

Multicenter experience from the UK and Ireland of use of lumen-apposing metal stent for transluminal drainage of pancreatic fluid collections ▶



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ABSTRACT

Background and study aims Pancreatic fluid collection (PFC) is a common complication of pancreatitis for which endoscopic ultrasound-guided drainage is first-line treatment. A new single-device, lumen-apposing, covered self-expanding metal stent (LAMS) has been licensed for PFC drainage. We therefore present our multicenter experience with the LAMS for PFC drainage in a multicenter prospective case series to assess success and complication rates.

Patients and methods All adult patients from 11 tertiary centers who had LAMS placement for PFC from July 2015 to July 2016 were included. Data including indications, technical success, clinical success, collection resolution, stent removal, early and late adverse events (AEs), mortality and recurrence at 6 months were collected.

Results 116 patients, median age 52.5 years (range 16–80) and 67% male, were treated with a single LAMS in each case. The indication was walled off necrosis (WON) in 70 and pseudocyst in 46. Median size of the PFC was 11 cm (5–21 cm) and the estimated median necrotic volume in

WON was 30% (5%–90%). Stent insertion was technically successful in 115 (99.1%) and clinically successful in 109 (94%). Early serious AEs (SAEs): n=7 sepsis, n=1 stent blockage with food, n=1 stent migration requiring laparotomy, n=1 stent dislodgement and n=1 bleeding requiring

embolization. Late AEs: n=1 buried stent and n=1 esophageal fistula. Non-procedure-related deaths: n=3 (2.5%).

Conclusion This multicenter case series demonstrates that use of the new LAMS is feasible, effective and relatively safe in draining PFC with a technical success rate of 99% and cumulative SAE rate of 11.2%.

Introduction

The incidence of pancreatic fluid collections (PFC) is 5% to 16% and 20% to 40% in acute and chronic pancreatitis, respectively [1]. Classification of PFC includes acute peri-pancreatic fluid collection (APFC), acute necrotic collection (ANC), pseudocyst and walled-off pancreatic necrosis (WON). APFC and ANC develop within four weeks of the onset of pancreatitis, usually resolve on their own, and may not need intervention unless secondary infection occurs. Pseudocysts and WON usually develop after 4 weeks and may require intervention if they are symptomatic or become infected.

Historically, PFCs were drained either surgically or percutaneously under radiological guidance. EUS-guided drainage was first reported in 1992 and since then several studies have reported success and complication rates of 80–100% and 10–20% respectively [2–5]. A prospective randomized controlled trial comparing surgical vs. EUS-guided drainage reported reduced morbidity and length of stay in the endoscopic group [6, 7]. A randomized controlled trial comparing minimally invasive surgery versus endoscopy for necrotising pancreatitis reported reduced incidence of major complications in the endoscopy group (5.9% Vs 34.4%, risk ratio 0.17; 95% CI, 0.04–0.71, $P=0.004$) [8]. EUS-guided drainage has increasingly been used as first-line treatment in management of PFC.

Double pigtail plastic (DP) stents, fully-covered self-expanding metal stents (FCSEMS) and lumen-apposing covered self-expanding metal stents (LAMS) have been used in the drainage of PFC. DP stents have equal efficacy in drainage of pseudocysts but they are less efficacious with high adverse event (AE) rates for WON [9]. This often necessitates reintervention and a recent retrospective comparative study (DP vs. FCSEMS vs. LACSEMS) reported that double pigtail stents were the sole negative predictive factor in drainage of WON, on multivariate analysis [9].

FCSEMS are effective in drainage of PFC, especially WON as it allows for debridement but risk of stent migration is between 10% and 20%. Three retrospective studies reported success rates of 80% to 94% for drainage of PFC with a serious AE (SAE) rate of 20% [10–12].

