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EUS-guided drainage of pancreatic fluid collections using lumen apposing metal stents: An international, multicenter experience

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ABSTRACT

Introduction: Lumen apposing metal stents (LAMS) have been used increasingly for drainage of pancreatic fluid collections (PFC). We present an international, multicenter study evaluating the safety and efficacy of LAMS in PFCs.

Methods: Consecutive patients undergoing LAMS placement for PFC at 12 international centers were included (ClinicalTrials.gov NCT01522573). Demographics, clinical history, and procedural details were recorded. Technical success was defined as successful LAMS deployment. Clinical success was defined as PFC resolution at three-month follow-up.

Results: 192 patients were included (140 males (72.9%), mean-age 53.8 years), with mean follow-up of 4.2 months ± 3.8. Mean PFC size was 11.9 cm (range 2–25). The median number of endoscopic interventions was 2 (range 1–14). Etiologies for PFC were gallstone (n = 82, 42.7%), alcohol (n = 50, 26%), idiopathic (n = 26, 13.5%), and other (n = 34, 17.7%). Technical success was achieved in 189 patients (98.4%). Clinical success was observed in 125 of 135 patients (92.6%).

Adverse events included bleeding (n = 11, 5.7), infection (n = 2, 1%), and perforation (n = 2, 1%). Three or more endoscopy sessions were a positive predictor for PFC resolution and the only significant predictor for AEs.

Conclusion: LAMS has a high technical and clinical success rate with a low rate of AEs. PFC drainage via LAMS provides a minimally invasive, safe, and efficacious procedure for PFC resolution.

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1. Introduction

Pancreatic fluid collections (PFCs) occur frequently as a complication of pancreatitis.

The updated Atlanta classification of acute pancreatitis classifies PFCs as acute (usually <4 weeks after pancreatitis) or chronic (usually >4 weeks after pancreatitis) [1]. PFCs that are acute are defined as an acute peripancreatic fluid collections (APFC) which occurs in interstitial edematous pancreatitis and acute necrotic collections (ANCs). Chronic PFCs are subdivided into pancreatic pseudocyst, which occurs as a complication of interstitial edematous pancreatitis, and walled-off necrosis (WON), which is surrounded by a radiologically identifiable capsule [2].

PFCs can be managed with drainage performed endoscopically, percutaneously, or surgically [3]. EUS-guided drainage of PFCs has now become first-line therapy [4,5]. Studies have shown high success rate (87%–97%) with low mortality (0%–1%) and adverse event (6%–34%) rates with EUS-guided drainage [6–8]. Surgery is more invasive and is associated with high rates of morbidity and mortality [5,9,10]. Percutaneous drainage is noted to have higher risks of infection or formation of pancreaticocutaneous fistula [8,11].

Indications for drainage include symptomatic PFC, obstruction or infection [2,3]. Size alone does not necessitate drainage, unless symptoms are present [12].

Minimally invasive approaches to drainage of PFCs have become the preferred method [13]. In comparison to traditional plastic stents, fully covered self-expanding metal stents (FCSEMS) offer more advantages. They offer a larger lumen, and permit a shorter procedure times because of the need for a single access point to the PFC [14,15].

The aim of this international, multicenter study was to evaluate the safety and efficacy of using lumen apposing metal stents (LAMS) in the drainage of PFCs. The secondary aim was to identify predictors of PFC resolution and adverse events (AEs).

2. Methods

All patients who underwent LAMS placement for PFC at 12 academic centers internationally between January 2014 and November 2015 were captured in a dedicated registry. PFCs were defined by the revised Atlanta classification, as a complication of acute pancreatitis and included acute fluid collections, pancreatic necrosis, pancreatic abscesses, and acute pseudocysts [2,6].

All patients were consented to be compiled into a central registry at each institution. Any patients previously reported in other publications were excluded from this particular study. The indications for drainage were persistent intractable abdominal pain, biliary or gastric obstruction, or infection. Patient demographics and etiology of acute pancreatitis were recorded. Procedure details such as the size and location of the PFC, the diameter of the stent used, and the number and type of endoscopic interventions along with post-procedural follow-up was recorded. Procedural details, including the size and location of the PFC, the diameter of the stent used, and the number and type of endoscopic interventions (e.g. direct endoscopic necrosectomy (DEN), hydrogen-peroxide assisted necrosectomy, nasocystic drainage) were recorded. Procedural and post-procedural adverse events (AEs) were also captured. Technical success (TS) was defined as successful deployment of the LAMS. Clinical success (CS) was defined as complete PFC resolution with LAMS removal at a three-month follow-up period confirmed by repeat cross sectional imaging. Recurrence was defined, as re-accumulation of a fluid collection, after successful resolution of WON seen on follow-up imaging. Adverse events, including infection, stent occlusion, stent migration, and bleeding were noted. Adverse events were graded according to the American Society for Gastrointestinal Endoscopy lexicon severity grading system [16,17].

