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Lumen-apposing metal stent through the meshes of duodenal metal stents for palliation of malignant jaundice

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Authors

Benedetto Mangiavillano[1,2], Rastislav Kunda[3,4], Carlos Robles-Medranda[5], Roberto Oleas[5], Andrea Anderloni[6], Adrien Sportes[7], Carlo Fabbri[8], Cecilia Binda[8], Francesco Auriemma[1], Leonardo H. Eusebi[9], Leonardo Frazzoni[9], Lorenzo Fuccio[9], Matteo Colombo[6], Alessandro Fugazza[6], Mario Bianchetti[1], Alessandro Repici[2,6]

Institutions

1 Gastrointestinal Endoscopy Unit – Humanitas Mater Domini – Castellanza (VA), Italy
2 Humanitas University, Pieve Emanuele (MI), Italy
3 Department of Surgery, Department of Gastroenterology and Hepatology, and Department of Advanced Interventional Endoscopy, Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, Brussels, Belgium
4 Department of Surgical Gastroenterology, Aarhus University Hospital, Aarhus, Denmark
5 Instituto Ecuatoriano de Enfermedades Digestivas (IECED), Guayaquil, Ecuador
6 Endoscopy Unit, Istituto Clinico Humanitas Research Hospital, Milan
7 Digestive Endoscopy, Institut Arnault TZANCK Gastroenterology Unit, Saint-Laurent-du-Var, France
8 Digestive Endoscopy Unit, Endoscopy Unit, Morgagni-Pietrantoni Hospital, Forlì, Italy
9 Endoscopy Unit, Department of Medical and Surgical Sciences, Sant'Orsola University Hospital, Bologna, Italy

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Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Corresponding author

Benedetto Mangiavillano, MD, Gastrointestinal Endoscopy Unit, Humanitas – Mater Domini, Via Gerenzano n.2, 21053–Castellanza (VA)., Italy
Fax: +0039 0331 476210
bennymangiavillano@gmail.com

ABSTRACT

Background and study aims Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard procedure for malignant jaundice palliation; however, it can be challenging when a duodenal self-expandable metal stent (SEMS) is already in place.

Patients and methods The primary aim of our study was to evaluate the technical feasibility of the placement of a lumen apposing metal stent (LAMS) through the mesh (TTM) of duodenal stents. The secondary aims were to evaluate clinical outcomes and adverse events (AEs) related to the procedures.

Results Data from 23 patients (11 F and 12 M; mean age: 69.5 ± 11 years old) were collected. In 17 patients (73.9 %) TTM LAMS placement was performed as first intention, while in six patients (26.1 %) it was performed after a failed ERCP. Thirteen patients (56.5 %) underwent the procedure due to advanced pancreatic head neoplasia. One technical failure was experienced (4.3 %). The TTM LAMS placement led to a significant decrease in the serum levels of bilirubin, ALP, GGT, WBC and CRP. No cases of duodenal SEMS occlusion occurred and no other AEs were observed during the follow-up.

Conclusions Concomitant malignant duodenal and biliary obstruction is a challenging condition. Palliation of jaundice using TTM LAMS in patients already treated with duodenal stent is associated to promising technical and clinical outcomes.

Introduction

Distal malignant biliary obstruction (MBO) can be caused by different types of tumors, including pancreatic cancer, biliary tract cancer, gallbladder cancer, and metastasis, leading to obstructive jaundice. Endoscopic retrograde cholangiopancreatography (ERCP) is considered the gold standard procedure for jaundice palliation in this setting [1]. However, the presence of surgically altered anatomy (i.e., Whipple intervention, Roux-en-Y gastric bypass, Billroth II surgery), periampullary diverticula, duodenal stent placement, gastric outlet obstruction, and malignant obstruction of the lumen can determine the failure of the procedure in about 5 % to 10 % of cases, requiring alternative methods of biliary decompression [2]. Percutaneous transhepatic biliary drainage (PTBD) and surgical bypass are well established alternatives in these patients, but are also associated with increased morbidity, hospital stay, costs, and patients discomfort [3, 4].

