps at initial attempt, were considered AEs. Significant bleeding was defined as hematesis/melena or a drop of hemoglobin > 2 g. AEs were divided into two groups: early AEs occurring in the first 24 hours and delayed AEs presenting more than 24 hours after stent insertion. Data collected for each procedure included demographics, the indication for LAMS insertion, baseline laboratory results, baseline and follow-up imaging of PFC, and EUS reports. All patients had an abdominal computed tomography (CT) scan of the abdomen prior to the procedure. The total collection volume was calculated by multiplying the size of the long axis and the short axis of the collection on the CT scan report. In cases of WON, necrosis/solid material percentage was evaluated by EUS during the procedure. Data missing from our database were collected from the hospital's electronic medical records (EMR) system. Complications and the need for further intervention were also assessed using patients' EMRs.

All procedures were performed by two highly experienced endosonographers (> 15 000 EUS procedures each) using a linear probe, under conscious sedation, with midazolam and fentanyl, in the left lateral position. The optimal position for LAMS insertion was decided using EUS images and vascular flow Doppler at the time of the procedure. Saline was injected into the collection prior to LAMS insertion when the collection seemed too small or too much solid debris was seen in the field of stent deployment. LAMS were deployed under EUS guidance using the Hot-AXIOS delivery system (Boston Scientific, Marlborough, Massachusetts, United States), with 100 W of pure cut current, with no fluoroscopy, balloon dilation, nor concomitant placement of double pigtail plastic stent. The size of the stent used was left at the endoscopist's discretion. After stent placement, aspiration was applied to remove as much liquid as possible. If immediate stent blockage occurred due to necrotic material, attempts were made to dislodge the material with a dilation balloon to allow further drainage of liquid components. The range of dilation was from 12 mm to 18 mm (depending on stent diameter). If the patient remained septic or symptomatic (ex: gastric outlet obstruction, pain) 72 hours after stent insertion, a CT scan was performed to look for evidence of incomplete drainage or AEs. Necrosectomy was then carried out if required using endoscopic snares and large forceps. A CT scan was performed for all patients 4 weeks after stent insertion to plan for stent removal. Follow-up of all patients was done by a multidisciplinary team of radiologists, interventional endoscopists, and pancreatic surgeons. This multidisciplinary team could decide to leave the stent in longer, if the collection had not resolved. Antibiotics were prescribed or continued for at least 2 weeks after stent placement in patients presenting with sepsis. Discontinuation of proton pump inhibitors, if possible, was also recommended for necrotic collections.

Patient characteristics and procedure details were summarized as means with standard deviations (SDs) or median with interquartile range (IQRs) accordingly. Continuous variables were analyzed with the Student's *t*-test or appropriate nonparametric tests, and categorical variables using Chi-squared tests. Univariate logistic regression was performed to determine factors associated with our endpoints. A multiple logistic regression model was then developed, using a reverse stepwise methodology, to include both clinically and statically important variables. The Akaike information criterion was also used to select the best fitted model. $P < 0.05$ was considered significant. SPSS V 22.0 (IBM, Armonk, New York, United States) and RStudio version 9.01 (R Foundation for Statistical Computing, Vienna, Austria) were used for all analyses.

Results

Over a 5-year period (2016–2021), a total of 108 consecutive patients were referred to EUS for drainage of PFC using LAMS. WON was the diagnosis in most cases (72/108, 66,7%) with an average collection size of 10 × 8 cm. Patient baseline characteristics are summarized in ▶ **Table 1**. Successful stent insertion was achieved in 103 cases (95.4%). Two patients had immediate perforation and were sent to the operating room. The other three patients had unsuccessful stent deployment or early stent migration. Predictors of technical failure were diameter of the collection ≤ 4 cm (odds ratio [OR] 24.0, 95% confidence interval [CI] 2.4–251, $P = 0.005$) and the presence of 50% or more of solid/necrotic-appearing material in the collection (OR 20.1, 95% CI, 2.3–429, $P = 0.01$). Most cases of technical failure (4/5) happened before 2019, during the first 50 attempted procedures. Technical failure was not predicted by the site of drainage (duodenum vs. stomach) or LAMS diameter.

Successful drainage of PFC was achieved in 91.3% of the remaining cases (94/103) with an average collection size of 2.1 × 1.2 cm at the time of LAMS removal. Of the WON cases, 45.8% (33/72) required at least one session of endoscopic necrosectomy to achieve clinical success (median: 2 sessions, range: 1–7). Logistic regression revealed that early stent removal (< 4 weeks) was a strong predictor of clinical failure during follow-up (OR 25.1, 95% CI 5.3–184.2, $P < 0.001$). This association persisted in the multivariate model (OR 25.5, 95% CI 4.9–202.3, $P = 0.003$), which also included pre-drainage collection diameter (≤ 10 cm vs. > 10 cm), LAMS diameter (≤ 20 mm vs. > 20 mm), higher necrotic/solid-appearing content (≤ 50 % vs. > 50%), and endoscopic necrosectomy (no vs. yes). The complete results of the logistic regression are presented in ▶ **Table 2**.

