Single-stage EUS-guided choledochoduodenostomy using a lumen-apposing metal stent for malignant distal biliary obstruction

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GRAPHICAL ABSTRACT

Background and Aims: EUS-guided choledochoduodenostomy (EUS-CD) using a lumen-apposing metal stent (LAMS) has recently been reported as an alternative treatment approach for patients with malignant obstructive jaundice and failed ERCP. We analyzed the safety and technical and clinical efficacy of EUS-CD using LAMSs in patients with malignant obstructive jaundice.

Methods: This was a retrospective study of consecutive patients with inoperable malignant distal bile duct obstruction who underwent EUS-CD using an electrocautery-enhanced (EC)-LAMS over a 3-year period (2015-2018). The main outcome measures were technical and clinical success (defined as a decline in serum bilirubin level by 50% at 2-week follow-up). Secondary outcomes were occurrence of adverse events, procedure time, and stent patency.

Results: Forty-six patients (47.8% women; median age, 73.1 ± 12.6 years) underwent direct EUS-CD using the biliary EC-LAMS. The procedure was technically successful in 43 patients (93.5%). The rate of clinical success was 97.7%. Adverse events occurred in 5 (11.6%) patients and included the following: 1 fatal bleeding 17 days after stent placement, 3 episodes of stent occlusion (food impaction), and 1 spontaneous migration (all 4 requiring reintervention). The mean follow-up was 114.37 days (95% confidence interval, 73.2-155.4).

Conclusions: EUS-CD using the EC-LAMS is effective. The rate of adverse events including one fatal event is not negligible and should be carefully considered before using the stent in this clinical setting. Prospective studies are required to validate our preliminary findings to fully assess the long-term efficacy and safety of the stent. (Gastrointest Endosc 2019;89:69-76.)

(footnotes appear on last page of article)

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INTRODUCTION

Transpapillary biliary drainage by ERCP is considered the first-line therapeutic approach in cases of malignant common bile duct (CBD) obstruction.[1] However, ERCP can fail in up to 10% of cases, particularly in patients with surgically altered anatomy, duodenal obstruction, indwelling enteral stents, or periampullary tumor infiltration, thus requiring alternative techniques to achieve biliary drainage.[2]

Percutaneous transhepatic biliary drainage (PTBD) or surgical approach are the traditionally alternative methods for biliary drainage.[3] Although PTBD is highly effective, the procedure is associated with significant morbidity and an adverse event (AE) rate of up to 26%.[4] In addition, the presence of external drainage has an adverse impact on the patient's quality of life. Surgical biliary bypass, on the other hand, is associated with higher morbidity and costs compared with endoscopic therapy.[3]

EUS-guided biliary drainage (EUS-BD), described for the first time by Giovannini and colleagues in 2001,[5] has been proposed as an alternative technique with high rates of technical and clinical success, fewer AEs, and lower costs than PTBD.[6-8] Despite these advancements, EUS-BD remains a complex endoscopic procedure that entails multiple technical steps. To overcome these limitations, an electrocautery-enhanced lumen-apposing metal stent (EC-LAMS) delivery system (Electrocautery Enhanced Delivery System and AXIOS Stent [HOT-AXIOS], Boston Scientific Corp, Marlborough, Mass, USA) has been developed to facilitate biliary drainage in a single procedural step. The use of LAMSs for EUS-guided choledochoduodenostomy (EUS-CD) in malignant CBD obstruction has previously been reported, with good technical and clinical success rates.[9-12] In this study, we aimed to analyze the technical and clinical efficacy, as well as safety, of EUS-CD with EC-LAMS in a large cohort of patients with malignant obstructive jaundice in whom ERCP had failed.

METHODS

This study was a retrospective analysis of a prospectively maintained database of all consecutive patients with malignant distal bile duct obstruction who underwent EUS-CD using the EC-LAMS after failed ERCP in a single tertiary referral university hospital between October 2015 and April 2018. The institutional review board of the hospital approved the observational study (NCT02855151) and the protocol was performed in accordance with the Helsinki Declaration.