In 2001 Giovannini et al. described the first endoscopic ultrasound-guided biliary drainage (EUS-BD) through transduodenal access using a needle knife [5]. Subsequently, EUS-BD has considerably evolved following the development of dedicated devices, such as lumen apposing metal stents (LAMS). LAMS are made of braided nitinol, fully covered with silicone to prevent tissue ingrowth and leakage, and have wide flanges on both ends to provide apposition of the external wall of the two targeted organs and avoid migration of the stents. Currently, three randomized controlled trials (RCTs) comparing EUS-BD vs ERCP have been published, showing similar safety of EUS-BD compared to ERCP, with fewer cases of tumor ingrowth [6, 7]. Moreover, in one of the studies a longer duration of patency coupled with lower rates of adverse events and reintervention and more preserved QOL were observed in patients undergoing EUS-BD [8].

Recently, LAMS have been incorporated into a delivery system with an electrocautery mounted on the tip (Hot-Axios; Boston Scientific Corp. Marlborough, Massachusetts, United States), which allows the device to be used directly to penetrate the biliary tract without the need of additional devices. In case of malignant jaundice developing after duodenal self-expandable metal stent (SEMS) placement, access to the papilla can be prohibitive or extremely difficult. Thus, the placement of a LAMS through the meshes (TTM) of the duodenal stent can offer an alternative approach to manage malignant jaundice.

The primary aim of our study was to evaluate, in patients with MBO with a previous indwelled duodenal SEMS and in patients with MBO and gastric outlet obstruction (GOO), the technical feasibility of placement of LAMS TTM of duodenal stents. The secondary aim was to evaluate clinical outcomes and adverse events (AEs) related to the procedures.

Patients and methods

Data from patients who underwent LAMS placement TTM of a duodenal stent were retrospectively collected in seven referral centers. Inclusion criteria were: age > 18 years; malignant jaundice with a concomitant gastric outlet obstruction requiring duodenal SEMS placement; malignant jaundice with a previous uncovered duodenal SEMS placed for malignant stricture; patients unfit for surgery; TTM LAMS deployment with or without guidewire placement. Exclusion criteria were: history of PTBD. LAMS were deployed by experienced endoscopists who had performed > 20 LAMS cases for different indications and > 1000 bilio-pancreatic EUS procedures. Technical success was defined as correct placement of the LAMS through the meshes of a duodenal SEMS. Successful clinical outcome was defined as a bilirubin level decrease > 15 % after 24 hours from the LAMS placement. AEs were divided into early, if they occurred < 24 hours, or late, if occurred ≥ 24 hours.

Technical characteristics of the LAMS

A LAMS is an electrocautery-enhanced fully-covered self-expanding metal stent made of nitinol meshes. The stent is preloaded in a 9F or 10.8F catheter, with a delivery system compatible with therapeutic echoendoscopes with a working channel of 3.7 mm diameter or larger. LAMS (Hot Axios – Boston Scientific; Natick, Massachusetts, United States) are currently available with different diameters and lengths: 6 mm × 8 mm, 8 mm × 8 mm, 10 mm × 10 mm, 15 mm × 10 mm and 20 mm × 10 mm. The 6-mm and 8-mm diameter stents are generally indicated for choledoco-duodenostomy (CDS).

EUS-BD TTM procedure

All therapeutic EUS with TTM LAMS placement were performed under deep sedation using carbon dioxide (CO_2) for insufflation. A linear array Olympus and Pentax echoendoscope was used during the procedures. All the procedures were performed in an endoscopy room equipped with X-ray.

When EUS-BD was performed, the common bile duct (CBD) or the gallbladder was identified by EUS from the duodenal bulb, the superior duodenal genu or from the mid descending duodenum. Doppler was used to exclude the presence of interposing vessels. CDS was not attempted in the presence of a CBD diameter < 10 mm, if the distance between the duodenal wall and the CBD was > 10 mm or in the presence of interposing vessels. The choice to drain the gallbladder or the CBD was at the discretion of the endosonographer, according to the scope stability, position and adequate CBD or gallbladder visualization. The endosonographer choose the easiest access to drain the jaundice, performing a CDS when possible, or a GDS as an alternative if the gallbladder was in situ.

The choice between the TTM LAMS placement technique, with or without previous insertion of a guidewire, and the size of the stent were decided during the procedure by the endosonographers on the basis of their experience.

