

EUS-guided biliary drainage with a novel electrocautery-enhanced lumen apposing metal stent as first approach for distal malignant biliary obstruction: a prospective study




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ABSTRACT

Background and study aims Endoscopic retrograde cholangiopancreatography (ERCP) represents the gold standard for jaundice palliation in malignant biliary obstruction (MBO) patients. Biliary drainage using electrocautery lumen apposing metal stent (EC-LAMS) is currently a well-established procedure when ERCP fails. We aimed to assess the technical and clinical success of a new EC-LAMS as the first approach to the palliation of malignant jaundice due to MBO in patients unfit for surgery.

Patients and methods Twenty-five consecutive patients undergoing endoscopic-guided biliary drainage with the new EC-LAMS were prospectively enrolled. Clinical success was defined as bilirubin level decrease > 15% 24 hours after EC-LAMS placement.

Results Mean age was 76.6 ± 11.56 years, and male patients were 10 (40%). EC-LAMS placement was technically feasible in 24 patients (96%) and clinical success rate was 100%. Only one patient (4%) experienced a misplacement rescued by an immediate second EC-LAMS placement. The mean duration of hospital stay was 4.66 ± 4.22 days. The median overall survival was 7 months (95% CI 1–7).

Conclusions In this preliminary study, the new EC-LAMS seems to allow a single-step palliative endoscopic therapy in patients affected by jaundice due to MBO, with high technical and clinical success and low adverse events. Further large prospective studies are warranted to validate these results.

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Introduction

Distal malignant biliary obstruction (MBO) results from different types of tumors, including pancreatic cancer, biliary tract cancer, gallbladder cancer, and metastasis, leading to obstructive jaundice. Endoscopic retrograde cholangiopancreatography (ERCP) represents the gold standard for jaundice palliation in this category of patients [1]. However, surgically altered anatomy (i. e., Whipple intervention, Roux-en-Y gastric bypass, Billroth II surgery), periampullary diverticula, gastric outlet obstruction, and malignant obstruction of the lumen might determine the failure of conventional ERCP in about 5% to 10% of cases, requiring alternative methods of biliary decompression [2]. Percutaneous transhepatic biliary drainage and surgical bypass are well-established alternatives in these patients but are associated with increased morbidity, a longer length of hospital stays, higher costs, and patient discomfort [3,4].

The first endoscopic ultrasonography (EUS)-guided biliary drainage (EUS-BD) was reported in 2001, through a transduodenal access with a needle knife [5]. Subsequently, EUS-BD has considerably evolved by virtue of development of dedicated devices such as lumen apposing metal stents (LAMS), specifically designed for endoscopic ultrasound procedures. LAMS are made of braided nitinol and are fully covered with silicone to prevent tissue ingrowth, with wide flanges on both ends to provide anchorage.

Recently, LAMS have been incorporated into a delivery system with electrocautery mounted on the tip (EC-LAMS), which allows the device to be used directly to penetrate the target structure without the need to utilize a 19G needle, a guidewire, and a cystotome for prior dilation. This has been described for drainage of peri-pancreatic fluid collections, common bile duct (CBD), gallbladder, and for the creation of gastro-jejunal anastomoses. The biliary drainage procedure performed with the EC-LAMS is a one-step procedure that requires less or no accessory exchange, thus potentially decreasing procedure time and risk of complications.

The procedure has been demonstrated to be safe and effective with a technical success rate of 98.2%, clinical success of 96.4%, and a low rate of complications [6]. A systematic review and meta-analyses showed clinical and technical success rates of 87% and 95%, respectively [7]. Currently, EUS-BD is indicated as a rescue therapy for jaundice palliation after ERCP failure [8].

A new EC-LAMS has been recently introduced with a new fully-covered bi-flange shape (Hot-Spaxus; Taewoong Medical Co, Ltd, Goyang-si, Korea), and data about its application for biliary drainage are scanty [9–11].