Study device

The EC-LAMS is a fully covered self-expanding metal stent (SEMS) made up of braided nitinol. The stent is preloaded in a 9F or a 10.8F catheter, with a through-the-scope electrocautery-enhanced delivery system compatible with therapeutic echoendoscopes with a working channel of 3.7 mm diameter or larger. The delivery system allows for endoscopic control and uses a locked 2-step release system to prevent unintended deployment of the second flange. The stent has bilateral anchor flanges to provide lumen-to-lumen apposition. These features are designed to reduce the risk of stent migration and of leakage alongside the stent. The EC-LAMSs are available in different diameters and lengths: 6 × 8 mm, 8 × 8 mm, 10 × 10 mm, and 15 × 10 mm. The 6 mm and 8 mm stents are believed to be more ideal for the EUS-CD procedure and were approved by the CE (European Commission) for EUS-guided biliary drainage. However, these stents are not yet available universally.

EUS-CD procedure

All the EUS procedures were performed with the patient under deep sedation with propofol, and using carbon dioxide for insufflation. The linear array Olympus GF-UCT-180 series echoendoscope, with the EU-ME2 echoprocessor, was used in all procedures. Procedures were performed in an endoscopy room equipped with fluoroscopy. All procedures were done by an endoscopist (A.A.) with a lot of experience in EUS (>500/year) and in EC-LAMS drainage (>100 EC-LAMS, placed for different indications, such as pancreatic fluid collection [PFC] drainage, gallbladder drainage, and biliary drainage).

The bile duct was localized by EUS from the duodenal bulb, and lack of interposing vessels was confirmed using Doppler flow. Transduodenal EUS-LAMS drainage was not attempted if there was neoplastic bulb infiltration or involvement, the CBD diameter was <10 mm, or the distance between the duodenal wall and the CBD was >10 mm. Selection of stent size was based on CBD diameter but was ultimately at the discretion of the endoscopist. The EC-LAMS catheter was then inserted into the working channel of the echoendoscope and secured to the inlet port of the working channel. The delivery system was connected to the electrosurgical generator (settings: pure cut mode, 100 W; ERBE ICC 200, AUTOCUT mode, effect 5 [ERBE Electrosurgery, Tübingen, Germany]).

The catheter was positioned tangentially to the bile duct and introduced into the duct with application of cautery, under EUS guidance. After the catheter was fully inside the target structure, the first flange of the stent was deployed under EUS view. After EUS confirmation of the correct position of the device inside the bile duct, the catheter was slightly withdrawn to create wall apposition, followed by deployment of the second end of the stent using the intrachannel release technique.[13] The endoscope was then gently withdrawn while the catheter control hub was slowly advanced to allow for the release of the second flange from the working channel of the echoendoscope. All patients were followed up daily until discharge, after

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which they were evaluated 30 days after discharge and every 3 months until their death.

Outcome measures

The primary outcomes for this study were technical and clinical success. Technical success was defined as placement of an EC-LAMS in the extrahepatic bile duct in a single-step approach. Clinical success was defined as a decrease in serum bilirubin level of 50% or more within 2 weeks after the procedure of biliary drainage. Secondary outcomes included AEs, procedure times, and rate of stent patency.

AEs were classified as intraprocedural and either immediate or late when they occurred within and after 1 week after stent placement, and were graded according to the American Society for Gastrointestinal Endoscopy lexicon.[14] Stent patency was defined as the time period between stent placement and its eventual obstruction. The total procedure time was defined as the time from insertion to exit of the echoendoscope from the mouth of the patient.

Statistical analysis

STATA (version 15.0) statistical software was used for data analysis. Continuous variables were reported using the mean ± standard deviation and range. Categorical variables were reported in terms of frequency counts and proportions.

RESULTS

Patient and clinical characteristics

Forty-six patients (47.8% women; median age, 73.1 ± 12.6 years) with malignant distal biliary obstruction and failed ERCP underwent direct EUS-CD using EC-LAMS. Patient and clinical characteristics are outlined in Table 1 (Fig. 1).

TABLE 1. Demographic data of 46 patients

Characteristics	Value
Male	24 (52.2)
Female	22 (47.8)
Age (years), mean (SD)	73.1 (12.6)
Cause of biliary obstruction	
Pancreatic cancer	40 (87)
Duodenal cancer	3 (6.5)
Ampullary cancer	2 (4.3)
Distal cholangiocarcinoma	1 (2.2)
Reason for failed ERCP	
Infiltration of the papilla by invasive cancer	19 (41.3)
Inability to get deep biliary cannulation	12 (26.1)
Gastric outlet obstruction	9 (19.6)
Ampulla obscured by duodenal stents	6 (13)

Values are number (%) except where stated otherwise.
SD, Standard deviation.