Previous small or retrospective studies have shown that a novel LAMS (Hot AXIOS, Boston Scientific, Boston MA USA) has a higher technical success rate (98.9%) than FCSEMS and DP stents with good clinical resolution of collections (92.5%) [13, 14]. Complication rates are between 5% and 9.4% [9, 15, 16]. Here, we report results of a multicenter prospective UK and Ire-

land experience with use of LAMS for transluminal drainage of PFC.

Patients and methods

Retrospective analysis of a prospective, multicenter, observational study of use of LAMS in transluminal drainage of PFC was conducted. All patients who had LAMS placement for PFC from July 2015 to July 2016 were included. Eleven tertiary referral centers for hepatopancreaticobiliary (HPB) medicine participated (St James's University Hospital Leeds, University College London Hospitals, Guy's and St. Thomas' Hospital London, King's College Hospital London, Glasgow Royal Infirmary, Royal Infirmary of Edinburgh, Freeman Hospital Newcastle, Addenbrooke's Hospital Cambridge, Manchester Royal Infirmary, Nottingham University Hospitals NHS Trust, Nottingham, The Adelaide and Meath Hospital, Dublin) in this study. A computed tomography (CT) scan or magnetic resonance imaging (MRI) was repeated at 4 weeks to assess for resolution of the collection and patients were followed up clinically for at least 6 months to assess for recurrence. Data were collected and stored centrally at Leeds Teaching Hospitals NHS Trust. The study protocol was approved by the local R&D department and information governance department at Leeds Teaching Hospitals NHS Trust. Because this was a prospective case series, it was exempted from ethical approval.

The following definitions were used during data collection. The definitions and explanations are listed in ► **Table 1**.

Electrocautery enhanced LAMS (ECE-LAMS)

The Hot AXIOS device consists of a through-the-scope LAMS delivery system with an electrocautery wire at the tip (► **Fig. 1** and ► **Fig. 2**). The stent is dumbbell-shaped, self-expanding, fully-covered, and made of nitinol. The electrocautery wire allows for passage of the catheter without the need to dilate the tract. This means that the endosonographer can deploy the stent in a controlled manner with no requirement for exchanges or use of a guidewire. For PFC drainage, stents are available in 2 sizes (lumen diameter × length between the flanges): 10 mm × 10 mm and 15 mm × 10 mm. There are also smaller sizes available for choledochoduodenostomy and gallbladder drainage procedures. The 10-mm saddle length and the dumbbell shape of the stent is designed to appose and anchor the gut to the PFC wall.

► **Table 1** Definitions used during data collection.

Definition	Explanation
Technical success	Appropriate stent position in to the PFC on an intention to treat basis.
Clinical success	Clinical improvement (ie. resolution of symptoms for which the procedure was indicated) and resolution of collection.
Stent misplacement	Incorrect placement of the stent in to the cavity after puncture into the PFC
Stent dislodgement	Dislodgement of stent due to manipulation eg, DEN
Direct endoscopic necrosectomy (DEN)	Removal of necrotic tissue and debris from the cyst cavity under direct endoscopic vision.
Stent migration	Migration of stent without manipulation. These were divided into clinically significant or insignificant.

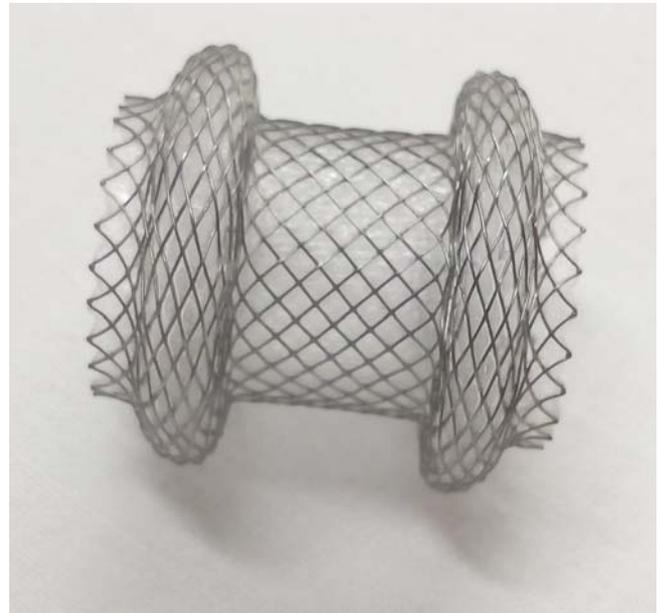
PFC, pancreatic fluid collection; DEN, direct endoscopic necrosectomy

