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Lumen-apposing-metal stent misdeployment: A procedure-related adverse event of endoscopic ultrasound-guided drainage - systematic review of issues and rescue management

Armellini E *et al*. The LAMS misdeployment: How to avoid and manage it

Abstract

BACKGROUND

The introduction of lumen-apposing metal stents (LAMS) for endoscopic ultrasound (EUS)-guided drainages has marked a turning point in the field of interventional ultrasound and it is gathering worldwide diffusion in different clinical settings. Nevertheless, the procedure may conceal unexpected pitfalls. LAMS misdeployment is the most frequent cause of technical failure and it can be considered a procedure-related adverse event when it hampers the conclusion of the planned procedure or results in significant clinical consequences. Stent misdeployment can be managed successfully by endoscopic rescue maneuvers to allow the completion of the procedure. To date, no standardized indication is available to guide an appropriate rescue strategy depending on the type of procedure or of misdeployment.

AIM

To evaluate the incidence of LAMS misdeployment during EUS-guided choledochoduodenostomy (EUS-CDS), gallbladder drainage (EUS-GBD) and pancreatic fluid collections drainage (EUS-PFC) and to describe the endoscopic rescue strategies adopted under the circumstance.

METHODS

We conducted a systematic review of the literature on PubMed by searching for studies published up to October 2022. The search was carried out using the exploded medical subject heading terms “lumen apposing metal stent”, “LAMS”, “endoscopic ultrasound” and “choledochoduodenostomy” or “gallbladder” or “pancreatic fluid collections”. We included in the review on-label EUS-guided procedures namely EUS-CDS, EUS-GBD and EUS-PFC. Only those publications on EUS-guided LAMS positioning were considered. The studies reporting a technical success rate of 100% and other procedure-related adverse events were considered to calculate the overall rate of LAMS misdeployment, while studies not reporting the causes of technical failure were

excluded. Case reports were considered only for the extraction of data regarding the issues of misdeployment and rescue techniques. The following data were collected from each study: Author, year of publication, study design, study population, clinical indication, technical success, reported number of misdeployment, stent type and size, flange misdeployed and type of rescue strategy.

RESULTS

The overall technical success rate of EUS-CDS, EUS-GBD and EUS-PFC was 92.8%, 96.1%, and 97.8% respectively. Significant rates of LAMS misdeployment have been reported for EUS-CDS, EUS-GBD and EUS-PFC drainage, respectively 5.8%, 3.7%, and 2.1%. Endoscopic rescue treatment was feasible in 86.8%, 80%, and 96.6% of cases. Non endoscopic rescue strategies were required only in 10.3%, 16% and 3.4% for EUS-CDS, EUS-GBD, and EUS-PFC. The endoscopic rescue techniques described were over-the-wire deployment of a new stent through the created fistula tract in 44.1%, 8% and 69% and stent-in-stent in 23.5%, 60%, and 10.3%, respectively for EUS-CDS, EUS-GBD, and EUS-PFC. Further therapeutic option were endoscopic rendezvous in 11.8% of EUS-CDS and repeated procedure of EUS-guided drainage in 17% of EUS-PFC.

CONCLUSION

LAMS misdeployment is a relatively common adverse event in EUS-guided drainages. There is no consensus on the best rescue approach in these cases and the choice is often made by the endoscopist relying upon the clinical scenario, anatomical characteristics, and local expertise. In this review, we investigated the misdeployment of LAMS for each of the on-label indications focusing on the rescue therapies used, with the aim of providing useful data for endoscopists and to improve patient outcomes.

Key Words: Lams misdeployment; Endoscopic ultrasound-guided drainage; Lams maldeployment; Biliary drainage; Gallbladder drainage; Pancreatic fluid collections; Lumen-apposing metal stents

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Core Tip: Scant data are available about rescue techniques in cases of lumen-apposing metal stents (LAMS) misdeployment which is the main cause of technical failure in endoscopic ultrasound-guided drainage procedures. We performed a systematic review of the literature about LAMS misdeployment and rescue techniques in the biliopancreatic setting, focusing on technical aspects and success rate of endoscopic maneuvers. In accordance with our results endoscopic rescue techniques are feasible in most cases (up to 96.6%). Three endoscopic rescue strategies have been identified: gaining wire access to the target through the created fistula and completing the procedure; placement of a new stent through the misdeployed LAMS to the target ("stent-in-stent") and repeated drainage procedures (*ex novo* or rendezvous). The choice of the endoscopic rescue maneuver is based on the clinical scenario, type of misdeployment and expertise of the endoscopic team.