Procedural outcomes

The bile duct was accessed through a transbulbar approach in 45 patients (97.8%) and with a transgastric (pre-pyloric region) approach in 1 patient (2.2%) (Figs. 2 and 3). In this patient, the transgastric approach was chosen due to instability of the tip of the echoendoscope in the bulb that would have rendered transbulbar drainage unsuccessful. Given that an appropriate position with a distance of <10 mm between the gastric wall and the CBD could be obtained with the endoscope in the stomach, the procedure was safely performed transgastrically. In 34 patients (73.9%), EUS-CD was performed immediately after failed ERCP in the same session. Stent dimensions are shown in Table 2. The procedure was technically successful in 43 of 46 patients (93.5%), with a mean procedural time of 14.7 minutes (range, 5-38 minutes). In 2 of the failed cases, stent misdeployment occurred due to the loss of positioning of the EUS probe in the duodenal bulb during the deployment of the first flange. This resulted in loss of EUS visualization and migration of the first flange of the stent into the space between the CBD wall and the duodenal wall. In these cases, biliary drainage was salvaged by advancing a guidewire through the existing fistula into the bile duct and then across the papilla. A rendezvous technique was then performed and a transpapillary 10 × 40 mm fully covered SEMS was placed in one case. In the second case, a second attempt with 10 × 10 mm EC-LAMS placement through the existing fistula was successful.

In the third failure case, the first flange of a 6 × 8 mm EC-LAMS was initially correctly opened inside the biliary duct but likely due to the small diameter of the CBD (11 mm), the final position of the deployed flange was traversing the CBD wall. Biliary drainage was obtained, however, when the endoscopist placed a double-pigtail 10F, 7-cm plastic stent across the LAMS to help prevent migration.

Nine (19.6%) patients were treated in a single session for concomitant duodenal obstruction by deployment of EC-LAMS for biliary obstruction followed by placement of a duodenal stent (Figs. 4 and 5). In 6 patients, EUS-CD was performed in the setting of an indwelling duodenal stent. In 5 cases, the LAMS was placed proximal to the duodenal stent and placed through the mesh of the stent in the remaining case. In 3 patients, a duodenal stent was placed in a subsequent session, after a mean of 127 days (range, 59-240 days), due to disease progression.

Clinical success was achieved in 42 of 43 patients (97.1%) in which EC-LAMS placement was successful. Trends in bilirubin levels are shown in Figure 6. Clinical failure occurred in a patient who had preoperative multiorgan failure (MOF). The patient died 17 days after the procedure because of fatal arterial bleeding.

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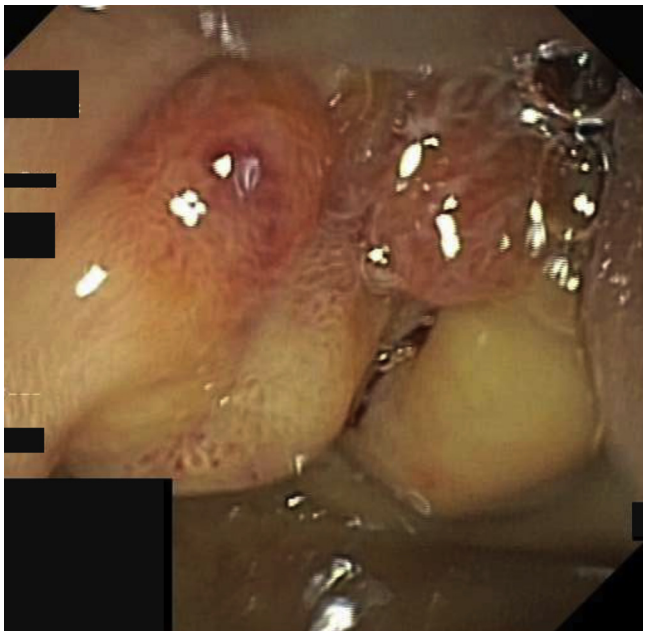

Figure 1. Endoscopic view of infiltration of the papilla by invasive cancer.