Drainage Protocol

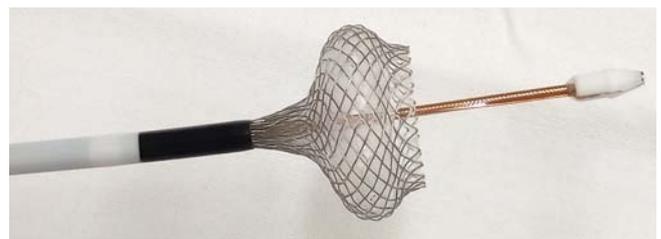
Prior to stent insertion, patients were clinically assessed and underwent cross-sectional imaging (CT or MRI) within 2 weeks of the drainage procedure. All patients had walled of necrosis (WON) or pancreatic pseudocysts (PP) as defined by the revised Atlanta Criteria [1]. Antibiotics were continued in patients with infected necrosis, and a single dose of prophylactic intravenous (IV) antibiotic was given during the procedure to patients without infected necrosis, according to local department protocols. Oral antibiotics were continued in some patients according to the local department protocols, for 3 days after the procedure. All procedures were carried out by experienced endosonographers who had experience in EUS-guided cyst-gastrostomy using standard techniques.

At EUS, the collection was assessed using a therapeutic linear echoendoscope and ultrasound workstation (Olympus UCT-240/260, Olympus EU ME-2, EG-3870UTK/3270UK, Pentax-Hitachi, Aloka). The size and type of the collection and the percentage of necrosis in the case of WON were assessed. The collection was punctured using the electrocautery wire at the tip of the catheter. Once the catheter was inside the fluid collection, the distal flange of the stent was deployed under EUS guidance. Following this, the catheter was slowly pulled back under EUS guidance until the distal flange tightly apposed the wall of the cyst cavity. Then, the proximal flange was deployed on the luminal side, either under endoscopic view or EUS guidance at the discretion of the endosonographer (► **Video 1**).

Two sizes of stent – 10 mm × 10 mm and 15 mm × 10 mm – were used in this study. Stent size was chosen by the endosonographer at the time of the procedure. No lavage and debridement was performed at the index procedure.



► **Fig. 1** Lumen apposing metal stent (LAMS).



► **Fig. 2** Partially deployed LAMS.



► **Video 1** Cyst gastrostomy with LAMS.

Direct endoscopic necrosectomy (DEN) protocol

Necrosectomy was carried out at the discretion of the attending physician if patients developed evidence of either infected necrosis or stent blockage. The LAMS was usually dilated with a radial expanding balloon (eg: Hercules-cook medical or CRE balloon-Boston Scientific) if a 10 mm × 10 mm stent was used. The tract was not dilated if a 15 mm × 10 mm stent was used as the 15-mm diameter allows a gastroscope to be advanced to the collection cavity without dilatation. Necrotic tissue was removed using a basket, Roth Net, ERCP extraction balloon or polypectomy snare. Irrigation was carried out using physiologic saline solution. The procedure was repeated in cases of recurrent sepsis or stent blockage with necrotic material. After DEN, a nasocystic drain was inserted to assist irrigation and drainage of collection at the discretion of the endoscopist.

Outcomes

The primary outcome of this prospective observational study was assessment of technical and clinical success and AEs associated with insertion of the LAMS for PFC. Secondary outcomes were assessment of collection resolution, number of procedures (necrosectomies, stent changes), stent migration, recurrence at 6 months, and 30- and 90-day mortality.