INTRODUCTION

The progress in interventional endoscopy, particularly in the field of endoscopic ultrasound (EUS), has changed the treatment algorithms for digestive and pancreaticobiliary diseases. The evolution of devices combined with improvements in endoscopic techniques, have allowed access to mini-invasive therapeutic solutions for complex diseases that affect areas beyond the gastrointestinal tract.

Nowadays, interventional EUS can manage local complications of acute pancreatitis[1], drain the biliary tree and gallbladder[2], establish gastrointestinal anastomoses[3], and treat tumors by radiofrequency ablation or injection of substances[4,5]. A paradigmatic example of this evolution is the approach to

biliopancreatic drainage. The first EUS-guided transluminal drainage of the biliary tree was performed in 2001. Giovannini *et al*[6] used a 10-Fr plastic stent to achieve trans-duodenal biliary drainage (BD) under EUS guidance in a patient with a pancreatic head mass after failed endoscopic retrograde cholangiopancreatography (ERCP). Since then, the evolution of EUS-guided drainage has led to the continuous improvement of available devices and of endoscopic techniques. The introduction of self-expanding metal stents (SEMS) and lumen-apposing metal stents (LAMS) for EUS-guided drainage is a turning point in the field of endoscopic drainage. The first transluminal stenting between two nonadherent lumens of the digestive tract using a bi-flanged covered metal stent with lumen-to-lumen apposition property was described by Binmoeller and Shah[7] in an *ex vivo* model. Itoi *et al*[8] reported the first use of LAMS in humans, describing the successful treatment of 15 symptomatic pancreatic pseudocysts and five acute cholecystitis cases in patients unfit for surgery.

Itoi and Binmoeller[9] successfully performed the first EUS-guided choledochoduodenostomy (EUS-CDS) with LAMS in a patient with unresectable pancreatic cancer and obstructive jaundice. Prior to that, the technique of LAMS deployment was the same as that of tubular stents (plastic or metal stents), which is a multi-step procedure with device exchanges that are exposed to the risk of adverse events (*i.e.*, loss of the wire and/or scope position, biliary leak). To address this issue, a new LAMS delivery system with an electrocautery tip [electrocautery-enhanced (EC)-LAMS-Hot-Axios, Boston Scientific Corp., Marlborough, Massachusetts, United States] was developed, giving rise to a single-stage technique[10,11]. Presently, two LAMS in different diameters and lengths are commercially available: The Hot Axios stent (Boston Scientific, Marlborough, Mass, United States) and the Hot Spaxus stent (Taewoong Medical Co. Gimpo, Korea) and new LAMS types are on the way. Other fully covered (FC) metal stents are available for similar indications: Aixstent (Leufen Medical, Aachen, Germany), Hanarostent (Mi-TECH-Medical Co, Seoul, South Korea), and NAGI stents (Taewoong Medical Co., Ltd., Ilsan, Korea)[11,12]. These stents are non-cautery and require a multi-step procedure for their insertion. LAMS loaded on an EC

delivery system requires precise execution of some sequential steps (puncture of the target lumen, retraction of the distal flange to the adjacent cavity wall, deployment, and release of the proximal flange) to achieve technical success, which is defined as the correct placement of the stent across the newly created tract.

There are various issues that may occur during LAMS deployment, resulting in stent misdeployment; unfavorable conditions range from unfamiliarity with the stent to patient movement, angled scope tip or confined space within the gastrointestinal cavity, small diameter of the target lumen[13], and target structure located at a distance of more than 15-20 mm[14]. Stent misdeployment usually results in a full-thickness defect of the gastrointestinal wall, possibly associated with the perforation of the target organ. Prompt identification of this complication is crucial to managing the perforation, possibly completing the procedure, and avoiding major consequences. This paper reviews EUS-guided drainage procedures using LAMS, with a focus on misdeployment and endoscopic rescue therapies.

MATERIALS AND METHODS

Data collection

This systematic review was performed in agreement with PRISMA guidelines. Two independent investigators (Cominardi A and Metelli F) performed a review on PubMed by searching for studies published up to October 2022. The search was limited to English-language articles and human studies, and it was carried out using the exploded medical subject heading terms “lumen apposing metal stent”, “LAMS”, “endoscopic ultrasound” and “choledochoduodenostomy” or “gallbladder” or “pancreatic fluid collections”. We included in the review on-label EUS-guided procedures namely EUS-CDS, gallbladder drainage (GBD) and drainage of pancreatic fluid collections (PFC). Boolean operators (NOT, AND, OR) were also used in succession to narrow and widen the search.