The median duration before LAMS removal was 48 days (range 2–950). LAMS remained in place for more than 4 weeks in 80.6% of patients (83/103). Late LAMS removal was either explained by patient non-compliance with follow-up or by patient ongoing need for necrosectomy and/or persistence of the collection. Patients with early stent removal (< 4 weeks) had clinical success in 70.0% of cases (14/20), which was significantly less than in the group with delayed stent removal (96.4%, (80/83), $P = 0.03$). Both groups were similar in characteristics otherwise (▶ **Table 3**). The occurrence of delayed AE was also similar in both groups (15.0% vs. 6.0%, $P = 0.42$).

▶ **Table 1** Baseline characteristics of patients.

Age (years)	Range	19–93
	Mean	60.1 ± 14.70
Gender: n (%)	Male	67 (62%)
Race: n (%)	White	103 (95.4%)
	African American	2 (1.8%)
	Asian	3 (2.7%)
Type of PFC: n (%)	WON	72 (66.7%)
	Pseudocyst	36 (33.3%)
Baseline laboratory values: Mean ± SD	ALT (IU/L)	41.7 ± 78.1
	AST (IU/L)	51.0 ± 120.5
	Bilirubin (µmol/L)	20.0 ± 41.5
	Alkaline Phosphatase (IU/L)	181.8 ± 236 .3
	Lipase (IU/L)	86.4 ± 47.4
Collection size: Mean ± SD (cm)	Longest axis	10.0 ± 4.2
	Shortest Axis	8.0 ± 3.2
Necrosis percentage:	Range	0–80
	Mean	36.4 ± 23.5
Site of insertion for drainage: n (%)	Gastric	102 (94.4%)
	Duodenal	6 (5.6%)
Size of stent: n (%)	6*8 mm	1 (0.9%)
	10*10 mm	20 (18%)
	15*10 mm	49 (45.4%)
	20* 10 mm	38 (35.2%)

PFC, pancreatic fluid collection; WON, walled-off necrosis; SD, standard deviation; ALT, alanine aminotransferase; AST, aspartate transaminase.

There were nine AEs (8.7%): six hemorrhages and three stent migrations. Two AEs (22.2%) required surgery and were classified as severe, four were treated by Interventional Radiology (44.4%) and were classified as moderate, and three (33.3%) resolved spontaneously or were managed during endoscopy and

▶ **Table 2** Logistic regression analysis of predictors of clinical failure of PFC drainage by LAMS.

	Univariate analysis			Multivariate analysis		
Variable	**OR**	**95% CI**	***P* value**	**OR**	**95% CI**	***P* value**
Time before LAMS removal: ≤ 4 weeks vs. > 4 weeks	25.1	5.3–184.2	**< 0.001**	25.5	4.9–202.7	**0.003**
Size of collection (long axis): ≤ 10 cm vs. > 10 cm	0.3	0.04–1.3	0.13	0.7	0.08–4.6	0.73
Dimension of LAMS: < 20 mm vs. 20 mm	1.1	0.2–4.3	0.93	0.4	0.04–3.1	0.42
Need for endoscopic necrosectomy: No vs. Yes	0.3	0.1–1.4	0.13	0.3	0.04–2.4	0.28
Necrotic material percentage: ≤ 50% vs. > 50%	1.6	0.4–11.1	0.55	1.7	0.3–17.1	0.61

PFC, pancreatic fluid collection; LAMS, lumen-apposing metal stent; OR, odds ratio; CI, confidence interval.

▶ **Table 3** Baseline characteristics and outcomes of patients with early vs. late stent removal.