Results

Patient characteristics

One hundred and sixteen patients (78 males, 38 females) from 11 tertiary referral centers from the UK and Ireland were included in the study (► **Table 2**). Median age was 52.5 years (range 16–80 years). All patients had confirmed PFC on cross-sectional imaging and the procedures were carried out between July 2015 and July 2016.

Median time from attack of acute pancreatitis to LAMS insertion was 10.7 weeks (range 4–180 weeks). The etiology of pancreatitis was gallstones (n=54), alcohol (n=42) idiopathic (n=15), post-endoscopic retrograde cholangiopancreatography (ERCP) (n=2), post-pancreatic surgery (n=1), drug-induced (n=1), and hyperlipidemia (n=1). Among the 116 patients, indications for drainage were pain in 48 (41%), sepsis in 49 (42%), gastric outlet obstruction or early satiety in 28 (24%), obstructive jaundice in 2 (2%) and inadequate previous percutaneous drainage in 2 (2%). The collection resolved partially with percutaneous drainage and patients developed sepsis. Hence, they were considered for EUS-guided cyst gastrostomy. Some patients had more than one symptom.

Procedure

Seventy (60%) patients had WON and 46 (40%) had pancreatic pseudocysts. Median maximum collection size on cross-sectional imaging was 11 cm (range 5–21 cm). In patients with WON on EUS assessment, median necrosis within the pancreatic collection was 30% (range 5%–90%). Patient and procedure characteristics are displayed in ► **Table 2**.

One hundred and one patients (87%) received IV antibiotics during the procedure (One center did not prescribe antibio-

tics). Of the 116 patients, 76 (66%) had the procedure under sedation and 40 patients (34%) had general anaesthesia. All patients except one had free-hand puncture into the cyst cavity without use of an EUS needle and wire. All but one procedure was done without fluoroscopy guidance but it was readily available within the department. The most common site of stent insertion was trans-gastric (112) followed by trans-esophageal (2) and trans-duodenal placement (2).

Seventy-eight patients (67%) had 15 mm × 10 mm stents and 38 (33%) had 10 mm × 10 mm stents. The stent was dilated in 16 (14%) at the index procedure. The procedure was technically successful in all but one patient (99.1%). In one patient, the stent was misplaced (distal end of the stent was not placed in to the cyst cavity) and removed and a second stent was placed successfully within the collection during the same procedure.

The procedure was clinically successful in 109 (94%) patients. Three patients required additional percutaneous drainage because of inadequate drainage at a different site. Median length of stay was 3 days in all patients (Range 0–208 days). Seventy-seven (66%) patients had the procedure while they were inpatients and 39 (34%) had the procedure as a day case procedure. Fifteen procedures (13%) were done after the patient was admitted to an intensive care unit.

The collection resolved in 109 (94%) patients and 3 (2.5%) required additional percutaneous drainage. The collection completely resolved in 1 of the 2 patients who died within 30 days. Collection resolution data were not available in 3 patients who were lost to follow up before first follow-up imaging and repeated attempts to contact them have been unsuccessful. Median time to resolution of the collection was 49 days (5–206) days. The stent was removed in 99 (85%) patients. In a further 8 patients (7%), the stent migrated spontaneously upon resolution of the collection, which was defined as clinically insignificant. The stent could not be removed in 2 patients who died within 30 days of the procedure. In 1 patient who had a buried stent and developed portal hypertensive gastropathy it was deemed that risks of stent removal outweighed the benefits, hence it was decided not to remove the stent. Overall stents have been removed endoscopically or spontaneously migrated in 106/109 (98%) patients in whom we have data for resolution of the collection. The stents remain in situ in 6 patients (5%) in whom repeated attempts at contact have been unsuccessful. When stents were removed, it was done without complication, using either a snare or stent-grabbing forceps. There was one recurrence of a collection during the follow-up period of 6 months.