Both investigators used a standardized data collection form to increase uniformity and reduce bias in reporting. In the case of discrepancy, the investigators resolved the

disagreement by discussion with a senior investigator (Armellini E). Only those publications on EUS-guided LAMS positioning were considered, whereas studies on drainage with other metallic or plastic stents were excluded. Meta-analysis, review and drainage performed in non-human models were also excluded.

The studies reporting a technical success rate of 100% and other procedure-related adverse events were considered to calculate the overall rate of LAMS misdeployment, while studies not reporting the causes of technical failure were excluded. Case reports were considered only for the extraction of data regarding the issues of misdeployment and rescue techniques.

The full paper of each identified article was retrieved, and references were evaluated to search for potentially missed articles. The data were extracted independently and entered standardized Excel spreadsheet (Microsoft Inc. Redmond, Washington, United States). For EUS-CDS and EUS-PFC drainage the following data were extracted from each study: Year of publication, study design, study population, clinical indication, technical success, reported number of misdeployment, LAMS type and size, flange misdeployed, and type of rescue strategy. For EUS-GBD the following data were collected from each study: Author, year of publication, study design, study population, clinical indication, access to GB (stomach or duodenum), technical success, reported number of misdeployment, LAMS type and size, flange misdeployed, and type of rescue strategy.

Data analysis

Baseline characteristics of study population, EUS-guided procedures, technical details, and procedure outcomes were summarized as means (SD) or medians (with interquartile range and range) for continuous data, and as frequencies and proportions for categorical data. Data were analyzed using the Statistical Package for Social Sciences (SPSS software v. 15.0, Chicago, Illinois, United States) for Windows.

RESULTS

EUS-CDS

Literature research identified 82 studies that were fully assessed for eligibility in this review. We excluded 57 studies since they did not meet our inclusion criteria. A total of 25 studies were included in our review[15-39]; in 20 studies LAMS misdeployment occurred[20-39] (study flow chart was shown in Figure 1).

A total of 1081 patients underwent EUS-CDS for malignant biliary obstruction (MBO), almost all after failed ERCP. The overall technical success rate of EUS-CDS was 92.8%. Excluding 5 case reports, a total of 63 LAMS misdeployment were reported, with a rate of 5.8%; the study detailed characteristics were summarized in Table 1. In 61 (92.4%) cases an Axios stent was employed for EUS-CDS. Spaxus stent was used in 3 (5.3%) cases. The procedures were performed with a pre-loaded guidewire in 23 (33.8%) cases, without a pre-loaded guidewire in 12 (17.6%) cases, whereas this data was not available in most of cases (48.6%).

In 24 (38.1%) cases the misdeployment of the distal flange was reported, in 3 (4.7%) cases the misdeployment involved the proximal flange, in 3 (4.7%) EUS-CDS LAMS was entirely misdeployed inside the common bile duct (CBD) and in 2 (3.2%) patients no bile flow was observed after LAMS deployment despite no evidence of LAMS misdeployment. The type of misdeployment was not properly described in 31 (49%) EUS-CDS. Seven other causes of technical failure were reported in four studies[15,22,24,38]: 1 massive bleeding, 1 inability to puncture the bile duct, 2 duodenal perforations, 1 failure of fistula creation, 1 mechanical failure and 1 patient intolerance. In three studies[31,33,37], the effective rescue therapy after LAMS misdeployment was considered a technical success by the authors and in one study[15] duodenal perforation during dilation of the fistulous tract was the cause of technical failure.

Including case reports, LAMS misdeployment was managed by endoscopy in 86.8% (n = 59/68) cases, while 4.4% (n = 3/68) misdeployment cases were treated by percutaneous transhepatic BD (PTBD), 2.9% (n = 2/68) by rendezvous *via* PTBD and during surgery, and 2.9% (n = 2/68) by surgery. In 2 cases the procedure was abandoned in favor of supportive therapy. In 44.1% (n = 30/68) cases of LAMS

misdeployment, the rescue strategy was LAMS removal followed by over-the-wire deployment of a new stent; in 7 (23.3%) cases a new LAMS was deployed and in 23 (76.7%) cases a SEMS was used.