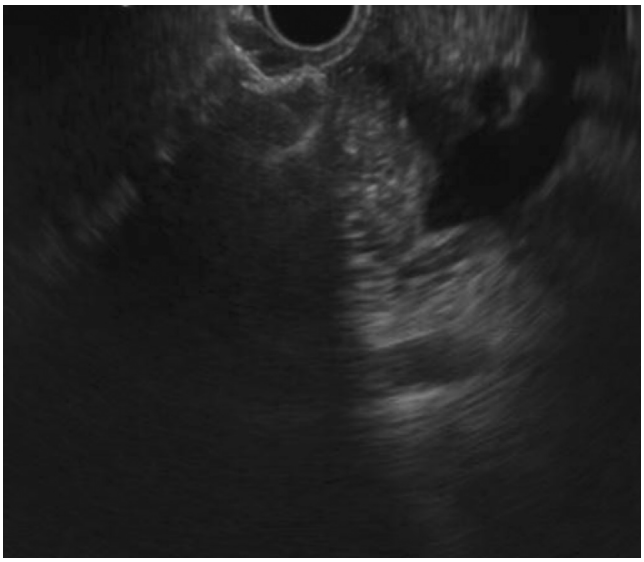

Figure 2. EUS view of the first flange deployment of the electrocautery-enhanced lumen-apposing metal stent (EC-LAMS) in a dilated common bile duct.

Follow-up

Postprocedural management included resumption of oral intake 1 day after the procedure. The mean postprocedure hospitalization time was 6.12 days (range, 2-29 days). The mean follow-up was 114.37 days (95% confidence interval, 73.2-155.4 days). During follow-up, 19 patients died after a mean of 105.3 days (±29.1 days) because of disease-related AEs. The 3-month and 6-month stent patency rates were 87% and 70%, respectively (Fig. 7).

Adverse events

Major AEs occurred in 5 patients (11.6%) after a mean of 83 days (range, 17-148 days). One case of fatal acute duodenal arterial bleeding occurred 17 days after LAMS placement in a patient with preprocedural MOF. In 3 patients, AEs occurred due to duodenal stent obstruction from disease progression. Biliary EC-LAMS malfunction occurred in 2 patients (after 82 and 101 days, respectively) due to food impaction requiring double-pigtail plastic stent placement through the EC-LAMS in order to re-establish stent patency, followed by duodenal stent placement with the stent-in-stent technique. In 1 case, a biliary 6 × 8 mm EC-LAMS, which had been placed in a CBD of 11 mm, migrated after 148 days. This was treated with placement of a transpapillary biliary SEMS using a rendezvous technique through the remaining CD fistula, and duodenal stent placement with the stent-in-stent technique was also performed in this patient. The last AE was an EC-LAMS obstruction after 67 days due to food impaction, which was treated with PTBD in another hospital.

DISCUSSION

The introduction of dedicated devices specifically designed for EUS-guided drainage, such as the LAMS stent (Boston Scientific, Marlborough, Mass, USA) first reported by Binmoeller and Shah[15] in 2011, provided an important contribution to facilitate improvement in the technical success, efficacy, and safety of EUS-BD. Further modification of the device (to the EC-LAMS) with addition of an electrocautery tip has allowed for additional changes in techniques, such as the single-stage technique to directly access the target lumen without the need to exchange devices (one-step procedure). This modified technique decreases the sequential steps, decreases the risk of AEs, reduces the procedural time, and reduces fluoroscopy exposure time.[13,16,17] The experience with such devices comes from EUS-guided drainage of PFC, where the target to drain is always big enough to allow the safe opening of the first flange of the stent. Although the relatively smaller size of the CBD poses a problem with the larger-diameter stents, the availability of smaller stents has overcome this problem, making drainage of the biliary duct feasible.

In this study, we reported our experience with EUS-CD in malignant distal biliary obstruction using the EC-LAMS by retrospectively analyzing a large prospectively maintained database. This study demonstrates that EUS-BD can be achieved with very high technical success (93.5%) as well as clinical success (97.1%). Technical failures occurred due to misdeployment of the first flange of the stent, either due to endoscope instability and loss of positioning, or due to inadequate CBD target size for stent deployment. Based on these observations, we now recommend using this technique in patients with more dilated