To this end, we performed a prospective study with a primary endpoint to assess the technical and clinical success of the new EC-LAMS as the first approach to the palliation of jaundice due to malignant biliary obstruction (MBO) in patients judged unfit for surgery because of advanced malignancy. Our secondary endpoints were to assess the rate of adverse events (AEs) and reintervention.

Patients and methods

Study population

This was a prospective pilot study conducted in patients who presented between January 2021 and May 2021 with inoperable jaundice due to malignant distal biliary obstruction and underwent direct endoscopic biliary drainage using the new EC-LAMS (Hot-Spaxus; Taewoong Medical Co, Ltd, Goyang-si, Korea), in four endoscopic referral centers.

Inclusion criteria were age ≥ 18 years; patients with distal malignant biliary obstruction unfit for surgery; dilated CBD (> 15 mm diameter) on either abdominal ultrasound, computed tomography, magnetic resonance or EUS; accessible gallbladder from the duodenum or the stomach for the drainage; and agreement to receive follow-up phone calls; able to provide written informed consent.

Exclusion criteria were coagulation and/or platelets hereditary disorders and/or INR > 1.5 ; PLT $< 50.000/\text{mm}^3$; use of anticoagulants that cannot be discontinued; pregnancy; and inability to sign the informed consent.

Hospitalized patients were clinically evaluated the day after the procedure and daily until discharge. All patients received a phone call on day 7 after the endoscopic procedure. All patients were seen by the treating physician on day 14, and received a phone call on day 30 and every three months for the first 6 months. Hemoglobin, white blood cells, C-reactive protein (CRP), total and direct bilirubin, alkaline phosphatase, and gamma-glutamyl transpeptidase were recorded before the procedure and at 24 hours and 14 days after the procedure.

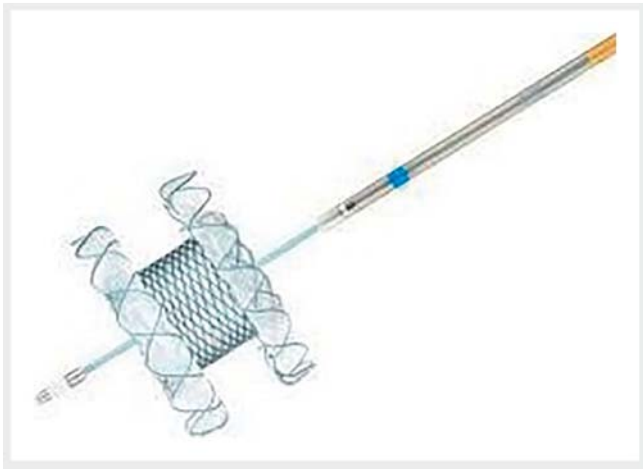
The procedures performed were choledocho-duodenostomy (CDS) and EUS-guided gallbladder drainage target site stomach/duodenum: cholecystogastrostomy (CGS) and gallbladder-duodenostomy (GDS). This study received Institutional Review Board approval at the participating centers and was registered on clinicaltrial.gov with the code: NCT04723199.

Study device

The EC-LAMS is a through-the-scope LAMS delivery system with a distal electrocautery tip (► **Fig. 1**). The stent comprises braided nitinol, fully covered with silicone, with wide flexible flanges on both ends and lengths ranging from 7 to 20 mm. Flares provide accommodative apposition regardless of the wall thickness and have a channel in which a 0.035-inch guidewire can be preloaded. The three available stents with respective diameters and bodies of 8×20 mm, 10×20 mm, and 16×20 mm are all delivered through a 10F delivery catheter with flange diameters of 23, 25, and 31 mm, respectively. The electrocautery tip allows passage of the catheter into the target structure without prior tract dilation, utilizing a current cutting set to pure cut mode of 80–120 Watts and 400–500 Vp. The Hot-Spaxus is approved for pancreatic pseudocysts and gallbladder drainage. All other indications are currently off-label.