2.1. Endoscopic technique

All endoscopic ultrasound guided PFC drainage procedures were performed by advanced endoscopists with extensive experience in PFC management (defined as having managed 50 or more PFCs). Cross sectional imaging was performed prior to any intervention. Broad spectrum antibiotics were administered in all patients prior to the procedure. All endoscopic procedures were performed under general anesthesia. The PFC was identified using a linear echoendoscope. Doppler flow was used to confirm absence of blood vessels in needle trajectory. The PFC was accessed via the Seldinger technique using a fine needle aspiration (FNA) needle followed by insertion of a guidewire. The created tract was then dilated with a balloon or bougie dilator to facilitate passage of the stent delivery system over the wire. In cases where the PFC wall was thick, a needle knife catheter or cystenterotome (Cook Endoscopy, Winston-Salem, NC) was used to dissect the tract. The LAMS delivery system was then advanced into the PFC and the stent was deployed under endosonographic, endoscopic, and fluoroscopic visualization. At endoscopist preference, an electrocautery enhanced delivery system for LAMS (Hot Axios; Boston Scientific, Boston MA) was also used. The device is a through-the-scope FCSEMS delivery system and includes an electrocautery wire at the distal tip, and a stent consisting of braided nitinol fully covered with silicone with wide flanges. The stent is sent through a catheter which is Luer-locked to the inlet channel port of the echoendoscope. The electrocautery tip has the benefit of allowing passage of the catheter into the PFC without requiring prior dilation of the tract [18]. The stent is then deployed under endosonographic, endoscopic, and fluoroscopic visualization.

Necrosectomy were performed using several instruments such as snares, art tooth forceps, Roth nets and biliary basket. The timing and frequency of necrosectomy were based on symptoms, repeat imaging and operator experience until clearance (Figs. 2 and 3).

Endoscopic retrograde cholangiopancreatography with pancreatic duct stent placement was performed if there was a suspicion for disrupted pancreatic duct or pancreatic duct stricture suggested by cross-sectional imaging.

2.2. Study outcomes

The primary study outcomes were the technical and clinical success rate of LAMS for the drainage of PFCs, defined as successful deployment of LAMS, and complete resolution of PFC at three-month follow-up, respectively. The secondary outcomes included the rate of PFC recurrence, predictors of PFC resolution and the rate of adverse events.

2.3. Statistical analysis

Univariate analysis was performed by using $\chi 2$ test or Fisher exact test for categorical variables and t test for continuous variables. Odds ratios (OR) were calculated with the logistic regression. Multiple logistic regression analysis was performed to study factors associated with PFC resolution and factors associated with adverse events. Statistical significance was determined a priori at $p \leq 0.05$. All statistical analyses were performed by using STATA 13.0 (StataCorp, College Station, TX).

3. Results

A total of 192 patients (140 males (72.9%), mean age 53.8 years) underwent EUS-guided transmural drainage of PFCs using LAMS.