Procedure-related adverse events

Procedure-related AEs were divided into early and late AEs. An early AE was defined as any AE that occurred within 7 days after the procedure whereas those occurring more than 7 days after the procedure were defined as late AE. The early SAEs were 5 episodes of sepsis requiring IV antibiotics, 2 requiring emergency DEN, 1 stent blockage with food, 1 stent migration, 1 stent dislodgement during a DEN procedure, and one major hemorrhage requiring 2 units of blood transfusion and gastric artery embolization. These patients developed sepsis despite an-

► **Table 2** Patient and procedure characteristics.

Patient demographics	
Patient characteristics	Number
Age (Median, Range)	52.5 (16–80)
Sex (Male : Female)	78:38
Aetiology	Gallstones 54 (46.5%) Alcohol 42 (36%) Idiopathic 15 (13%) Post-pancreatic surgery 1 (0.8%) Post-ERCP 2 (1.7%) Drug-related 1 (0.8%) Hyperlipidemia 1 (0.8%)
Indication for intervention ¹	Pain 48 (41%) Infected collection 49 (42%) Gastric outlet obstruction/satiety 28 (24%) Inadequate previous drainage 2 (1.7%) Obstructive jaundice 2 (1.7%)
Collection characteristics	
Type of collection	WOPN 70 (60%) Pancreatic pseudocyst 46 (40%)
Size of collection (median, range)	11 cm (5–21 cm)
Necrosis in WON (median, range)	30% (10–90%)
Procedure characteristics	
Sedation : GA	76:40
Antibiotics	101 (87%)
Freehand : Wire-guided puncture into cyst	115:1
Site of stent insertion	Trans-gastric 111 (96%) Trans-duodenal 3 (2.5%) Trans-esophageal 2 (1.7%)
Stent size	15×10 mm 78 (67.3%) 10×10 mm 38 (32.7%)
Inpatient vs day case	Inpatients 77 (66%) Day cases 39 (34%)
Intraprocedural dilatation post-stent insertion	16 (13.7%)
Technical success	99%
Clinical success	94%

ERCP, endoscopic retrograde cholangiopancreatography; WON, walled off necrosis
¹ Some had more than one symptom.

tibiotics, which resolved with a 3- to 5-day course of IV antibiotics. There was no difference in incidence of sepsis between patients who received antibiotics and those who did not. The patient whose stent migrated required a laparotomy for stent-induced small bowel obstruction. There was one death in which the patient developed pulseless electrical activity (PEA) cardiac

► **Table 3** Complications.

Serious adverse events	
Early <7 days	Late ≥ 7 days
Sepsis requiring IV antibiotics 5 (4.3%)	Esophageal fistula 1 (0.86%)
Sepsis requiring emergency DEN 2 (1.7%)	Buried stent 1 (0.86%)
Major hemorrhage 1 (0.86%)	Death 1 (0.86%)
Stent migration 1 (0.8%)	
Stent blockage with food 1 (0.86%)	
Death 1 (0.86%)	

DEN, direct endoscopic necrosectomy

arrest 24 hours after the procedure and died. The cause of death was secondary to pulmonary embolism.

The late SAEs were 1 buried stent and 1 fistula between the esophagus and the subphrenic space. The patient whose stent was buried in a gastric fold developed portal hypertension secondary to splenic vein thrombosis. He developed gastric varices and portal hypertensive gastropathy and it was considered that the risk of serious bleeding outweighed the benefits of stent removal. There was 1 death at 23 days' post-procedure where the patient developed new renal collections away from the existing collection and died of multiorgan failure. The collection into which the stent was inserted had resolved at the time of death, and it was deemed that this mortality was not related to stent insertion. The 30-day, 3-month and 6-month all-cause mortality rates were 1.7%, 2.5%, and 3.4%, respectively. Details of the complications are summarized in ► **Table 3**.