LAMS placement without wire

After identifying the target point TTM, the LAMS delivery system was inserted into the working channel of the scope and locked to the inlet port. The delivery was connected to the generator with a pure cut mode. The tip of the LAMS delivery system was then placed tangentially to the bile duct, or the gallbladder, and introduced under EUS guidance into the duct with application of cautery. Once inside the targeted organ,

the first flange of the LAMS was deployed. Subsequently, the catheter was slightly withdrawn till the appositioning of the distal flange to the wall of the CBD or the gallbladder, then the second flange was deployed, inside the working channel of the echoendoscope using the intra-channel release technique. The echoendoscope was withdrawn while the LAMS outer sheet was advanced releasing the stent out from the operative channel deploying the proximal flange inside the duodenal lumen TTM of the duodenal SEMS.

LAMS placement over the wire

Once the target point TTM was identified, access to the biliary lumen was obtained using a 19G EUS-needle (Expect 19 G; Boston Scientific,,Natick, Massachusetts, United States) through which a 0.018" guidewire (Novagold; Boston Scientific, Natick, Massachusetts, United States) was advanced into the duct or gallbladder. Subsequently the EUS needle was removed, leaving the guidewire in place, and the LAMS delivery system was mounted over the wire (OTW). After the delivery system was locked to the working channel, the technique was carried out as previously described, removing the guidewire at the end of the procedure.

Statistical considerations

Continuous data are shown as mean ± standard deviation (SD) or median and interquartile range (IQR) when not normally distributed. Categorical data are displayed as absolute proportion and percentage (%). Serum values were reported as T0 before the procedures and as T24 24 h after LAMS placement. Tests of hypothesis significance for paired laboratory data, i. e. paired *t*-test or Wilcoxon signed-rank test were provided, as appropriate.

Results

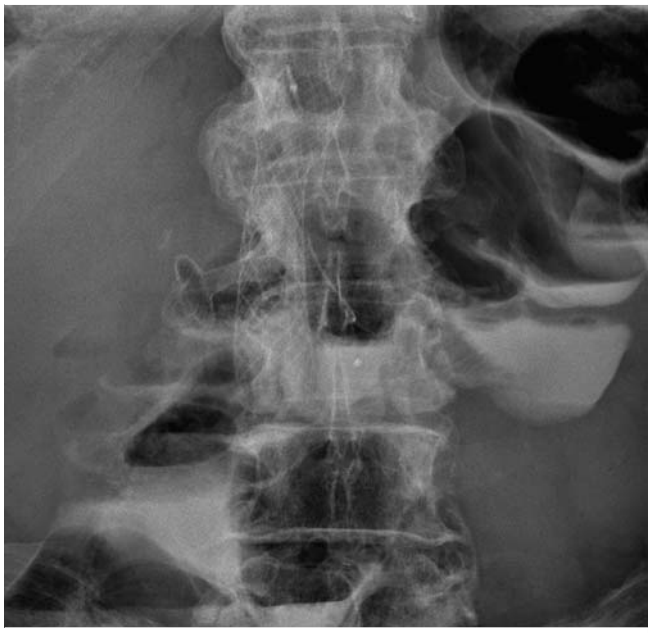
From February 2016 to April 2020, 23 patients (12 males; mean age: 69.5 ± 11 years old) from seven referral endoscopic centers underwent LAMS placement TTM of a duodenal stent for palliation. On the day of the procedure, the mean gastric outlet obstruction score (GOOS) [9] was 2.3 ± 0.9; in particular, four patients (17.4 %) in which a duodenal SEMS was not in place at time of LAMS deployment had a median GOOS of 1 (IQR 0–1) while the 19 patients (82.6 %) with the duodenal SEMS already indwelled presented with a mean GOOS of 2.72 ± 0.46.

In 17 patients (73.9 %), TTM LAMS placement was performed as first intention, whereas in six patients (26.1 %) it was performed after a failed ERCP attempt. Thirteen patients had an advanced pancreatic head neoplasia (56.5 %) (▶ **Table 1**). In four patients (17.4 %) LAMS was placed TTM during the same endoscopic session of the duodenal SEMS deployment (▶ **Fig. 1**), while in 19 patients (82.6 %) LAMS was placed after a median of 7 days (IQR 5–15; range 2–127 days) from the duodenal stenting. Eleven patients received chemotherapy (CT) (47.8 %) and only three received CT plus radiotherapy (RT) (13 %). After duodenal SEMS placement, all patients were able to restart oral intake the day after the procedure.