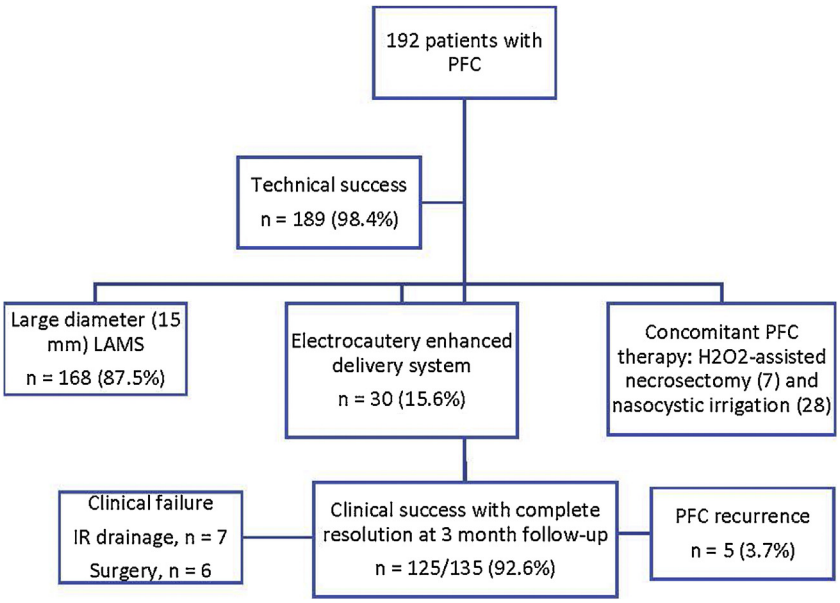

Fig. 1. Patient treatment flowchart.

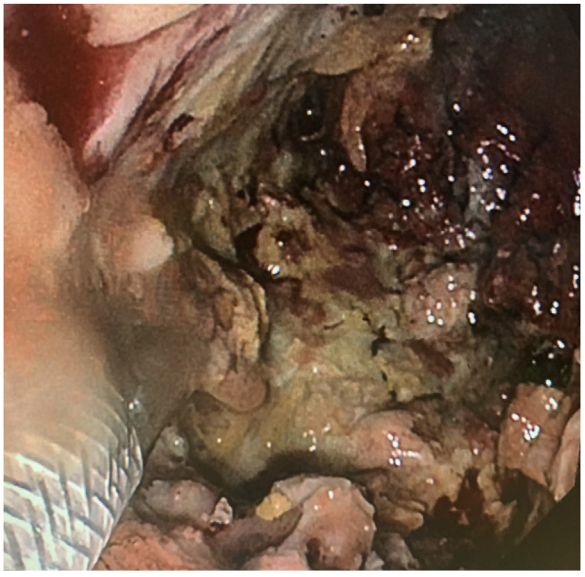

Fig. 2. Direct endoscopic necrosectomy with a rat tooth forceps.

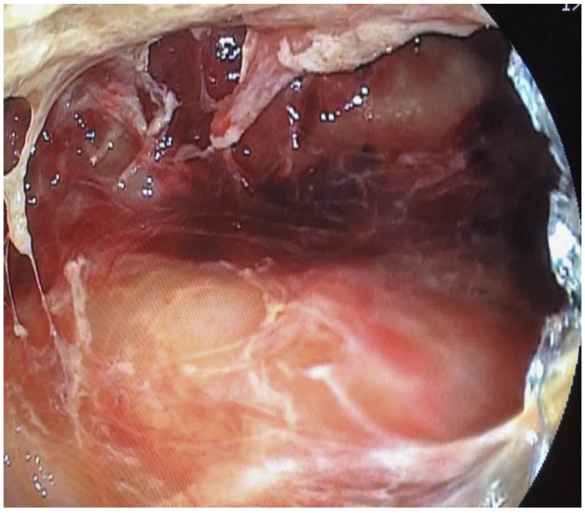

Fig. 3. Complete clearance of the necrotic cavity after 3 sessions.

Mean PFC size was 11.9 cm (range 2–25). There was 41 pseudocyst and 151 WON. Prior failed endoscopic (18) or percutaneous (13) intervention for therapy of PFC had been performed in 31 (16.1%) patients at outside institutions. The median number of endoscopic interventions was 2 (range 1–14). Underlying etiologies for PFCs included gallstone (n = 82, 42.7%), alcohol (n = 50, 26%), idiopathic (n = 26, 13.5%), and other (n = 34, 17.7%). The mean PFC size was 11.9 cm (range, 2–25 cm). Baseline demographics and PFC characteristics are listed in Table 1.

Large diameter (15 mm) LAMS were used in 168 cases (87.5%). An electrocautery enhanced delivery system for LAMS (Hot Axios) was used in 30 cases (15.6%).

Six patients had double drainage due to the size of the collection, four concomitantly and two at a later time. Concomitant PFC therapy with LAMS included H_2O_2-assisted necrosectomy (7) and nasocystic irrigation (28). Mean follow-up was 4.2 months ± 3.8.

3.1. Technical and clinical success

Technical success was achieved in 189 patients (98.4%). Clinical success with complete PFC resolution and LAMS removal was observed in 125 of 135 patients (92.6%). PFC recurrence occurred in 5 cases (3.7%). Fourteen (7.3%) patients with large infected collection extending into the pelvis underwent subsequent drainage by interventional radiology, and six (3.1%) patients went on to surgery for debridement, using video assisted retroperitoneal debridement. Patient treatment flowchart seen in Fig. 1.