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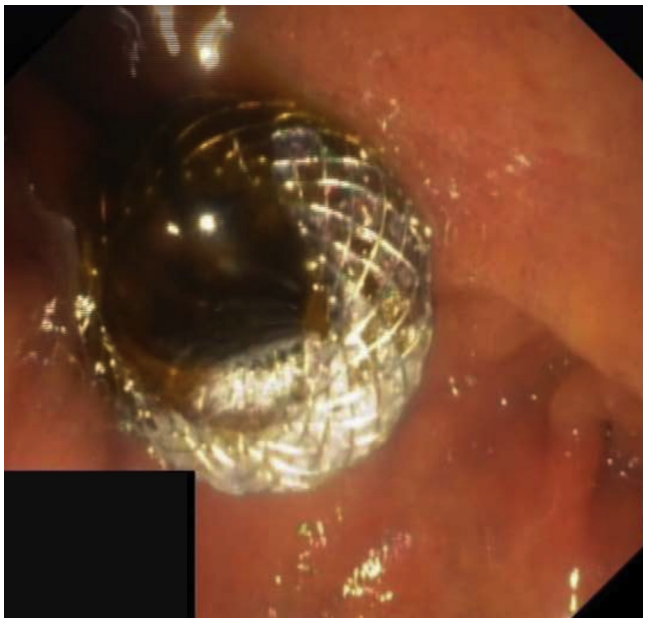

Figure 3. Final endoscopic appearance of the electrocautery-enhanced lumen-apposing metal stent deployed in the duodenal bulb.

TABLE 2. Characteristics of patients who underwent endoscopic ultrasound-guided choledochoduodenostomy

Characteristic	Value
Diameter of common bile duct (mm), mean (SD)	17.26 (3.34)
Bile duct access	
Transbulbar	45 (97.8)
Transgastric	1 (2.2)
Stent diameter	
6 × 8 mm	21 (45.7)
8 × 8 mm	19 (41.3)
10 × 10 mm	6 (13)
Technical success	43/46 (93.5)
Clinical success	42/43 (97.7)
Procedure time (minutes), mean (SD)	14.73 (9)
Postprocedure hospital length of stay (days), mean (range)	6.12 (2-29)
Adverse events	5 (11.6)

Values are number (%) except where stated otherwise.
SD, Standard deviation.

CBD (ie, more than 15 mm) to allow for correct and safe opening of the first flange inside the CBD. As the currently available EC-LAMS system does not allow for recapturing of a partially deployed stent, one should consider pre-loading a guidewire in the EC-LAMS delivery system in order to proceed to over-the-guidewire stent placement in case of misdeployment of the EC-LAMS.

These data are consistent with other published studies, which reported high technical and clinical success rates, confirming the feasibility and efficacy of this kind of EUS-CD-guided approach.[10,11] A recent randomized trial comparing EUS-BD using SEMS and ERCP shows similar technical success rates (90.9% vs 94.1%, $P = .67$), treatment success (97 vs 91.2%, $P = .61$), and AEs (21.2% vs 14.7%, $P = .49$).[18] In a similar retrospective study, technical success rate was comparable between the 2 groups (93.26% vs 94.23%) with a significantly reduced procedural time (30.10 and 35.95 minutes; $P = .05$) and risk of pancreatitis (0% vs 4.8%; $P = .059$) in the EUS group.[19]

The single-stage technique using the EC-LAMS allows the procedure to be performed in only one step, without the need for any additional exchange of accessories, rendering the EUS-CD easier and faster, with a mean procedural time in our study of 14.7 minutes. The current study also suggests promising patency rates of stents placed during EUS-BD. The 3-month and 6-month stent patency rates were 87% and 70%, respectively. This can have a major clinical impact, reducing the need for readmission and reintervention. Of note, 3 of 15 patients (20%) with duodenal obstruction compared with 1 of 27 patients (3.7%) without duodenal obstruction developed stent obstruction, highlighting a higher risk of stent obstruction in the presence of duodenal obstruction.

The AE rate in this study was 11.6%. Although there was a serious AE with fatal hemorrhage, this was a delayed event and further investigation revealed that the patient had multiple co-morbidities, including MOF, cholangitis, and periduodenal collateral vessels, even before EUS-BD. It is certainly feasible that subsequent vessel and/or mucosal erosion due to the presence of the stent, as well as progressive worsening of coagulopathy and the patient's general conditions, may have contributed to the fatal bleeding.

The risk of bleeding in EUS-guided drainage with LAMS has been recently highlighted in several studies.[20,21] The available data are mainly on the LAMS in PFC drainage, where the size of the stent used is generally bigger than the LAMS used for biliary drainage, and where it has been hypothesized that the erosion of big vessels in the retroperitoneum after the cavity collapsed could be responsible for this AE. Bleeding after EUS-CD with LAMS has already been reported[10]; however, further studies are needed to evaluate the rate and possible predictive factors of this AE.