▶ **Table 1** Types of neoplasia of the patients who underwent TTM LAMS

Patients	Number (%)
Pancreatic head adenocarcinoma	13 (56.5 %)
Advanced ampulloma	2 (8.7 %)
Breast cancer metastases	2 (8.7 %)
Distal CBD neoplasia	2 (8.7 %)
Pancreatic NET	1 (4.35 %)
Duodenal adenocarcinoma	1 (4.35 %)
Gallbladder neoplasia	1 (4.35 %)
Recurrence of a previous distal esophageal adenocarcinoma	1 (4.35 %)

TTM, through the mesh; LAMS, lumen apposing metal stent; CBD, common bile duct; NET, neuroendocrine tumor



▶ **Fig. 1** X-ray image showing the LAMS inside the mesh of the duodenal SEMS.

LAMS placement led to a significant decrease in serum levels of total and direct bilirubin, alkaline phosphatase, gamma-glutamyl transferase, white blood cells, and C-reactive protein at 24 hours after the procedure (▶ **Table 2**). All patients were free from jaundice after a median follow-up of 241 days (IQR 81–387 days), and no cases of duodenal SEMS occlusion were observed. The major technical features and clinical outcomes for each patient are reported in ▶ **Table 3**.

Technical features

Fourteen patients (60.9 %) underwent gallbladder-duodenostomy (GDS) and nine patients underwent choledoco-duodenostomy (CDS) (39.1 %). Among patients undergoing CDS, the mean diameter of CBD was of 18.3 ± 6.0 mm. Four procedures

▶ **Table 2** Decrease in serum levels, in terms of percentage and mean or median value, before and 24 hours after TTM LAMS placement.

	%	T0 (serum value)	T24 h (serum value)	*P*
Total bilirubin	17.1 %	14.6 ± 9.3 mg/dL	12.1 ± 8.6 mg/dL	0.002
Direct bilirubin	18.1 %	10.5± 7.8 mg/dL	8.6 ± 7.2 mg/dL	0.002
Aspartate transaminase (AST)	29.2 %	133.7± 760.4 U/L	94.6± 47.3 U/L	0.170
Alanine transaminase (ALT)	37.1 %	130.5± 95.5 U/L	84 ± 55.3 /L	0.136
Alkaline phosphatase (ALP)	4.8 %	540 (426–1458) U/L	514 (394–1232) U/L	0.015
gamma-glutamyl transferase (γGT)	6.9 %	506 (300–756) U/L	471 (225–652) U/L	0.012
Amylase	2.7 %	123.4 ± 82.7 U/L	120.1 ± 61.5 U/L	0.781
White blood cells (WBC)	16.9 %	11.2 ± 6.1 × 10^3/Ul	9.3 ± 3.9 × 10^3/Ul	0.013
C-reactive protein (CRP)	16.3 %	9.2 (7.5–18.5) mg/dL	7.7 (4.5–12.3) mg/dL	0.002

TTM, through the mesh; LAMS, lumen apposing metal stent.
Paired t-test or Wilcoxon signed-rank test were applied, as appropriate.

▶ **Table 3** Technical features and clinical outcomes for each patient.

Patient number	Sex and age	CDS/GDS	OTW	Duodenal stent	Clinical outcome until death
1	F, 69 yr	CDS	No	Indwelled	No AEs
2	M, 76 yr	CDS	Yes	Indwelled	Technical failure
3	M, 77 yr	GDS	No	Placed during the same session	No AEs
4	M, 74 yr	CDS	No	Indwelled	No AEs
5	M, 76 yr	CDS	Yes	Placed during the same session	No AEs
6	M, 71 yr	CDS	Yes	Placed during the same session	No AEs
7	F, 33 yr	GDS	yes	Placed during the same session	No AEs
8	M, 56 yr	CDS	No	Indwelled	No AEs
9	M, 79 yr	CDS	No	Indwelled	No AEs
10	F, 61 yr	GDS	No	Indwelled	No AEs
11	F, 57 yr	CDS	No	Indwelled	No AEs
12	F, 78 yr	CDS	No	Indwelled	No AEs
13	F, 69 yr	GDS	No	Indwelled	No AEs
14	F, 73 yr	GDS	No	Indwelled	No AEs
15	M, 68 yr	GDS	No	Indwelled	No AEs
16	F, 86 yr	GDS	No	Indwelled	No AEs
17	F, 71 yr	GDS	No	Indwelled	No AEs
18	M, 68 yr	GDS	No	Indwelled	No AEs
19	F, 85 yr	GDS	No	Indwelled	No AEs
20	M, 62 yr	GDS	No	Indwelled	No AEs
21	M, 68 yr	GDS	No	Indwelled	No AEs
22	F, 69 yr	GDS	No	Indwelled	No AEs
23	M, 74 yr	GDS	No	Indwelled	No AEs

CDS, choledoco-duodenostomy; GDS, gallbladder-duodenostomy;
AE: adverse event.