3.2. Procedure related adverse events

Procedure related adverse events included bleeding (n = 11, 5.7%) of which eight were managed endoscopically (balloon tamponade of puncture site or clips placement) and three required interventional radiology for embolization of splenic artery (2) and hepatic artery pseudoaneurysm (1). Other adverse events were infection (n = 2, 1%), and perforation (n = 2, 1%), managed endoscopically. There were no deaths related to the procedure.

Table 1
Basic demographics and PFC characteristics of 192 patients (PFC = pancreatic fluid collections).

Characteristic	
Age, mean ± SD, years	53.8 ± 15.7 years
Male sex, n (%)	140 (72.9&)
Etiology of pancreatitis, n (%)	
Gallstone	82 (42.7%)
Alcohol	50 (26%)
Other	34 (17.7%)
Idiopathic	26 (13.5%)
Mean PFC size, in cm	11.9 (range 2–25)
Prior failed PFC therapy, n (%)	31 (16.1%)

Table 2
Predictors of PFC resolution.

Predictors of PFC resolution		
	OR	p-Value
Adverse events	3.01 (0.47–19.1)	0.24
Number of sessions	0.77 (0.63–0.97)	0.03
Age	0.99 (0.96–1.02)	0.71
Sex	1.68 (0.64–4.41)	0.28
PFC length	1.00 (0.99–1.01)	0.64
Axios diameter	0.53 (0.16–1.78)	0.31

3.3. Predictors for PFC resolution and adverse events

Increasing number of endoscopic sessions was a positive predictor for PFC resolution, after adjusting for PFC size, age, sex, and stent diameter (OR 0.77 (0.63–0.97), p = 0.03). Increasing number of endoscopic sessions was also the only significant factor for adverse events, after adjusting for PFC size, age, sex and PFC resolution (OR 1.4 (1.1–1.8), p = 0.002).

3.4. Clinical success predictors

After conducting multivariate stepwise logistic regression analysis on nominal variables (age — 55 or below an above 55; gender, PFC size less than 100 and greater than 100 mm; location of PFC — in the body/tail or head; debris present or not; type of PFC — WON or PP; necrosectomy performed or not; LAMS stent diameter size 10 mm or 15 mm; non cautery enhanced LAMS or cautery enhanced use; number of endoscopic sessions — more than 3 or less) only total number of endoscopic sessions was a statistically significant predictor (more than 3 endoscopic sessions) and increased the odds of clinical resolution by more than 50% (or 2.5 times more likely to result in resolution failure) [p value 0.05, OR 2.5, 95% CI (1–5.2)] (Table 2). Although LAMS size was not a statistically significant predictor, it was the next closest value to statistical significance as a predictor for resolution (p value of 0.17) with a trend favoring large LAMS (15 mm) more likely to increase the resolution odds [OR 2.2, 95% CI (0.7–6.6)].

3.5. Adverse events predictors

After conducting Multivariate stepwise logistic regression nominal variables (age — 55 or below an above 55; gender, cyst size less than 100 and greater than 100 mm; location of cyst — in the body/tail or head; debris present or not; type of PFC — WON or PP; Necrosectomy performed or not; Axios stent diameter size 10 mm or 15 mm; Cold Axios or Hot Axios use; number of endoscopic sessions — more than 3 or less) for adverse events predictors, only total number of endoscopic sessions was a statistically significant predictor. Endoscopic sessions of more than 3 increased the odds of adverse events (5 times more likely to result in adverse events) [p value 0.005, OR 4.8, 95% CI (1.6–14.5)] (Table 3). Although Cyst location odds [OR 3.5, 95% CI (0.1–1.07)], and presence of debris [OR 6.5, 95% CI (0.8–54.6)] were not statistically significant predictors (p value of less than 0.2) and were possibly potential predictors for adverse events. The presence of debris increased the odds of adverse events, while a cyst location in pancreas head reduced the odds of adverse events.

Table 3
Predictors of adverse events.

Predictors of adverse events		
	OR	p-Value
PFC resolution	2.5 (0.41–15.4)	0.231
Number of sessions	1.4 (1.14–1.81)	0.002
Age	1.0 (0.96–1.04)	0.80
Sex	2.1 (0.42–10.2)	0.36
PFC length	0.9 (0.98–1.01)	0.71

4. Discussion

Endoscopic drainage is now widely accepted as the first line therapy for PFC drainage. Varadarajulu et al. conducted a randomized control study showing that endoscopic treatment was associated with lower cost, shorter hospital stays and better physical and mental health of patients [19].

