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Performance Characteristics of a Lumen-Apposing Metal Stent for Pancreatic Fluid Collections: A Prospective Cohort Study

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Abstract

Background: Endoscopic ultrasound-guided transmural drainage is the preferred management of pancreatic fluid collections (PFCs). Optimizing drainage is important and there remains debate as to the choice of stent. A recent trend towards the use of lumen-apposing metal stents (LAMS) has emerged.

Aim: To evaluate the performance characteristics of a LAMS based on a prospective protocol (CT scan 1 week after placement to assess for resolution and need for necrosectomy followed by stent removal within 3 weeks).

Methods: This is a descriptive prospective cohort study performed at a single centre. The primary outcome was clinical success. Secondary outcomes were technical success, procedure time, total number of endoscopic procedures with or without necrosectomy, stent indwell time, stent functionality and adverse events.

Results: Thirty-seven patients (21 males, mean age 46.5 years) underwent placement of LAMS for 41 PFCs (median size 12 cm). There were 18 pseudocysts and 23 walled-off necrosis. Clinical success was seen in 33 of 41 (80%) PFCs. Of the remaining eight patients, six underwent surgery and two patients died from underlying malignant disease (although their PFC had completely resolved). Technical success and stent functionality were 100%. The median procedure time was 14 min (interquartile range 11 min to 20 min). Of the 23 walled-off necrosis, 9 (39%) required necrosectomy. The median stent indwell time was 19 days (interquartile range 14 to 22 days). There were no serious adverse events.

Conclusions: Our protocol demonstrates excellent performance characteristics of LAMS. Their clinical efficacy and favourable safety profile suggest that they may be the preferred modality for endoscopic ultrasound-guided management of PFCs.

Keywords: *Cyst drainage; Endoscopic ultrasound; Pancreatic pseudocyst; Walled-off necrosis*

INTRODUCTION

There is consensus among most experts now that endoscopic ultrasound-guided transmural drainage (EUS-TD) is the preferred intervention for the initial drainage of pancreatic fluid collections (PFCs) (1–3). The choice of stent has been an important determinant of success as it optimizes drainage adequacy and enables direct endoscopic necrosectomy (DEN) (4, 5). There has been an evolution in the choice of stent, starting with double-pigtail plastic stents (DPPS), followed by fully covered self-expanding metal stents (FCSEMS) with or without an anchoring DPPS within, and most recently to the use of lumen-apposing metal stents (LAMS) for EUS-TD (6–8). However, even though the LAMS appear more effective, they are significantly more expensive upfront and there is conflicting data regarding their cost benefit. Cost modelling studies suggest they are more expensive than plastic stents (9, 10), but data

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from two retrospective studies suggest that there is no significant difference in overall cost for successful treatment of a PFC when comparing the more expensive LAMS with the less expensive DPPS or FCSEMS (6, 7). In addition, LAMS demonstrate other advantages such as technical convenience leading to a shorter procedure time and improving safer access for DEN (11). However, there has been a report that raises concern with their time of indwell, specifically relating to stent burial and stent-induced bleeding (12).

Prior studies have largely been based on retrospective data, without the use of consistent pre-defined protocols. The aim of our study was to create a protocol that prospectively examines the performance characteristics of a LAMS when used in the EUS-TD of PFCs.

METHODS

This is a descriptive prospective cohort study of EUS-TD for the management of PFCs performed by two endosonographers (P.D.S. and G.S.) at the University of Alberta Hospital (UAH), Edmonton, Alberta. All consecutive patients referred for a PFC between October 2017 and September 2019 were included as long as they had an appropriate indication for drainage. Indications for EUS-TD included abdominal pain, limitation of oral intake, symptoms of gastric or biliary obstruction, anorexia/weight loss, enlarging PFC or suspicion of infection in the PFC. Cross-sectional imaging of the abdomen (CT or MRI) was reviewed to assess for feasibility of endoscopic drainage. Patients with coagulopathy (International Normalized Ratio > 1.5), thrombocytopenia (platelets < 50,000 mm^3) or active anticoagulation/antiplatelet medication had appropriate measures taken to ensure safe intervention. Patient demographic data including age, sex, cause of pancreatitis and size of PFC were collected.