(17.4%) were performed OTW: three CDS and one GDS performed after a transbulbar guide-wire (Novagold; Boston Scientific, Natick, Massachusetts, United States) was released in the CBD using a 19G EUS needle. In all patients except one the LAMS final deployment was performed using the intra-channel release technique (95.6%) [10]. X-rays were used at the end of all the procedures to check the correct expansion and location of both biliary and duodenal stents. The diameter and length of the duodenal SEMSs were 22 mm × 60 mm in nine cases (39.1%), 22 mm × 90 mm in twelve cases (52.2%), 22 × 100 mm (4.35%) in one case, and 22 × 120 mm in another case (4.35%). All duodenal SEMSs were uncovered (Wallflex; Boston Scientific, Natick, Massachusetts, United States or Niti-S Taewoong; Korea). All LAMSs were Hot-Axios (Boston Scientific, Natick, Massachusetts, United States): 6 mm × 8 mm in seven cases (30.4%), 8 mm × 8 mm in one case (4.4%) and 10 mm × 10 mm in 15 cases (65.2%). In all 14 patients who underwent a GDS, a 10 × 10 mm LAMS was used. In two patients a biliary uncovered SEMS (8.7%) had been deployed during a previous procedure, and in another patient an hepatico-gastrostomy (HGS) was in place and occluded. In one patient, due to the presence of cholangitis and cholecystitis, an HGS was also performed during the same session. Technical success was achieved in 22/23 (95.6%) patients. In one patient an early migration of the proximal flange out of the CBD into the duodenal lumen occurred immediately after LAMS deployment (4.4%); thus, the LAMS was immediately removed and the patient underwent a CGS during the same endoscopic procedure. The LAMS was then removed and a trans-gastric drainage of the gallbladder with a second LAMS was performed.

Demographic characteristics of the included patients and the technical aspects of the procedures are reported in ▶ **Table 4**.

▶ **Table 4** Demographic characteristics of the patients and technical aspects of the combined procedures.

Number of enrolled patients	23
Age (years ± SD)	69.5 ± 11
Sex	11 F and 12 M
Previous failed attempt of ERCP	26.1% (6 patients)
Type of anastomosis	14 GDS (60.9%) and 9 CDS (39.1%)
Palliative treatment	100%
LAMS type	7 patients (30.8%): 6 × 8 mm 1 patient (4.4%): 8 × 8 mm 15 patients (65.2%): 10 × 10 mm
Procedure performed after guide-wire placement	17.4% (4 patients: 3 CDS and 1 GDS)
Intrachannel release	95.6% (22 patients)
Type of duodenal SEMS	39.1% (9 patients): 22 × 60 mm 52.2% (12 patients): 22 × 90 mm 4.35% (1 patient): 22 × 100 mm 4.35% (1 patient): 22 × 120 mm
Placement duodenal SEMS and LAMS during the same session	4 patients (17.4%) (3 CDS and 1 GDS)

ERCP, endoscopy retrograde cholangiography; SEMS, self expanding metal stent; LAMS, lumen apposing metal stent; CDS, choledoco-duodenostomy; GDS, gallbladder-duodenostomy.

Adverse events

No early or late bleeding, perforation, stent occlusion or acute pancreatitis were encountered. Patients were discharged a median 3 days (IQR 2–3) after the LAMS placement. All patients were followed until death (median survival time from LAMS placement: 241 days, IQR 81–387). No LAMS-related (perforation, occlusion, migration, cholecystitis, cholangitis, bleeding) or duodenal SEMS-related (perforation, occlusion or migration) AEs were recorded.