Procedures

Informed consent obtained from all subjects prior to undergoing procedures. A therapeutic linear echoendoscope was used in all cases in a room with fluoroscopic capabilities using carbon



► **Fig. 1** Hot-Spaxus preloaded on its electrocautery delivery system.

dioxide (CO₂) insufflation by an endoscopist with proven experience in ERCP and in EUS biliary drainage (EUS-BD). ERCP experience was defined as more than 250 ERCP performed per year, and EUS-BD experience is defined as at least 10 bile duct drainages performed in the 12-month period before participating in the present study.

Procedures were performed both with deep sedation using propofol with anesthesiologic assistance, or under general anesthesia, according to local policies for therapeutic EUS procedures. Once the target structure was identified correctly from the stomach or duodenum, a doppler examination was used to rule out interposed vessels and identify the best site for stent insertion. Placement of the EC-LAMS was performed at the discretion of each endosonographer by using the freehand technique or after puncture of the target organ/cavity with a standard 19G fine-needle aspiration needle, followed by guidewire placement. Proximal flange release was performed under endoscopic or EUS view, the latter, by utilizing the “intrachannel release” technique in which the flange is released inside the operative channel of the echoendoscope and pushed out as the endoscope is withdrawn.

The choice of the stent diameter was decided by the endosonographer on the basis of the drained targeted organ (gallbladder or CBD). The choice of performing CGS, CDS or GDS was instead decided on the basis of the stable scope position and possible interposed vessels. The EC-LAMS placement was performed as first approach. In case of technical failure of the procedure, the patients were treated according to the available local protocols.

Study parameters/endpoints

Technical success was defined as adequate access and successful placement of the stent through the walls of the gastrointestinal tract into the gallbladder or the CBD. Clinical success was defined as bilirubin level decrease >15% 24 hours and >50% 14 days after EC-LAMS placement.

The safety of the procedure was estimated based on the rate of AEs, which were defined as “early” if they occurred during the procedure up to 48 hours after; “late” if they occurred between 48 hours and one month after the procedure and “long-term” if they occurred one month after the procedure.

Statistical analysis

Categorical variables were expressed as frequencies with percentages, whereas continuous variables were presented as mean with standard deviation. Comparison between pre-procedural and post-procedural values of bilirubin and CRP was computed by means of paired Student’s t-test. A subgroup analysis according to the procedure (biliary versus gallbladder drainage) was performed. The analysis was performed using R Statistical Software (Foundation for Statistical Computing, Vienna, Austria), and the level of significance was established at the 0.05 level (2-sided).

Results

Patients

Patient characteristics and procedural indications are summarized in ► **Table 1**.

During the study period, 25 consecutive patients undergoing EUS-guided biliary drainage were enrolled, without previous attempt at ERCP. The mean age was 76.6 ± 11.56 years and 10 patients (40%) were men. None of these patients were referred from external hospitals.

Indications for drainage were biliary obstruction due to pancreatic neoplasia in 15 patients (60%), ampullary cancer in two patients (8%), and biliary cancer in six patients (24%). The remaining two patients presented with pancreatic metastasis and malignant biliary stricture due to colon cancer. Antibiotics were not administered peri-operatively because none of the patients presented with cholangitis.

Ten patients (40%) had been treated previously with chemotherapy, whereas none had received radiotherapy. Of 25 patients who underwent the new EC-LAMS placement, 14 patients (56%) were treated with cholecystogastrostomy (CGS), seven patients (28%) with choledocoduodenostomy (CDS), and four patients (16%) with GDS.

Overall, 10 patients (40%) were treated with an 8 × 20 mm, 13 patients (52%) with a 10 × 20 mm stent and two patients (8%) with a 16 × 20 mm. The freehand technique was used in 13 cases (54.1%), and the intrachannel stent release technique of the proximal flange was used in all the patients (► **Table 1**). No antibiotic therapy was administered in any of the patients.