Recent meta-analyses on EUS-BD reported AE rates of 17% to 23%.[22,23] In these studies, all types of EUS-BD were included (ie, transhepatic gastrostomy, rendezvous techniques, or transduodenal approaches) and different types of devices, such as plastic stents or fully covered SEMSs, were used to achieve biliary drainage. When considering this broad group of EUS-guided techniques, some serious AEs were reported, such as pneumoperitoneum, bile leakage, and peritonitis, that were thought to

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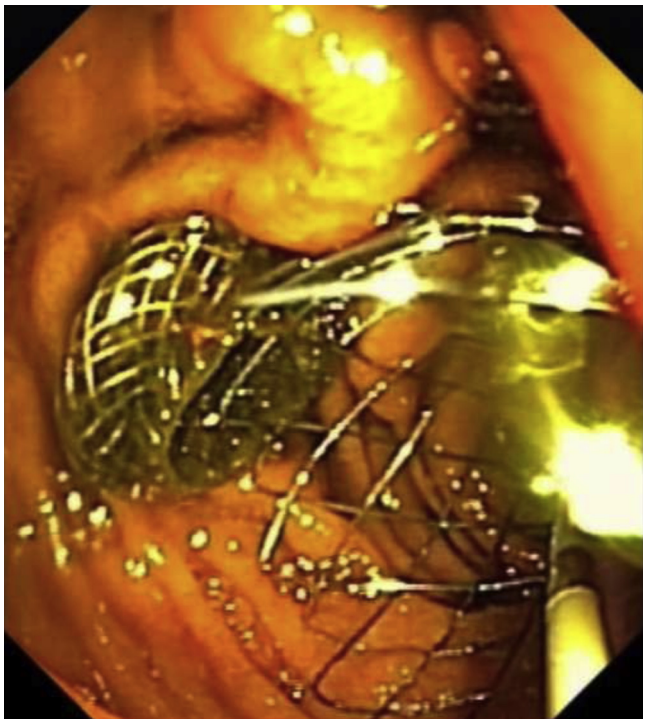

Figure 4. Final endoscopic appearance of the electrocautery-enhanced lumen-apposing metal stent and duodenal self-expanding metal stent in a case of concomitant malignant biliary and duodenal obstruction.

Figure 5. Final fluoroscopic view of biliary electrocautery-enhanced lumen-apposing metal stent and duodenal self-expanding metal stent.

be mainly related to the use of nondedicated devices for the transmural fistula.

The main disadvantage of using plastic stents is the high risk of bile leakage into the peritoneal space, which may cause bile peritonitis. Insertion of a plastic stent requires

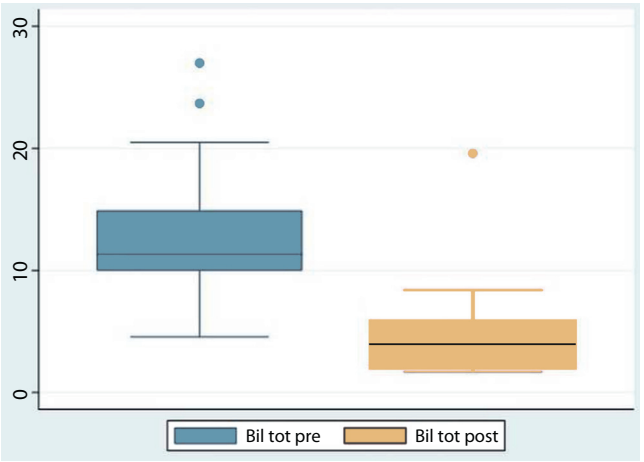

Figure 6. Trend of decreasing bilirubin level at 2 weeks after EUS-guided choledochoduodenostomy.