	Stent removed < 4 weeks	Stent removed > 4 weeks	P value
Number of patients[1]	20/103	83/103	
Age (years)	62.3 ± 12.8	60.2 ± 15.1	0.51
Male sex: n (%)	16 (80.0%)	49 (58.5%)	**0.03**
Race: n (%)			
▪ White	19 (95.0%)	79 (95.2%)	
▪ African American	0 (0%)	1 (1.2%)	
▪ Asian	1 (5.0%)	2 (2.4%)	0.31
Type of PFC: n (%)			
▪ Pseudocyst	7 (35.0%)	27 (32.5%)	
▪ Won	13 (65.0%)	56 (67.5%)	0.53
Baseline laboratory (mean ± SD)			
▪ ALT	64.1 ± 120.5	34.2 ± 60.7	0.54
▪ AST	116.5 ± 244.1	32.1 ± 44.8	0.26
▪ Bilirubin	21.1 ± 32.5	19.5 ± 43.9	0.34
▪ Alkaline Phosphatase	227.4 ± 365.2	167.1 ± 269.3	0.64
▪ Lipase	163.8 ± 270.2	69.2 ± 102.4	0.37
Collection size (mean ± SD)			
▪ Long axis	10.2 ± 4.5	10.1 ± 4.5	0.13
▪ Short axis	8.0 ± 3.1	8.1 ± 3.2	0.49
Necrosis percentage	40.7 ± 22.3	33.7 ± 23.1	0.73
Size of stent: n (%)			
▪ 6*8 mm	0 (0%)	1 (1.2%)	
▪ 10*10 mm	5 (25.0%)	15 (18.1%)	
▪ 15*10 mm	7 (35.0%)	42 (50.6%)	
▪ 20*10 mm	8 (40.0%)	25 (30.1%)	0.92
Clinical outcome: n (%)			
▪ Success	14 (70.0%)	80 (96.4%)	**0.03**
Endoscopic necrosectomy: n (%)			
▪ Yes	9 (45.0%)	24 (28.9%)	0.10
Delayed Adverse events: n (%)			
▪ Yes	3 (15.0%)	5 (6.0%)	0.42

[1]Only patients with successful LAMS deployment were considered (n = 103/108).
PFC, pancreatic fluid collection; WON, walled-off necrosis; SD, standard deviation; ALT, alanine aminotransferase; AST, aspartate transaminase

were considered mild. There were no procedure-related deaths. The duration before AEs varied from 0 to 60 days with a median of 27 days. Individual details of AEs and management are shown in ▶ **Table 4**. There was one early AE, occurring less than 24 hours after stent insertion: bleeding at the site of the stent, which resolved spontaneously. The other eight AEs were classified as delayed, occurring more than 24 hours after stent insertion. Logistic regression analysis of delayed AEs revealed no predictors. Notably, delayed stent removal (> 4 weeks) was not associated with delayed AEs (OR 2.4, 95% CI 0.4–11.6, $P = 0.30$). Factors included in the logistic regression were timing of stent removal (≤ 4 weeks vs. > 4 weeks), pre-drainage collection diameter (≤ 10 cm vs. > 10 cm), LAMS diameter (≤ 20 mm vs.

▶ **Table 4** Details of delayed adverse events.

Type of AE	Details of the AE	Management
Bleeding (5 cases)	Splenic artery erosion: 3 cases	Treated in IR (2 cases) or by surgery (1 case)
	Gastric artery erosion: 1 case	Treated in IR
	Gastroepiploic artery erosion: 1 case	Treated in IR
Stent migration (3 cases)	Intestinal migration with secondary bowel obstruction: 1 case	Treated by surgery
	Buried stent: 2 cases	Removed with APC during endoscopy

AE, adverse event; IR, Interventional Radiology; APC, argon plasma coagulation.

▶ **Table 5** Logistic regression analysis of predictors of delayed adverse events.

Variable	Univariate analysis			Multivariate analysis		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Time before LAMS removal: ≤ 4 weeks vs. > 4 weeks	2.7	0.5–12.1	0.20	2.4	0.4–11.6	0.30
Size of collection (long axis): ≤ 10 cm vs. > 10 cm	1.2	0.3–5.2	0.94	1.1	0.2–5.6	0.93
Dimension of LAMS: < 20 mm vs. 20 mm	0.9	0.2–4.8	0.97	0.6	0.07–4.5	0.60
Necrotic material percentage: ≤ 50% vs. > 50%	0.2	0.01–1.3	0.17	0.2	0.01–1.6	0.21
Need for endoscopic necrosectomy: no vs. yes	1.2	0.2–4.7	0.85	0.96	0.1–5.6	0.97

OR, odds ratio; CI, confidence interval; LAMS, lumen-apposing metal stent.

> 20 mm), higher necrotic/solid-appearing content (≤ 50 % vs. > 50%), and endoscopic necrosectomy (no vs. yes) (▶ **Table 5**).

Discussion

In this retrospective review of 108 consecutive cases of PFC drainage using LAMS, we report high rates of technical (95.4%) and clinical success (91.2%), and low rates of AEs (8.7%). This is one of the largest cohorts yet and its results align with a recently published meta-analysis of 726 cases that showed a pooled technical success rate of 97.5%, a pooled clinical success rate of 90.0%, and a pooled AE rate of 19.1% [13]. There is no consensus about what constitutes clinical success after PFC drainage: the definition and patient follow-up vary in the literature [13, 16], which makes it difficult to make comparisons between studies. In this study, patients were followed up for 6 months to monitor for recurrence, but we still found a very high clinical success rate. This study confirms that LAMS offer a long-term relief of symptomatic PFC. Of note, all drainage procedures were done without fluoroscopy or general anesthesia. The integrated one-step delivery system for LAMS makes this procedure quick and readily available at the bedside, in the Intensive Care Unit, or in an outpatient setting [17].