The stent-in-stent technique was the treatment of choice in 16 (23.5%) cases of misdeployment; in 7 (43.7%) cases SEMS was used, in 1 (6.3%) a plastic stent and in 8 (50%) the stent type was not specified. In 8 (11.8%) cases rendezvous procedure was performed by EUS/endoscopic technique. EUS-CDS was repeated in 4 (5.9%) cases. In 1 (1.5%) case EUS-GBD was used as a rescue strategy (see Table 2).

EUS-GBD

We identified 213 studies using our search strategy; 185 studies were excluded since they did not meet inclusion criteria. A total of 28 studies reported cases of EUS-GBD[8,22,29,37,40-84] including 16 studies in which LAMS misdeployment occurred[22,29,50-63]. The study flow chart is shown in Figure 2.

A total of 667 patients underwent EUS-GBD for acute cholecystitis since they were unfit for surgery. Only in one study patients were treated by EUS-GBD for unsuccessful BD with ERCP[60]. Study characteristics are summarized in Table 3. The overall technical success of EUS-GBD was 96.1%. We identified 25 LAMS misdeployments among the studies included. LAMS misdeployment rate was 3.7% among all the EUS-GBD considered. In 19/25 (76%) cases an Axios stent was employed for EUS-GBD, while a Spaxus stent was used in the remaining 6/25 (24%) cases.

Only 8 studies reported if the GB was accessed from the stomach (n = 7/11, 63.6%) or duodenum (n = 4/11, 36.4%)[22,51-55,59,61]. The misdeployment of the proximal flange occurred in 9/25 (36%) cases, while the distal flange was misdeployed in 16/25 (64%) cases. The use of a guidewire was reported in 16/25 (64%) cases of misdeployment. Endoscopic management was the treatment of choice in 21/25 (84%) cases of LAMS misdeployment during EUS-CDS. In 15 of these 25 (60%) complicated EUS-GBD collected in our study, the initial failed LAMS deployment was overcome by reinsertion of a FC-SEMS through the LAMS lumen, the so-called "stent-in-stent" strategy; only in

1/15 a double pigtail stent was inserted. In 2/25 (8%) cases, the misdeployed stent was removed and a new LAMS was re-deployed over the guidewire across the fistula created during the first attempt for EUS-GBD.

In 3/25 (12%) cases, the LAMS was endoscopically removed, and the gastrointestinal wall perforation was closed by endoscopic clipping followed by transpapillary stent placement in 1 case. No further endoscopic maneuvers were attempted in the remaining 2 cases in favour of supportive care. Surgical management was the therapeutic option in 3/25 (12%) cases of misdeployment. In 1 (4%) case, emergent percutaneous cholecystostomy was performed after unsuccessful stent-in-stent placement attempt. In 1 (4%) case, palliation was the preferred strategy (see Table 2).

EUS-PFC

We collected 48 studies from the literature that were fully assessed for eligibility in this review; 20 studies were excluded since they did not meet our inclusion criteria. A total of 28 studies were included in our review[10,12,57,64-88] including 15 studies in which LAMS misdeployment occurred[10,12,70,77-88] (Figure 3). The overall technical success of EUS-PFC drainage was 97.8%. The cause of technical failure corresponded to LAMS misdeployment in all the studies except in one reporting two cases of technical failure due to a difficult scope position that prevented the advancement of the EC-LAMS device outside the operative channel of the echoendoscope.

Excluding two case reports, we collected 1655 patients who underwent EUS-PFC drainage in which 34 LAMS misdeployment occurred, with a rate of 2.1%. All study characteristics were reported in Table 4. In 12 (35.3%) cases misdeployment of the distal flange occurred, in 2 (5.9%) cases the proximal flange was deployed and then migrated entirely into the PFC. In most cases included in our study (20; 58.8%), the issue of misdeployment was not clearly described. A case report reported the misdeployment of the stent in a non-target organ. In 4 cases data regarding rescue strategy were not available and the procedure was abandoned in one case.

The LAMS misdeployment in EUS-PFC drainage was managed as following: In 20/29 (69%) cases an over-the-wire deployment of a new stent was performed (10/20 with LAMS, 2/20 with SEMS, 8/20 with plastic stents), in 5/29 (17%) cases the EUS-guided PFC drainage was repeated, in 1/22 (3.4%) case surgical drainage was performed. The stent-in-stent strategy was the rescue treatment in 3/29 (10.3%) cases of LAMS misdeployment; in 2 (66.6%) cases a LAMS-in-LAMS technique was performed and in 1 (33.3%) case a SEMS was deployed inside the misdeployed LAMS (see Table 2).