None of the patients received a coaxial stent placement through the EC-LAMS and none of the EC-LAMS dilated during the same session. Finally, none of the patients received a scheduled EC-LAMS removal.

Outcomes

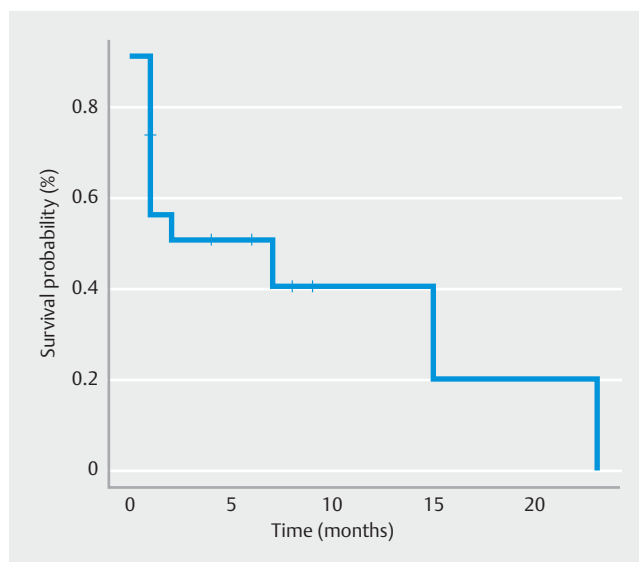
Treatment outcomes were reported in ► **Table 2**. The median follow-up length was 8 months (95% CI 4–9). EC-LAMS placement was technically feasible in 24 patients (96%). Clinical success was achieved in all 25 patients with successful LAMS place-

► **Table 1** Baseline patient and procedure characteristics.

Variable	Total (n = 25)
Age	76.6±11.56
Gender male	10 (40%)
Baseline total bilirubin level (mg/dL)	9.16±12
Baseline PCR (mg/L)	15.74±2.71
Indication to biliary drainage	
▪ Pancreatic neoplasia	15 (60%)
▪ Ampullary cancer	2 (8%)
▪ Biliary cancer	6 (24%)
▪ Pancreatic metastasis	1 (4%)
▪ Malignant stricture due to colon cancer	1 (4%)
Previous chemotherapy	10 (40%)
Previous radiotherapy	0 (0%)
Treatment	
▪ Cholecystogastrostomy	14 (56%)
▪ Choledochoduodenostomy	7 (28%)
▪ Gallbladder-duodenostomy	4 (16%)
Stent used	
▪ 10×20 mm	13 (52%)
▪ 16×20 mm	2 (8%)
▪ 8×20 mm	10 (40%)
Freehand technique	13 (52%)
Intrachannel release of the proximal flange	25 (100%)
Variables were reported as absolute numbers (percentage) or mean (standard deviation) when appropriate	

► **Table 2** Treatment outcomes.

Outcome	Total (n = 25)
Technical success	24 (96%)
Clinical success	24 (96%)
24-h post-treatment total bilirubin level (mg/dL)	4.35±3.23
14 days post-treatment total bilirubin level (mg/dL)	1.23±0.57
24-h post-treatment CRP (mg/L)	7.13±1.74
Adverse event rate	1 (4%)
Duration of hospital stay	4.66±4.22
Median overall survival	7 months (95% CI 1–7)
Variables were reported as absolute numbers (percentage) or mean (standard deviation) when appropriate CI, confidence interval; CRP, C-reactive protein.	



► **Fig. 2** Kaplan-Meier curve reporting median overall survival.

ment, and none of the patients had their LAMS removed during the follow-up. Only five patients (20%) were alive at the end of the follow-up.