Procedural Details

LAMS Technique

The stent used for this study was the Hot AXIOS LAMS (Boston Scientific Corporation, Marlborough, MA, USA). This is commercially available as an electrocautery-enhanced delivery system, which enables the creation of a cyst-enterostomy (cyst-gastrostomy or cyst-duodenostomy depending on the site of puncture) and placement of the stent in quick succession using a single device. As there is no need for guide-wire placement and management, the entire procedure can be performed under endosonographic visualization in a regular endoscopy suite without the need for fluoroscopy. The details of the steps involved in LAMS placement have been well documented in literature.

We do not dilate the LAMS with a balloon dilator and instead allow the stent to expand on its own account over the ensuing 2 to 4 days. We also do not perform necrosectomy at the same session as the initial deployment and would let the clinical/radiographic progress of the patient determine that need (see below).

UAH LAMS Protocol for Management of PFCs

Our protocol for LAMS in the management of PFCs is to perform a CT scan 1 week after the initial stent placement (Figure 1). This is to document radiographic evidence of resolution or to assess the remaining size of the decompressed cyst and quantify the amount of necrotic material within. If there is symptomatic and radiographic resolution, the stent is removed within the following 2 weeks. However, DEN is undertaken if there are symptoms of a systemic inflammatory response (e.g., fever, leukocytosis and/or increased C-reactive protein) or if radiographic criteria suggest presence of necrotic material. In our protocol, we set a stent indwell time of no more than 3 weeks to minimize the risk of stent burial and stent-induced bleeding as suggested by Bang et al. (12). Multiple sessions of DEN, if necessary, are done within this 3-week period after which the stent is removed with gentle traction by capturing the luminal flange using rat-tooth forceps.

Patients with suspected pancreatic duct (PD) disruption and leak on cross-sectional imaging underwent concomitant endoscopic retrograde cholangio-pancreaticography (ERCP) with placement of a plastic PD stent.

Outcome Measures

Primary Outcome

Clinical success: defined as sustained resolution of the PFC at 3 months after stent removal. After successful drainage and removal of the LAMS, a fluid collection occurring as a result of disconnected duct syndrome within this 3-month period was not considered a failure of the LAMS.

Secondary Outcomes

(a) Technical success: defined as successful stent placement.
(b) Procedure time: calculated as the time from esophageal intubation with echoendoscope to time of procedure completion and removal of the echoendoscope ('scope in–scope out' time).
(c) Number of additional interventions (including endoscopy, with or without necrosectomy, and surgery): any and all intervention(s) between day of initial stent placement up to 3 months after stent removal.
(d) Stent indwell time: calculated as number of days from initial stent placement until removal.
(e) Stent functionality: defined as the absence of stent-related re-intervention during period of stent indwell.
(f) Adverse events (AEs): defined as those occurring within 30 days after the initial stent insertion and include stent burial, stent migration, stent-related bleeding, perforation, and procedure-related and all-cause 30-day mortality.

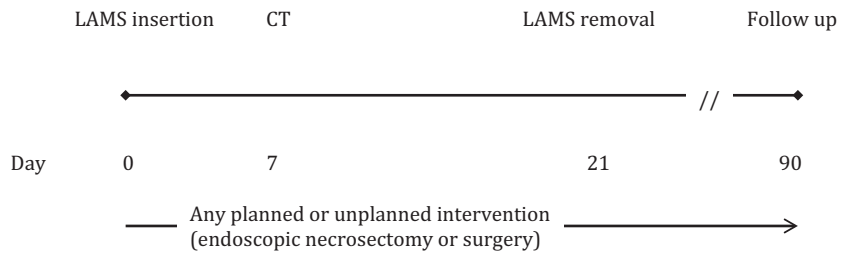

Figure 1. Institutional protocol for management of pancreatic fluid collections.