There were nine AEs (8.7%). Bleeding was the most common AE, followed by stent migration. Importantly, delayed AEs were not associated with the timing of stent removal (> 4 weeks) in contrast to the cohort published by Bang et al. [10]. Erosion of large arteries by the stent mesh after the collapse of the collection can be fatal. Several publications, including the recent ASGE guidelines, have highlighted the need for close monitoring of patients [9, 10, 16, 20, 21]. However, these recommendations are based on retrospective studies, and until we get robust, prospective data, it remains uncertain if delayed stent removal (> 3–5 weeks) is the driving factor responsible for bleeding. Other factors, harder to account for in a retrospective design, such as the location of the collection and the distance of the stent from the splenic hilum or other major vessels, could cause bias. In fact, a large database study including 1018 patients from 18 centers in the UK did not find any association between delayed removal of LAMS (> 8 weeks) and bleeding or other AEs [17].

The risk of AEs must be balanced with the potential for increased clinical success with later stent removal. Early removal of LAMS was suggested soon after the marketing of LAMS as it was thought that it would reduce the number of AEs. However, it can also result in insufficient drainage and need for further interventions. Inflammation and tissue necrosis after acute pancreatitis can take several weeks to resolve [22]. In this cohort, stents were left in approximately 50% longer than the usually recommended 4 weeks, with a median duration of 48 days (~6.5 weeks). Patients in whom the stent was removed early (< 4 weeks), in compliance with the ASGE guidelines, had a higher rate of clinical failure and need for reintervention. In a recent prospective study, Dhillon and al. reported only 80% clinical success when removing LAMS exactly 3 weeks after insertion [20]. Ahmad et al. have also advocated for longer stent placement to allow for complete resolution of collections and have proposed to delay stent removal to 6 weeks for PFC with

solid debris [21]. Placing transmural double plastic pigtails stents at the time of LAMS removal is an alternative to allow for continuous drainage of PFC after 4 weeks, while potentially reducing the risk of AEs [10, 21]. However, plastic stents have a high chance of migration and occlusion [15, 23]. In a prospective randomized controlled trial (RCT), transmural plastic stents after metal stent removal were shown not to be beneficial at 6 months on recurrence of collections in disconnected duct syndrome [24]. The authors report that technical difficulties in placing the plastic stents and a high rate of stent migration could explain these results.

Finally, we report a technical success rate similar to the previously published series [17, 25, 26]. Attempted drainage of smaller collections (≤ 4 cm diameter) and/or collections with apparent high necrotic/solid content (> 50%) was a strong predictor of technical failure. The flanges of the 15-mm and 20-mm AXIOS stents measure 24 or 29 mm, accordingly. Limited working space, due to a smaller diameter and/or necrotic/solid material, may prevent successful deployment of the internal flange and may result in early stent migration. In these cases, injection of fluid to distend the collection and/or use of a "forward-deployment technique" can help overcome this issue (unpublished observations). Moreover, small collections (< 4 cm) are rarely symptomatic and drainage should be avoided if possible. Most cases of technical failure happened during the first 50 procedures, which suggests that there is a learning curve for LAMS insertion. Similar learning curves for 25 procedures per endoscopist have been described for other EUS-guided procedures [27, 28].

Our study is limited by its retrospective design and its inherent bias. There is always a risk of unknown factors causing bias in the observed associations. It is also limited by the relatively small number of patients included. However, this is one of the largest series published and it represents real-life conditions. This study is also, to our knowledge, the first to challenge the recent ASGE guidelines by putting in perspective clinical success and AE rates depending on the timing of LAMS removal. Most cases included in this study were large WONs (> 10 cm in diameter). Larger collections are generally more likely to be symptomatic, and hence, to require drainage. This limits the generalizability of our study to smaller collections and other non-necrotic collections, which may pose different challenges. A prospective RCT is now needed to further understand the optimal duration of LAMS for PFC drainage.

Conclusions

This study demonstrates that LAMS are safe and highly effective for both immediate and long-term management of PFC. Late removal of LAMS was not associated with an increase in AEs, as compared with early removal, and it was linked to better clinical outcomes, with less need for reintervention. We believe that, in selected cases, leaving the LAMS in longer than 4 weeks is acceptable, as it may increase the chance of clinically successful drainage, without increasing the risk of AEs.

Conflict of Interest

Anand Sahai is a consultant for Boston Scientific. Philippe Willems, Sarto Paquin and Eslam Ismail have no conflict of interest to report.

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