DISCUSSION

Technical success of EUS-drainage is defined as the correct deployment of the stent between the gastrointestinal wall and target organ with evidence of bile flow in patients who underwent EUS-BD[24,25,32] or content flow/established access to the cavity in EUS-PFC or EUS-GBD cases[52,57,96]. Among the studies we collected, different terms were used to define this complication, including misdeployment, dislodgement, and flange migration. We adopted the term 'misdeployment', as reported in the European Society of Gastrointestinal Endoscopy guidelines for therapeutic EUS[14]. Stent misdeployment emerges as the primary cause of technical failure in the procedure of EUS-guided drainage.

According to the American Society for Gastrointestinal Endoscopy lexicon for endoscopic adverse events, LAMS misdeployment can be considered a procedure-related adverse event when it hampers the completion of the planned procedure and/or results in significant clinical consequences (*i.e.*, prolongation of existing hospital stay and elicitation of the need for another procedure)[89]. Misdeployment can be defined as an incident if it does not interfere with the completion of the planned procedure or change the plan of care. Therefore, stent misdeployment can be managed successfully by endoscopic rescue maneuvers to allow the completion of the procedure; however, complications with different levels of severity can occur in some cases. In EUS-BD, stent misdeployment may be associated with spillage of bile and secretions into the peritoneal cavity or retroperitoneal space, resulting in peritonitis and

pneumoretroperitoneum[90]. Recently Fabbri *et al*[91] proposed a classification of misdeployment types during EUS-guided gastroenterostomy as follows: Proximal flange misdeployment, distal flange misdeployment, stent misdeployment perforating other organs, and stent misdeployment into the peritoneum. This model considers which flange is misdeployed and the anatomical localization of the stent after misdeployment and can be supposedly adopted for all EUS-guided procedures involving the use of LAMS.

EUS-CDS

The rate of ERCP failure is 2%-10% and it is due to surgically altered anatomy, gastric outlet obstruction, duodenal and/or bile duct tumor infiltration, indwelling enteral stent, periampullary diverticula, impacted stones, and technical difficulties[92]. European guidelines suggest EUS-BD guidance as the second-line treatment for patients with MBO. The optimal drainage strategy depends on the underlying disease (benign/malignant) and location of the obstruction (distal/hilar)[15].

EUS-BD proved to be equally effective with fewer adverse events and re-intervention compared to PTBD especially in gastric outlet obstructions[93]. In addition, EUS-BD is less invasive, leads to better nutrition, prevents electrolyte imbalances, and provides better quality of life[94]. As experience in EUS-BD continues to grow, comparative studies of EUS-CDS and ERCP have reported encouraging data in support of EUS-CDS as the primary treatment for distal MBO, challenging the role of ERCP[95].

In a meta-analysis, the technical and clinical success rates of EUS-CDS using LAMS were 93.6% and 94.8%, respectively, with pooled rate of overall adverse events of 17.1% and procedure-related adverse events of 6.2%[96]. In our research, LAMS misdeployment rate was 5.8%, and LAMS misdeployment represented the main cause of technical failure in EUS-CDS. Notably, technical failure was due to other causes in only seven cases (0.6%). In up to 90.1% of cases, the endoscopist managed LAMS misdeployment with an endoscopic rescue strategy during the index procedure.

The most common endoscopic rescue technique involved misdeployed LAMS removal and over-the-wire deployment of a new stent through the same fistula tract (50%). SEMS were employed in most cases (76.7%). Other rescue strategies used include stent-in-stent (30%), EUS-guided/endoscopic rendezvous with transpapillary placement of a biliary SEMS (13.3%), and repeated EUS-drainage procedure (6.7%).