Ethics

The institutional ethics review board of the University of Alberta Hospital approved the study (protocol ID 00060719).

Statistical Analysis

Data were entered into a REDCap database and descriptive statistics were analyzed using SPSS (IBM version 23.0).

RESULTS

Patient Characteristics

Between October 2017 and September 2019, 42 patients were referred for endoscopic drainage of PFCs (Table 1). Five patients did not undergo EUS-TD due to concerns of necrotic debris occupying >80% of the PFC volume. The other 37 patients underwent a total of 41 EUS-TD procedures for symptomatic PFCs (2 patients had EUS-TD performed twice for separate PFCs and 1 patient had 3 separate PFCs drained). There were 21 males (57%) and the mean age was 46.5 ± 17.6 years (range 9 to 85 years). The etiology of the PFC was acute pancreatitis secondary to gallstones in 12 of 37 (32%), alcohol in 10 of 37 (27%), idiopathic in 7 of 37 (19%) and other causes in 8 of 37 (22%) patients. The 'other' category includes pancreatitis secondary to ERCP in two, pancreatic cancer in two and hypertriglyceridemia in one, as well as PFC development as a result of leakage secondary to distal pancreatectomy in two and trauma in one patient.

PFC Characteristics

Of the 41 PFCs that underwent drainage, 18 were pancreatic pseudocysts (PPs, 44%) and 23 were walled-off necrosis (WON, 56%) (Table 1). Measuring the longest dimension on cross-sectional imaging, the mean PFC size was 12 cm ± 4.6 cm (range 5 cm to 21.6 cm). The baseline characteristics of patients and PFCs are summarized in Table 1.

Procedure Characteristics

Of the 41 PFCs, EUS-TD was performed under general anesthesia in 37 (90%), whereas in the other 4 (10%), conscious sedation was used. PFCs were accessed via a trans-gastric approach in 39 of 41 (95%) compared with a trans-duodenal approach in 2 of 41 (5%). A 10-mm × 10-mm LAMS was placed in the first 2 patients, but DEN with a diagnostic gastroscope was much easier through a 10-mm × 15-mm LAMS and, therefore, the latter size LAMS was used in all

Table 1. Baseline patient demographics and characteristics of PFCs

Patients referred, *n*	42
Patients who got LAMS	37
Patients who did not get LAMS (>80% necrosis)	5
Males, *n*	21
Age in years, mean ± SD (range)	46.5 ± 17.6 (9–85)
PFCs in 36 patients, *n*	41
PP	18
WON	23
Size of PFC in cm, mean ± SD (range)	12 ± 4.6 (5–21.6)
Type of sedation used, *n*	
Conscious sedation	4
General anesthesia	37
EUS-TD approach, *n*	
Trans-duodenal	2
Trans-gastric	39
LAMS size, *n*	
10 × 10 mm	2
10×15 mm	38
6 × 8 mm	1
Time from LAMS to CT in days, median (IQR)	8 (7–9)
Endoscopic necrosectomy for WON, *n* (%)	9/23 (39)
3 sessions	2
2 sessions	1
1 session	6

CT, Computerized tomography; EUS-TD, Endoscopic ultrasound-guided transmural drainage; IQR, Interquartile range; LAMS, Lumen-apposing metal stents; PFCs, Pancreatic fluid collections; PP, Pancreatic pseudocyst; SD, standard deviation; WON, Walled-off necrosis.

subsequent procedures (38 of 41 PFCs, 93%). One patient with a PP had the inadvertent placement of a 6-mm × 8-mm LAMS, but this was recognized only when the stent was removed.

Follow-up CT scanning as per protocol was done at a median of 8 days (interquartile range [IQR] 7 to 9 days).

Three patients (8%) had concomitant ERCP and insertion of a trans-papillary plastic pancreatic stent for a documented PD leak.