Mean total bilirubin level decreased from 9.16 ± 12 mg/dL at baseline to 4.35 ± 3.23 mg/dL at 24 hours ($P < 0.001$) and 1.23 ± 0.57 mg/dL at 14 days ($P < 0.001$), whereas mean CRP decreased from 15.74 ± 2.71 mg/L at baseline to 7.13 ± 1.74 mg/L at 24 hours. Only one patient (4%) experienced an AE, namely EC-LAMS misplacement with the distal flange of the EC-LAMS opened between the gallbladder and the stomach inside the abdomen, which was rescued by an immediate second EC-LAMS placement. The second stent was placed, as the initial one, with the freehand technique, repuncturing freehand the gallbladder, and opened by the intrachannel release. Reviewing the video of the procedure, the malplacement was secondary to an excessive withdrawing of the device by the endosonographer during the distal flange release. An abdominal computed tomography (CT) scan performed 12 hours after the procedure showed a correct LAMS placement with small bile extravasation inside the peritoneum. Patient remained asymptomatic and was discharged 3 days post-procedure to complete a 5-day course of antibiotics. A second abdominal CT scan showed complete resolution of abdominal bile extravasation a week after the procedure. No case of bleeding nor stent migration was registered during the follow-up and none of the patients required reintervention for stent occlusion. Mean duration of hospital stay was 4.66 ± 4.22 days, and median overall survival was 7 months (95% CI 1–7; ► **Fig. 2**).

As reported in ► **Table 3**, of 18 patients treated with gallbladder drainage (CGS and GDS), 17 (94.4%) experienced technical success. If considering that the AE was immediately treated (intraoperative AE), all 18 patients had clinical success (100%). The only AE observed in our series was experienced in a patient treated with CGS. On the other hand, all seven patients treated

► **Table 3** Treatment outcomes in different subgroups.

Gallbladder drainage	
Outcome	Total (n = 18)
Technical success	17 (94.4%)
Clinical success	18 (100%)
Adverse event rate	1 (5.5%)
Duration of hospital stay	4.47 ± 3.48
Median overall survival	8 months (95% CI 1–9)
Bile duct drainage	
Outcome	Total (n = 7)
Technical success	7 (100%)
Clinical success	7 (100%)
Adverse event rate	0 (0%)
Duration of hospital stay	4.82 ± 4.12
Median overall survival	6 months (95% CI 1–8)

CI, confidence interval.

with CDS had technical and clinical success (100%), with no AEs reported.

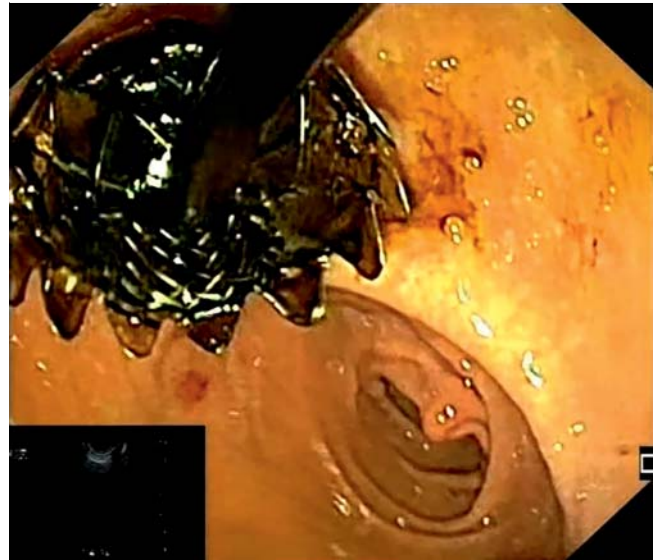
Discussion

EC-LAMS is currently a well-established technique for drainage of jaundice caused by MBO, with technical and clinical success rates of more than 90% with an acceptable AE rate [12]. Placement of an EC-LAMS was primarily reserved only for patients in whom conventional ERCP was unsuccessful [13] or for patients in whom endoscopic drainage by ERCP was not feasible because of surgically altered anatomy [14].