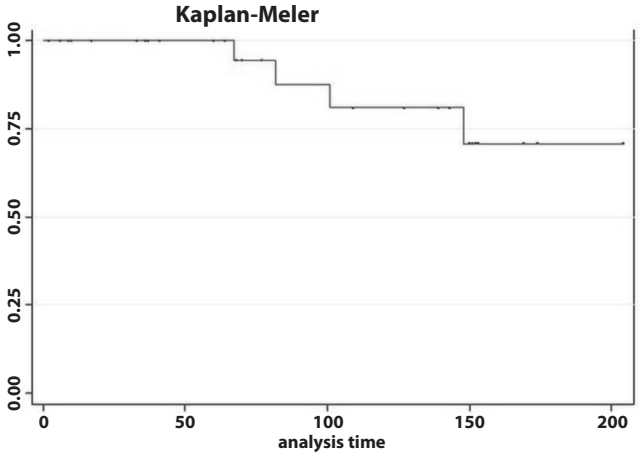

Figure 7. Kaplan–Meier curve showing cumulative stent patency of the electrocautery-enhanced lumen-apposing metal stent.

a fistula tract with a diameter at least equal to or larger than the diameter of the inserted stent. Thus, bile leakage through the gap between the newly formed fistula and the stent may occur. In contrast, because of expandability, a SEMS will automatically seal the gap between the stent and the fistula, thus preventing bile leakage, unless SEMS misplacement or migration occurs. For these reasons, the recently published guidelines from the Asian EUS group recommend the use of a metal stent over the plastic stent for EUS biliary drainage.[24] Moreover, in a recent systematic review of EUS-BD, the rate of AEs was different in relation to the type of the stent used. AEs after SEMS placement were significantly lower when compared with plastic stents (17.52% vs 31.03%; $P = .013$).[23]

In our cohort, the rate of AEs was lower in comparison with previous data, without any cases of bile leakage, post-procedure pancreatitis, peritonitis, or pneumoperitoneum, likely due to the specific design of the EC-LAMS, which allows the creation of a stable and sealed fistula between the

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bile duct and the duodenum. Moreover, the technique is performed across the duodenal bulb, avoiding any passage in the pancreatic parenchyma and thus reducing the risk of acute postprocedural pancreatitis. Furthermore, the AE rate from our series (11.6%) appears significantly lower than the recently reported rate of drainage-related AEs with PTBD (26%).[4] The mean postprocedure hospital length of stay in our cohort was 6.12 days, whereas a study that analyzed hospital length of stay after PTBD placement reported a median of 12 days.[25] Our data appear to be consistent with previous studies, which had a better safety profile, clinical success, fewer re-interventions, costs, and length of hospital stay with EUS-BD compared with PTBD.[6,8,25]

Nevertheless, one of the major advantages of EUS guidance is the possibility of multiple access points, depending upon patient and ductal anatomy. Unlike ERCP, an approachable papilla is not a requisite for successful EUS-guided biliary or pancreatic ductal drainage. In our cohort, EUS-CD was performed in 6 cases despite the presence of an indwelling duodenal stent, and EUS-CD with duodenal stent placement was performed during the same procedure due to concomitant biliary and gastric outlet obstruction in 9 patients.

This study has some limitations, including the retrospective design. In addition, all EUS-BD procedures were performed by experts in interventional EUS procedures in a tertiary care referral center. Therefore, results from this study may not be easily reproducible. Furthermore, the lack of a control group (eg, another EUS-guided technique or radiological approach) does not allow for direct comparison of different techniques.

In conclusion, to our best knowledge, this is the largest cohort of EUS-CD with EC-LAMS in a single center with long-term follow-up. Our study suggests that EUS-CD for unresectable distal biliary obstruction in patients with failed ERCP is effective and can be performed even in a single sequential approach after a failed ERCP or in a single session with palliation of gastric outlet obstruction by duodenal stent placement. As with other interventional EUS procedures, EUS-CD with EC-LAMS should be performed by endoscopists skilled in interventional EUS, ERCP, and who have experience with the LAMS delivery system. Further randomized controlled trials are needed to compare the efficacy of this method with alternative drainage methods, as well as to determine the optimal procedural and stent-related factors that will contribute to improved safety and efficacy.

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Abbreviations: AE, adverse event; CBD, common bile duct; EC-LAMS, electrocautery-enhanced lumen-apposing metal stent; EUS-BD, endoscopic ultrasound-guided biliary drainage; EUS-CD, endoscopic ultrasound-guided choledochoduodenostomy; MOF, multi-organ failure; PFC, pancreatic fluid collection; PTBD, percutaneous transhepatic biliary drainage; SEMS, self-expanding metal stent.

DISCLOSURE: *Drs Anderloni and Sethi have been consultants/speakers for Boston Scientific and Olympus. Dr Repici has been a consultant/speaker for Boston Scientific and Fujifilm.*

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