Early AEs were predominantly sepsis-related and resolved with IV antibiotics for 3 to 5 days. Two patients required DEN procedures. The late AEs were 1 buried stent and 1 esophago-subphrenic fistula. The patient who developed the fistula was managed with IV antibiotics and required nasojejunal feeding for 30 days. The fistula resolved with the feeding.

WON

Seventy patients had the procedure for WON. Median collection size was 11 cm (range 5–20 cm) and estimated necrotic volume was 30% (5%–90%). The technical success rate was 100% and the clinical success rate was 94% (66 patients). Thirty-seven patients (37/70, 53%) had a median of 2 DEN procedures (range 1–5). The collection resolved in 66 patients (94%) and median time to collection resolution was 45 days (range, 8–206). The stent was removed in 59 patients (84.28%). Median length of stay was 8.5 days (range 0–208 days). Fifteen patients (21%) had the procedure as a day case procedure. There was no recurrence of WON during the follow-up period of 6 months.

In the WON group, the LAMS migrated spontaneously in 6 patients upon resolution of the collection and none of these were clinically significant. The cumulative SAE rate was 14.2% (10/70). Details of the SAE outcomes are described in ► **Table 4**.

► **Table 4** SAE according to type of collection.

Type of SAE	Pseudocyst	Walled of necrosis
Sepsis requiring antibiotics	1	4
Sepsis requiring DEN	0	2
Major hemorrhage	1	0
Stent blockage with food	1	0
Stent migration causing bowel obstruction	0	1
Mortality within 30 days	0	2
Buried stent	1	0
Fistula	0	1
Cumulative SAE	4/46 (8.69%)	10/70 (14.2%)
SAE, serious adverse event; DEN, direct endoscopic necrosectomy		

Pseudocysts

Forty-six patients had the procedure for pseudocysts. Median collection size was 10 cm (5–21 cm). The procedure was technically successful in 45 patients (98%) and was clinically successful in 44 patients. The collection resolved in 42/44 patients (95%). Median time to collection resolution was 48 days (7–203 days) and the stents were removed in 40 patients. Median length of stay was 1 day (Range 0–91 days). Twenty-four (54.5%) patients had it as a day case procedure. There was one recurrence of pseudocyst during the follow-up period.

There were spontaneous stent migrations in 2 patients upon resolution of collection and these were not clinically significant. The cumulative SAE rate was 8.7% (4/46; stent blockage with food, buried stent, major hemorrhage and sepsis)

Discussion

This multicenter study on use of LAMS in PFC confirms that insertion of LAMS is relatively safe and effective for drainage of PFC. The through-the-scope delivery system appears to aid stent deployment into the collection and that was again confirmed in our study, with an overall technical success rate of 99%. Three other retrospective studies have reported similar technical success rates of 97% to 98.5% for LAMS [14–16]

We observed that the overall median length of stay (LOS) was 3 days (0–105 days); the LOS was significantly lower for pseudocysts with a median LOS of 1 day (Range 0–91 days) compared to 8.5 days in patients with WON (Range 0–105 days, $P=0.01$). One-third of all patients (39, 34%) were able to be discharged either on the same day or the day after the procedure. This study demonstrates that endoscopic drainage with LAMS can be safely done as a day case procedure, particularly in the case of a pancreatic pseudocyst. Bang et al, in a retrospective case-control study, reported similar median LOS of 2 days for LAMS drainage [17]. A randomized controlled trial comparing endoscopic drainage (plastic stents) vs. surgical drainage

for pseudocysts reported a median LOS of 2 vs. 6 days ($P<0.001$) [6]. The TENSION trial which compared surgical vs. endoscopic step-up approach, recently published in abstract form, reported reduced LOS, reduced rate of pancreatic fistula, and significant reduction in costs with the endoscopic step-up approach even though superiority of the endoscopic step-up group was not shown [7, 18] LAMS may be associated with reduced morbidity and may be cost-effective in management of PFC compared to surgical drainage. However, randomized controlled trials are needed to establish this.