Outcome Measures

Primary Outcome

Clinical success was seen in 33 of 41 (80%) PFCs. Of the remaining eight patients, six underwent surgery (one had unrelenting abdominal sepsis, two had extensive necrosis extending into both para-colic gutters, one had the gastroduodenal artery traversing the PFC contraindicating DEN, one had a large hiatal hernia with intra-thoracic stomach and one had a small remnant of PFC in the mesentery that was drained during an elective cholecystectomy) (Table 2). Two patients died from sequelae of underlying pancreatic adenocarcinoma, and not related to the EUS-TD as their PFC had completely resolved prior to their death.

Two patients developed a recurrent fluid collection within 3 months from disconnected duct syndrome. Both required EUS-TD with the placement of two seven French DPPS for long-term indwell. This was not considered to be an AE or failure of the LAMS but instead a part of the natural history of the underlying necrotizing pancreatitis and was treated appropriately.

Table 2. Outcome measures of LAMS in PFCs

Primary outcome	
Clinical success, *n* (%)	33/41 (80)
Secondary outcomes	
Technical success, *n* (%)	41/41 (100)
Procedure time in minutes, median (IQR)	14 (11–20)
Endoscopic necrosectomy for WON, *n* (%)	9/23 (39)
Stent indwell time in days, median (IQR)	19 (14–22)
Stent functionality, *n* (%)	41/41 (100)
Adverse events	
Buried stent	1
Stent migration	0
Bleeding	0
Perforation	0
Procedure-related 30-day mortality	0
All-cause 30-day mortality[a]	2

IQR, Interquartile range; WON, Walled-off necrosis.

[a]Both patients died from underlying advanced pancreatic cancer.

Secondary Outcomes

(a) *Technical success*: The LAMS were successfully placed in all 41 of 41 (100%) PFCs without any technical difficulty.

(b) The median *procedure time* was 14 min (IQR 11 min to 20 min).

(c) *Number of additional interventions (including endoscopy, with or without necrosectomy) and surgery.* A total of 9 of 23 (39%) patients with WON required repeat endoscopy during stent indwell. Of these, all nine patients underwent necrosectomy with two patients requiring three sessions, one patient requiring two sessions and another six patients requiring just one session. Of these, only one patient required urgent endoscopy prior to the 1-week CT scan. She presented 2 days after stent insertion with a systemic inflammatory response (fever, leukocytosis) and underwent EGD but the LAMS had not fully expanded to allow DEN. She was managed conservatively with antibiotics and underwent her CT at day 7, followed by DEN at day 9 and another DEN with stent removal at day 23. For surgical interventions, please see above in *Clinical success*.

(d) The median *stent indwell time* was 19 days (IQR 14 to 22 days).

(e) *Stent functionality*: The LAMS remained functional during its period of indwell in all 41 of 41 (100%) PFCs. No intervention was necessary to manipulate the stent once deployed.

(f) *Adverse events*: The patient that had inadvertent placement of a 6-mm × 8-mm LAMS for PP was found to have stent burial at 14 days during the removal procedure. Under fluoroscopic guidance, the stent was retrieved successfully with rat-tooth forceps with no complication. There were no occurrences of stent migration, stent-related bleeding, or perforation in the remaining cohort. There were two deaths within 30 days not related to the procedure (discussed above).

DISCUSSION

Much has been published recently on the management of PFCs. Data now suggest the utility of EUS-TD with a step-up approach to DEN, if necessary, as the preferred initial intervention (1–5). However, there is debate not only over the type of stent (DPPS versus FCSEMS versus LAMS), but also the type of PFC (PP versus WON) in which the stent will be placed. Data suggest that DPPS may be preferred in PPs, whereas larger calibre metal stents, including LAMS, be reserved for WON or patients that are sicker and require a quick intervention (13). With the latter clinical scenarios, LAMS have significant advantages because of a single electrocautery-enhanced delivery device, which allows for a quick and safe deployment, a wider diameter for improved