Traditionally, multiple plastic stents are used to drain PFCs [6,20–22]. Unfortunately, there are many limitations to plastic stents such as a smaller diameter, migration rates and the need for repeat access through the enterostomy created for stent placements. A pilot study by Shah et al. of 33 patients with symptomatic pseudocysts and WON showed TS rate of 91%, PFC resolution of 93%, and adverse event rate (abdominal pain, stent migration, access-site infection, stent dislodgement) of 15% [9]. A study by Rinninella et al. used LAMS with a cautery enhanced delivery system to drain PFCs in a large cohort of patients from 13 European tertiary care centers [18]. This study had a TS rate of 98.9%, PFC resolution rate of 92.5% and adverse event rate of 5.4%, including perforation, bleeding, pneumoperitoneum, stent dislodgement during direct endoscopic necrosectomy (DEN), and post-drainage infection. Similar results were seen in the Walter et al study which demonstrated a TS rate of 98%, and CS rate of 93% in patients with pancreatic pseudocyst and in 81% of patients with WON [23]. An adverse event rate (perforation and infection) of 9% was reported in this study.

Siddiqui et al. conducted a retrospective, multicenter study on 82 patients with symptomatic PFC (12 pseudocyst, 68 WON) which showed a TS rate of 97.5%, CS rate of 90%, and an adverse event rate of 9.8% [5]. There was 1 WON recurrence in this study. A large retrospective study by Sharaiha et al. with 124 patients with WON across 17 centers showed a TS rate of 100% and CS rate of 86.3% [24]. In this study, 13 patients required a percutaneous drain, and 3 required surgery. The overall LAMS stent migration rate was 5.6%, which demonstrated a lower rate in comparison to other stents for WON using DEN.

In our study, we found a technical success rate of 98.4% and PFC resolution rate of 92.6%. PFC recurrence occurred in 3.7% of cases. Increased number of sessions (>3) was a positive predictor for PFC resolution and increased the odds of clinical resolution by more than 2.5 times (OR 2.5, 95% CI (1–5.2). This emphasizes the need for debridement in the setting of walled off pancreatic necrosis. Increased number of sessions (>3) was also the only significant factor for adverse events, with patients' odds of experiencing adverse events was 5 times more likely (OR 4.895% CI (1.6–14.5), p = 0.005). We hypothesize that increasing the number of endoscopic interventions will increase the chance for bleeding, infection, or perforation during the procedure. Nevertheless, the adverse events reported are within the range of previously reported

studies [18,23,24]. This is probably related to the strict selection of endoscopists with large experience in PFC drainage.

A final point to discuss is the training in therapeutic endosonography which is a crucial step prior to offering those drainage procedures. In our institution and many other tertiary centers, the training is focused on learning diagnostic EUS and ERCP before learning EUS guided drainage of pancreatic fluid collections [25].

In conclusion, our study showed that LAMS placement for PFCs has both high technical and clinical success rates with a low rate of adverse events. In the majority of cases, PFC drainage via LAMS provides a minimally invasive, safe, and efficacious endoscopic method to achieve PFC resolution. Increased number of endoscopic sessions was a significant positive predictor for PFC resolution as well as adverse events.

Disclosures

- Nikhil A. Kumta, MD, MS is a consultant for Apollo Endosurgery, Boston Scientific, and Olympus.
- Michel Kahaleh MD: has received grant support from Boston Scientific, Fujinon, EMcison, Xlumena Inc., W.L. Gore, MaunaKea, Apollo Endosurgery, Cook Endoscopy, ASPIRE Bariatrics, GI Dynamics, NinePoint Medical, Merit Medical, Olympus and MI Tech. He is a consultant for Boston Scientific, Xlumena Inc., Concordia Laboratories Inc., ABBvie, and MaunaKea Tech.
- Prashant Kedia MD is a consultant for Boston Scientific, Endogastric solutions and Apollo Endosurgery.
- Ali Siddiqui MD is a consultant for Boston Scientific, Cook Endoscopy and Medtronic. He has received research grant support from Boston Scientific and Medtronic. He is a speaker for ABBVIE.
- Paul Tarnasky MD is a consultant for Boston Scientific.
- Amy Tyberg is a consultant Endogastric Solutions.

Conflict of interest

None declared.

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