As reported in literature, the most common causes of LAMS misdeployment are related to difficult scope position[17,28,39] and small CBD diameter (< 15 mm)[21,27,34]. In a retrospective analysis by Jacques *et al*[23] involving 52 patients who underwent LAMS placement using various techniques, the technical and clinical success rates were 88.5% and 100%, respectively. In univariate analysis, CBD diameter > 15 mm, use of a 6-mm LAMS, and use of a one-step technique (direct puncture using the electrocautery system without needle puncture) were predictors of technical success in EUS-CDS. In another study, the authors performed EUS-CDS using a one-step technique in 97.1% (n = 68/70) of patients and achieved 98.6% of technical success[24]. The more frequent use of a pre-loaded guidewire in the group of patients with CBD < 15 mm compared to those with CBD ≥ 15 mm (33% *vs* 3.6%, P = 0.036) might have contributed to the comparable technical success, clinical success, and adverse event rates between the two groups. On the other hand, Di Mitri *et al*[21] reported seven cases of LAMS misdeployment in 31 patients with distal MBO who underwent EUS-CDS. CBD was ≤ 15 mm in six of the seven patients. In five cases, rescue therapies involved placing a fully covered self-expanding metal stent (FCSEMS) over the previously inserted guidewire, restoring the connection through the iatrogenic fistulous tract. In the remaining two cases, bile duct decompression after the puncture prevented the correct visualization of the CBD on EUS imaging and the possibility of approaching the CBD again; these cases were managed successfully by percutaneous- and laparoscopic-endoscopic rendezvous techniques. The authors assumed that the small caliber of the CBD forced the tip of the LAMS delivery catheter to be too close to the facing wall of the CBD and in an oblique direction, increasing the risk of misdeployment, even with the use of a small-size LAMS. In the largest study (256 patients enrolled) included in our review, Fugazza *et*

al[26] reported that significantly higher technical success was achieved in patients with a larger CBD diameter compared to those with a smaller CBD diameter. The authors demonstrated that larger CBD size, use of a needle with a guidewire, fluoroscopy guidance, and LAMS placement in the proximal CBD were more likely in the non-expert group than in the expert group; however, technical [101 (94.4%) *vs* 138 (92.6%); *P* = 0.574] and clinical success [96 (95.0%) *vs* 134 (97.1%); *P* = 0.415] did not statistically differ between these two groups.

The use of a delivery system pre-loaded with a guidewire in complex cases (*i.e.*, endoscope instability in the duodenal bulb or smaller CBD diameter) was emphasized by Anderloni *et al*[97] because it allowed rescue using an over-the-wire stent placement in cases of LAMS misdeployment, and the single-step technique was preferred in cases of dilated CBD > 15 mm.

Wire access into the CBD could be regained in some cases, allowing endoscopic rescue maneuvers to be performed, even in cases of non-identifiable CBD on EUS imaging[28,35]. Our data show that over-the-wire deployment of a tubular stent, particularly a biliary SEMS, was the preferred rescue procedure for LAMS misdeployment during EUS-CDS (47.5%). We suppose that this technique was preferred since EUS-BD with SEMS has long been a consolidated technique for BD and that SEMS placement can be performed without EUS guidance, which may be lost in these circumstances.

EUS-GBD

Laparoscopic cholecystectomy is the standard approach for acute calculus cholecystitis. In cases of severe inflammation, adhesive disease, bleeding in the surgical area, or suspected bile duct injury, open cholecystectomy may be required to achieve safe dissection and gallbladder resection. In recent years, EUS-GBD has emerged as the preferred alternative to surgical treatment over percutaneous GBD (PGBD) or endoscopic transpapillary GBD (ETP-GBD) and is included in the international guidelines for grade II cholecystitis and recommended for grade 3 cholecystitis in

patients with American Society of Anesthesiologists scores ≥ 3 or Charlson Comorbidity Index ≥ 6[98,99]. It has a technical and clinical success rate of 94.65% [95% confidence interval (CI): 91.54-96.67; I^2 = 0.00] and 92.06% (95%CI: 88.65-94.51; I^2 = 0.00), respectively. The rates of adverse events associated with EUS-GBD, including perforations, misdeployment, bile leakage, stent migration into the gallbladder or peritoneum, bleeding, gastroduodenal perforation, pneumoperitoneum, and recurrent acute cholecystitis due to stent occlusion, varies between 8% and 17%[100-102]. EUS-GBD showed higher technical and clinical success rates and lower recurrence rates than those of ETP-GBD[103].

Moreover, several studies have compared EUS-GBD with PGBD, demonstrating similar technical and clinical success rates for both procedures[43,104-106]; however, EUS-GBD was associated with significantly fewer adverse events, including lower mortality, lower post-procedure pain, shorter hospital stay, and fewer readmissions and reinterventions. According to our data, LAMS misdeployment occurred in 2.6% of the patients who underwent EUS-GBD. In almost 63% of cases, LAMS misdeployment occurred when EUS-GBD was performed through the stomach.