drainage and access for necrosectomy, as well as decreased migration due to their characteristic bi-flanged design (7, 11). Despite the recent trend towards the growing use of LAMS, their high upfront cost appears prohibitive, although there are conflicting data on the overall cost associated with their use. Using a cost model analysis, Chen et al. suggested that LAMS are costlier compared with DPPS when used in the management of both PP and WON (9, 10). However, our group has recently published a retrospective comparison between DPPS, FCSEMS and LAMS in PFC management (7). We found that despite the higher initial cost of a LAMS, the overall cost associated with clinical success was less when compared with DPPS or FCSEMS. Bekkali et al. also did not find any significant cost differences between FCSEMS (€4,427) and LAMS (€3,500) for WON (14). The reasons for these conflicting results are unclear. However, these studies have been done in different jurisdictions and there may be significant differences in parameters used for the costing data, e.g., comparing cost model analysis versus the actual real-life costs associated with these interventions. Variations in the protocol, as well as in the rates of complications may have contributed to these differences as well.

Another issue with LAMS, in addition to the cost, was the initial concern regarding significant AEs. Bang et al., during their initial experience, reported a significant occurrence of stent-related bleeding and stent burial when LAMS were left in situ for up to 6 weeks, an indwell time typically used previously for FCSEMS (12). The authors speculate that the inherent lumen-apposing nature of the stent design may be responsible for burial and suggest that the indwell time be reduced to 3 weeks to prevent this AE.

This recommendation became the basis for the protocol we instituted at our centre with the introduction of LAMS for PFC management. A CT scan is performed 1 week after stent placement followed by removal of the LAMS within 3 weeks. Based on clinical and radiographic criteria, DEN is performed within this 3-week period, regardless of how many interventions are needed. As the fluid component of the PFC drains, mechanical occlusion of the LAMS with necrotic debris can occur and therefore early debridement may be necessary (15). Balloon dilation of the freshly placed LAMS to facilitate DEN during the index procedure is not our practice but has been described (16). The utility of this intervention is unclear. We prefer to allow spontaneous expansion over 48 h to 72 h prior to intervening with DEN. We found that the 10- × 15-mm LAMS used in our study allowed for spontaneous clearance of the necrotic material in approximately two-thirds of the patients with WON. Also, it facilitated easy passage of a standard diagnostic gastroscope to perform DEN without concern of stent dislodgement. The particular type of LAMS we used (Hot AXIOS) is also available in a 10 mm × 20 mm size and this may provide even better drainage and access for necrosectomy but there is no published literature yet to support this claim.

Most of the literature regarding the use of LAMS and its comparison with other stents has been done in a retrospective manner. The primary purpose of our current study was to institute a protocol for PFC management with which we were able to prospectively assess the performance characteristics of a LAMS when used for EUS-TD. Although there is literature supporting the use of DPPS for PP and larger calibre metal stents for WON, based on our published experience with the clinical and cost efficacy with the use of LAMS (7), our practice has been to preferentially use this LAMS for all types of PFCs when intervention is indicated. An exception would be a subset of PFC patients with the disconnected duct syndrome, requiring a longer period of stent indwell, who are not candidates for LAMS and are instead treated with the placement of multiple DPPS left in situ indefinitely. However, one cannot predict at the time of the initial EUS-TD whether there will eventually be the disconnected duct syndrome so this development may require a subsequent intervention after the removal of the LAMS.

Bang et al., however, have recently described their randomized controlled trial comparing LAMS with plastic stents for WON (17). The LAMS group had a shorter procedure time (15 min versus 40 min, $P < 0.001$), but the stent-related AEs (32.3% versus 6.9%, $P = 0.01$) and procedural costs (US $12,155 versus $6,609) were higher with LAMS compared with plastic stents. The authors do note that the AEs became fairly similar between the two groups once a decision was made to remove the LAMS after 3 weeks instead of leaving them in for longer.

We also found that the technical aspects of the LAMS, such as placement and procedure time, are significant advantages as they are easy and quick to deploy and do not require multiple accessories, wire exchanges or balloon dilation. Moreover, none of our patients required a fluoroscopy suite to aid in placement. These attributes have also been described by other investigators and partly account for the increase in the safety profile associated with LAMS.