The technical success rates for WON and pseudocysts were 100% and 98%, respectively. Clinical success rates were 94% and 98%. The wide diameter of this LAMS allows for drainage of collections and easy access for DEN. That has been confirmed in our study where 37 patients underwent 74 DEN procedures (median 2, range 1–5). Of the 74 DEN procedures, there was 1 stent dislodgement (1.3%) during the DEN procedure. In our cohort, 53% of patients with WON underwent DEN and 1 patient in the pseudocyst group required a further endoscopic procedure for stent blockage. Overall, 78 patients (67%) with WON had larger-diameter stents (15 mm × 10 mm) inserted for the drainage procedure. In a recent retrospective study, multivariate analysis demonstrated that clinical success was 6 times more likely if the larger-diameter stent (15 mm) was used (odds ratio 6.9; 1.4–34.5; $P=0.02$) [16]. A recent retrospective study of 313 patients comparing plastic stents to FCSEMS to LAMS in drainage of WON reported that the mean number of endoscopic procedures required for collection resolution was significantly lower in the LAMS group compared to the FCSEMS and plastic stent groups (2.2 vs. 3 vs. 3.6, respectively; $P=0.04$) [9]. Two retrospective observational studies comparing DP stents, FCSEMS and LAMS reported less efficacy and higher rates of AEs with DP stents compared to FCSEMS and LAMS [9, 12]. Multivariate analysis in 1 retrospective study reported that DP stents were a negative predictive factor in resolution of WON (OR 0.18; 95% CI 0.06–0.53; $P=0.002$) [9]. This is probably because the solid necrotic matter occludes the narrow diameter of plastic stents and does not allow for DEN procedures through the stents. Necrosectomy in this setting requires additional procedures.

The overall rate of resolution of collections was 94% and there was only 1 recurrence of a collection during the follow-up period of 6 months. Two retrospective studies of similar sample size reported a clinical resolution rate of 86% to 92% [14, 16].

There were 8 (6.4%) spontaneous migrations of LAMS into the gastric cavity upon resolution of the collection. We found no migrations of the stent into the cyst cavity. That may be due to the negative pressure in the abdomen and compression of intra-abdominal viscera on the stent. A retrospective study of 82 patients reported 2 spontaneous migrations on resolution of the collection [11]. We observed an overall stent migration rate of 7.2%, which appears to be lower than the reported incidence of stent migration with FCSEMS (10%–20%) [10–12].

The number of early SAEs reported in this study was 11 (9.4%) and late events excluding death were 2 (1.7%) (► **Table 3**). Thirty- and 90-day mortality rates were low at 1.7% and

2.5%, respectively. Cumulative SAE rates for WON and pseudocyst were 14.2% and 8.69%, respectively. A recent interim analysis of a randomized controlled trial comparing LAMS and plastic stents in management of WON reported that the risk of AEs was as high as 50% in the LAMS groups. This included delayed bleeding after insertion, buried stents and obstructive jaundice [19]. However, there was complete resolution of collection in all these patients. Rinninella and Siddiqui et al reported similar SAE rates in their retrospective studies [14, 15].

The main limitations of this study are lack of a randomized comparator group and differences in follow-up of our patients. There was no set protocol for DEN procedures and these were carried out at the discretion of the endoscopist. It is not clear if collections resolved quicker if patients had a planned DEN procedure within 7 days of the index procedure. Bang et al postulated that this may prevent the late complications reported in their interim analysis [19].

Conclusion

In summary, we found LAMS to be effective and relatively safe for endoscopic drainage of PFC and WON. Use of LAMS was associated with low morbidity and the observed rates of migration/dislodgement were lower than described in previous studies using FCSEMS. The large diameter of LAMS allows for DEN procedures without dilatation. However, randomized controlled trials comparing LAMS with FCSEMS and plastic stents are needed to assess the therapeutic benefit of LAMS.

Competing interests

None

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