Although studies comparing gastric and duodenal LAMS access for EUS-GBD did not find any significant differences in technical or clinical success or adverse event rates[107], the duodenum is a less mobile organ and is closer to the GB than the stomach. Therefore, there is a theoretically lower risk of LAMS migration when GB access is *via* the duodenum.

In 68% of cases, LAMS misdeployment involved the distal flange. This suggests that a careful choice of the position and proper advancement of the LAMS inside the GB are critical to avoiding misdeployment. The use of guidewire, reported in 68% of cases of misdeployment, helped to maintain secure access to the newly created fistula between the gastrointestinal system and GB. The most frequently performed rescue maneuver was the placement of LAMS or a longer SEMS through the lumen of the misdeployed stent (stent-in-stent strategy). The stent-in-LAMS was particularly the rescue strategy of choice in up to 60% of LAMS misdeployment cases.

Surgery or PTBD after endoscopic closure of the luminal perforation was required after the failure of endoscopic therapies[55,56,61]. LAMS removal and clip closure of digestive tract wall defect was the treatment of choice in 3 patients (one of them was treated by ETP-GBD while no further endoscopic maneuver was performed in the remaining two patients, for which no post-procedural complication was reported). This strategy allows a second drainage attempt during the index procedure or later in selected patients. According to our data, two patients died after LAMS misdeployment, one for surgical complications and one left to supportive care.

EUS-PFC drainage

EUS-guided transmural drainage is considered the first-line treatment option for PFC, including walled-off necrosis (WON) and pancreatic pseudocysts[108]. Transluminal drainage in the "before-LAMS age" was achieved by the placement of double-pigtail plastic stents and afterward, by biliary/esophageal FC SEMS, which were associated with risks of migration, leakage, ulceration, and bleeding[109]. The LAMS design has the advantage of supporting drainage, preventing migration, and allowing direct access inside the WON cavity for endoscopic necrosectomy because it has a larger diameter, shorter length, and stent-anchoring flanges[110].

In our study, LAMS misdeployment during EUS-guided PFC drainage occurred in 34/1655 (2.1%) patients. This result agrees with the high technical success rate of these procedures reported in the literature (97.6%)[111]. Distal flange misdeployment in the peritoneal cavity, external to the cystic wall, was reported in up to 35.3% of cases[77,78,80,81,85]. Over-the-wire placement of a new stent (LAMS, SEMS, or double pigtail stents/plastic) through the novel fistula tract was the rescue therapy of choice in 69% of misdeployments. In 50% of cases, LAMS were deployed over the guidewire to complete the procedure as initially planned. The re-insertion of the same LAMS was performed in 15% of cases, resulting in a lower cost; these cases were counted as technical successes. In a study by Khan *et al*[78] involving 208 patients who underwent

EUS-PFC drainage, seven cases of LAMS misdeployment were managed by repeated EUS-guided drainage during index endoscopy (n = 6/7).

There were two cases (5.9%) of complete LAMS misdeployment inside the PFC. In such cases, Mendoza Ladd *et al*[81] decided to leave the LAMS inside the PFC, and they deployed a new one through the fistula. After LAMS dilation, direct endoscopic necrosectomy was performed. Both stents were successfully removed four weeks later. The deployment of LAMS into an adjacent organ (the splenic flexure of the colon), described as WON, was reported by Despott *et al*[83], who identified the misdeployment only at the post-procedure scan (computerized tomography). After bowel preparation through a naso-jejunal tube to bypass the gastrocolic fistula, simultaneous upper and lower gastrointestinal endoscopies were performed, and the LAMS was removed. Both the colonic and gastric perforations were closed using over-the-scope clips. Although data regarding predictive factors related to LAMS misdeployment were lacking in the studies included in our review, Curieses Luengo *et al*[88] identified excessive flexion of the echoendoscope tip due to severe inflammatory duodenal stenosis as an unfavorable condition for correct LAMS deployment.

CONCLUSION

The use of LAMS has been demonstrated to have high technical and clinical success rates in EUS-CDS, EUS-GBD and EUS-PFC drainage, however significant rates of LAMS misdeployment are reported in 5.8%, 3.7%, and 2.1% of cases, respectively. In a relevant rate of LAMS misdeployment, endoscopic rescue management has been shown to be technically feasible and effective in completing the procedure and avoiding major complications.

Although no algorithm is available for defining to guide the appropriate rescue strategy for each case, three endoscopic tecniques have been identified: (1) Gaining wire access to the target through the newly created tract and completing the procedure; (2) “Stent-in-stent” over the wire; and (3) Repeated procedures (*ex novo* or rendezvous).