Our clinical success of 80% is slightly below that described in literature. A potential reason for this discrepancy is our stringent definition of clinical success, i.e., an intervention-free follow-up of 3 months from the time of LAMS removal. In our cohort, 8 of 41 PFCs did not meet this criterion and were deemed treatment failures. Of these, however, one patient underwent surgery for 'unrelenting abdominal sepsis' thought to be secondary to the presence of the LAMS (even though CT scanning documented complete resolution of the cyst) and two patients died within 30 days of EUS-TD from underlying advanced pancreatic malignancy. The malignancy-associated PFC in both of these patients had completely resolved with the LAMS. Nonetheless, as these patients did not reach the

3-month follow-up, they were considered 'failures' even though the LAMS had successfully resolved the respective PFCs. In essence, only the remaining three patients were true failures and the clinical success may be considered 91%, more in accordance with published literature. The three patients that were 'true' failures were likely unsuccessful because of inappropriate indications. One patient had the lesser sac PFC extending down both para-colic gutters into the pelvis. However, this patient was in an intensive care setting with a presumed infected WON and was considered high risk for surgery, prompting initial intervention with EUS-TD. Another patient had the gastroduodenal artery traversing the middle of the PFC precluding DEN, and the last patient, despite repeated DEN, had a persistent collection in the mesentery that was not accessible for necrosectomy. All three patients underwent successful surgical intervention, although the first two patients required multiple procedures and a prolonged hospital stay. Appropriate patient selection is, therefore, critical in optimizing the outcomes with managing PFCs. We recommend that EUS-TD is not appropriate in patients with necrosis occupying >50% of PFC volume or PFC extending beyond the reach of DEN (such as into the para-colic gutters, into the mesentery or into the pelvis).

A number of AEs have been reported with the use of LAMS, including stent-related bleeding and stent burial. Prolonged stent indwell appears to be directly related to the occurrence of these AEs as discussed above (12). It is interesting to note that in our study, strict adherence to the protocol was associated with a safety profile lower than what has been published in literature (12, 17), in particular stent-related bleeding. The only AE we encountered was the instance of stent burial seen after the inadvertent placement of a 6-mm × 8-mm LAMS and this was recognized only during the time of removal even though it was well within 3 weeks. However, using both endoscopic and fluoroscopic guidance, the LAMS was removed successfully. We believe that a defined indwell period of no more than 3 weeks and strict adherence to performing all scheduled procedures, including DEN, within this time frame and removal of the stent at 3 weeks is the major reason why we have not seen AEs in our cohort.

There certainly are limitations to our study. This is a single centre study with relatively small numbers. However, we feel that the learning curve with the use of LAMS is fairly steep and expertise can be achieved in a relatively short period of time. We would expect most interventional endosonographers to replicate these results fairly uniformly. Furthermore, only a specific type of LAMS (Hot AXIOS) was used for this study and therefore our findings cannot be generalized to other LAMS at this time.

In conclusion, our study provides evidence that adherence to a defined protocol with cross-sectional imaging and appropriate endoscopic intervention results in favourable outcomes with the use of LAMS in the treatment of PFCs, although there are studies suggesting restricting their use to WON. Randomized controlled trials with larger sample sizes are needed to validate these recommendations and assess the generalizability of these results.

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Conflicts of Interest: G.S. is a Consultant for Boston Scientific Corporation and has received honoraria for speaking and proctoring engagements. However, no funding was received for the purposes of this study. A.D., S.L., S.S., and P.D.S. have no conflict to disclose.

Author Contributions: A.D.: Construction of the database and critical revision of the manuscript. S.L.: Statistical analysis and critical revision of the manuscript. S.S.: Statistical analysis and critical revision of the manuscript. P.D.S.: Acquisition of data and critical revision of the manuscript. G.S.: Study concept and design, acquisition of data, drafting and critical revision of the manuscript, and study supervision.

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