More recently, development of different techniques, such as the freehand technique or intrachannel release, introduction of the water-filled technique among endosonographers [15] and greater expertise have led to placement of EC-LAMS as initial therapy in patients with MBO when ERCP is not feasible [16, 17]. In addition, in patients with pancreaticobiliary malignancies, conventional ERCP may be particularly challenging when there is an indwelling duodenal self-expandable metal stent placed to relieve gastric outlet obstruction at the time of jaundice development [18].

In our prospective study, the EC-LAMS was placed as the initial intervention in all enrolled patients. Notably none of the patients had surgically altered anatomy or duodenal stricture potentially limiting access to the CBD or the gallbladder (► **Fig. 3**).

The technical and clinical success rates were high (96% and 100%), and the rate of AEs was negligible. Moreover, no late or long-term AEs were observed during the follow-up period. As observed in a recently published study by our group [10], no case of bleeding was registered in this study. This is likely due to the smooth and soft shape of the proximal and distal flange



► **Fig. 3** Proximal flange of a 10×20 mm Hot-Spaxus inside the gastric cavity after a cholecystogastrostomy (CGS).

of this new EC-LAMS, which may lead to a lower risk of bleeding if compared to the other competitor LAMS presenting straight and hard spikily extremity that can cause contralateral wall erosion, resulting in a possible bleeding. The only AE observed was stent misplacement, which was immediately rescued by placing a second EC-LAMS, ultimately resulting in clinical success [19]. The mean duration of hospital stay was less than 5 days, and no readmissions were observed during the patient's follow-up.

To date, only one retrospective study by Moon et al. has reported outcomes with this new EC-LAMS for MBO palliation in 17 patients [20]. However, all of the stents were placed multi-stage with initial placement of an 0.035-inch guidewire through a 19 G fine-needle aspiration (FNA) needle. The procedure was technically feasible and clinically effective in all but one patient (94.1%), with a 17.6% overall AE rate.

In our opinion, one of the advantages of this new EC-LAMS is the possibility of placing the stent inside a small cavity or in a small CBD or a small gallbladder. During stent placement, delivery can be moved up and down by the endosonographer, while the distal flange is deployed by the assistant, maintaining the flange at the same point at the tip of the device after entering the target organ.

Based on this premise, this new EC-LAMS may be safely used as first-line therapy in patients with malignant jaundice unfit for surgery. In addition, use of EUS-guided treatment that allows both histopathological diagnosis through fine-needle biopsy [20] and a therapeutic approach in a single stage may reduce both the cost associated with the devices needed for a theoretically failed attempt at ERCP (eg. sphincterotome, needle knife and guidewire) and the rate of potential post-ERCP AEs such as post-ERCP pancreatitis, bleeding or perforations [21].

Finally, the potential for a single-stage EC-LAMS to relieve malignant obstruction obviates the logistic challenges in institutions with limited fluoroscopic equipped rooms for ERCP.

Despite being a prospective series, this study has some limitations. First, the limited sample size might be underpowered to assess the benefits and long-term AEs of the new EC-LAMS placement used as first-line therapy in patients with malignant jaundice unfit for surgery. Second, only patients unfit for surgery were included in the study, hence data on patients who underwent adjuvant chemotherapy before surgical resection were not available. Finally, the heterogeneity in the technical approach with about half of the procedures conducted with the guidewire and the other with the freehand technique may result in a methodology bias and calls for a note of caution in interpretation of our results.

Conclusions

In conclusion, this new EC-LAMS facilitates palliative endoscopic biliary drainage as an initial approach in patients with malignant jaundice who are unfit for surgery, with high technical and clinical success and low AE rates. Further large prospective trials are warranted to validate these results as well as to determine the cost-effectiveness of these devices compared to conventional ERCP.

Competing interests

Dr. Benedetto Mangiavillano and Prof. Jong Moon are consultant for Taewoong medical.

Clinical trial

ClinicalTrials.gov
NCT04723199
TRIAL REGISTRATION: Prospective trial at <http://www.clinicaltrials.gov/>

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