When endoscopic rescue procedures are not feasible, non-endoscopic options include percutaneous drainage or surgery.

In our analysis, the preferred strategy for LAMS misdeployment in EUS-CDS was LAMS removal and over-the-wire deployment of a new stent (44.1%), frequently SEMS (76.7% of cases), followed by stent-in-stent strategy (23.5%) and endoscopic rendezvous (11.8%). In EUS-GBD, the preferred technique was the stent-in-stent strategy (60%) using a SEMS in 93.3% of cases.

In EUS-PFC, the procedure of choice was LAMS removal followed by over-the-wire deployment of a new stent (69%), which was a LAMS or a plastic stent, in 50% and 40% of cases respectively. In conclusion, LAMS misdeployment is a relatively common adverse event, especially in EUS-BD. Endoscopic rescue strategies are feasible, and they vary depending on type of procedure, endoscopic technique used, and experience of the operators.

ARTICLE HIGHLIGHTS

Research background

Scant data are available about rescue techniques in cases of lumen-apposing metal stents (LAMS) misdeployment which is the main cause of technical failure in endoscopic ultrasound (EUS)-guided drainage procedures. We performed a systematic review of the literature about LAMS misdeployment and rescue techniques in the biliopancreatic setting, focusing on technical aspects and success rate of endoscopic maneuvers.

Research motivation

LAMS misdeployment is a relatively common adverse event in EUS-guided drainages. There is no consensus on the best rescue approach in these cases and the choice is often made by the endoscopist relying upon the clinical scenario, anatomical characteristics, and local expertise.

Research objectives

The overall technical success rate of EUS-guided choledochoduodenostomy (EUS-CDS), gallbladder drainage (EUS-GBD) and pancreatic fluid collections drainage (EUS-PFC) was 92.8%, 96.1%, and 97.8% respectively. Significant rates of LAMS misdeployment have been reported for EUS-CDS, EUS-GBD and EUS-PFC drainage, respectively 5.8%, 3.7%, and 2.1%. Endoscopic rescue treatment was feasible in 90.2%, 84%, and 96.6% of cases. Non endoscopic rescue strategies were required only in 8.8%, 16% and 3.4% for EUS-CDS, EUS-GBD, and EUS-PFC.

Research methods

We conducted a systematic review of the literature on PubMed searching for studies published up to October 2022 about on-label EUS-guided procedures namely EUS-CDS, EUS-GBD and EUS-PFC. The search was carried out using the exploded medical subject heading terms 'lumen apposing metal stent', 'LAMS', 'endoscopic ultrasound' and "choledochoduodenostomy" or "gallbladder" or "pancreatic fluid collections".

Research results

The overall technical success rate of EUS-CDS, EUS-GBD and EUS-PFC was 92.8%, 96.1%, and 97.8% respectively. Significant rates of LAMS misdeployment have been reported for EUS-CDS, EUS-GBD and EUS-PFC drainage, 5.8%, 3.7%, and 2.1%, respectively. Endoscopic rescue treatment was feasible in 86.8%, 80%, and 96.6% of cases. Non endoscopic rescue strategies were required only in 10.3%, 16% and 3.4% for EUS-CDS, EUS-GBD, and EUS-PFC. The endoscopic rescue techniques described were over-the-wire deployment of a new stent through the created fistula tract in 44.1%, 8% and 69% and stent-in-stent in 23.5%, 60%, and 10.3%, respectively for EUS-CDS, EUS-GBD, and EUS-PFC. Further therapeutic option were endoscopic rendezvous in 11.8% of EUS-CDS and repeated procedure of EUS-guided drainage in 17% of EUS-PFC.

Research conclusions

Stent misdeployment can be managed successfully by endoscopic rescue maneuvers to allow the completion of the procedure. In accordance with our results endoscopic rescue techniques are feasible in most cases (up to 96.6%). Three endoscopic rescue strategies have been identified: Gaining wire access to the target through the created fistula and completing the procedure; placement of a new stent through the misdeployed LAMS to the target ("stent-in-stent") and repeated drainage procedures (*ex novo* or rendezvous).

Research perspectives

LAMS misdeployment is the main cause of technical failure of EUS-drainages and it is potentially harmful to the patient. Knowledge of risk factors, classification of misdeployment and of rescue endoscopic techniques is useful to improve patient outcome and the safety of the procedure. Further prospective studies describing these issues are expected.

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