Discussion

Ampullary and periampullary malignant diseases, such as pancreatic head neoplasia, distal cholangiocarcinoma, gallbladder neoplasia, or peripancreatic metastatic lesions are usually diagnosed at an advanced stage. Thus, patients are unfit for surgery and only palliative treatment can be accomplished, since CT and RT are no longer indicated for end-stage disease [11]. When a patient is judged unfit for surgery, survival is often less than 6 months and only palliative treatment can be proposed [12]. Concomitant MBO and duodenal obstruction causing gastric outlet obstruction are rare, present in 6% to 9% of all periampullary malignancies [13]. Endoscopic duodenal stenting with SEMS insertion is, nowadays, a standardized endoscopic procedure for the relief of the malignant GOO, with a clinical success rate ranging between 84% to 93%, and a technical success rate ranging between 93% and 97% [14, 15]. Moreover, procedural costs and hospital stay are lower compared to the surgical palliation [16, 17].

Endoscopic biliary drainage is currently the most common treatment for jaundice in patients with MBO mainly by ERCP with stent placement [18, 19].

Endoscopic treatment can be challenging when MBO and duodenal obstruction arise simultaneously or if the MBO occurs subsequent to duodenal SEMS placement. In recent years, LAMS have changed the approach to MBO. EUS-BD is currently performed as a rescue therapy for jaundice palliation after ERCP failure [20]; however, recent RCTs have shown non-superiority of ERCP vs EUS-BD as first intention for biliary drainage [6–8]. The procedure has been described as safe and effective with a low rate of complications [21]. A recent systematic review and meta-analyses showed clinical and technical success rates of EUS-BD of 87% and 95%, respectively [22].

In our series, no case of recurrent GOO occurred, probably due to the short survival of these patients. In case of a duodenal SEMS occlusion and a TTM LAMS in place, a second duodenal stent can be deployed inside the previous one, ideally not covering the LAMS. If the stenosis occurs at the level of the LAMS, an EUS-guided gastro-jejunostomy [23] should be considered, since the placement of a metal duodenal stent over the LAMS could cause its occlusion.

Once a duodenal stent is in place, patients with distal MBO have a high-risk of ERCP failure, related to difficulty of CBD cannulation, difficult access to the second part of the duodenum due to SEMS ingrowth, or due to a malignant encasement of the papilla [24]. If the papillary area is reachable, cannulation can still be challenging, implying the need for more advanced cannulation techniques such as pre-cut, double guidewire (DGW) technique or pancreatic septotomy, with a high risk of post-ERCP pancreatitis (PEP) [25].

On the contrary, a recent report did not observe any cases of post-procedural pancreatitis among 46 patients who underwent EUS-BD after failed or unfeasible ERCP [26].

To our knowledge, only two case reports have been published in the literature about placement of a LAMS TTM of an uncovered duodenal stent after failed ERCP [27, 28]. In our series, we experienced a 95.6 % technical success rate and no early or late AEs were recorded. In particular, no post-procedural pancreatitis was reported. None of the patients experienced abdominal pain immediately or days after TTM LAMS placement. Only one case of technical failure (4.4 %) occurred, during which complete migration of the LAMS inside the duodenal lumen was observed. The LAMS migration occurred in one of three patients who underwent both CT and RT, whereas all other patients underwent only CT or no treatment. Notably, tissue treated by RT often becomes hard and rigid; this could explain the early migration of the LAMS immediately after its deployment [29]. The clinical outcome of the enrolled patients showed a decrease of about one-fifth of the T0 value of the bilirubin and of about one-third of the transaminase value 24 hours after from the procedure. In our cohort, GDS and CDS provided similar outcomes with no significant differences between the two procedures. However, it is still controversial whether GDS should be considered only in case of failure of CDS. Thus, larger studies comparing GDS and CDS in patients with or without duodenal SEMS are warranted to define if the two procedures are equally effective.

Hepaticogastrostomy has been proposed as an alternative procedure for biliary drainage, although it is challenging in expert hands. Thus, in our opinion, with the advent of LAMS, HGS should be limited to cases with malignant hilar obstruction or, more rarely, to patients in which LAMS placement is not feasible due to surgically altered anatomy. Nevertheless, studies comparing these two approaches would provide additional data to define the most appropriate options for palliative jaundice treatment.

Conclusion

In conclusion, concomitant malignant duodenal and biliary obstructions are rare and challenging conditions for the endoscopist. When a stricture occurs in the papillary area or above it, placement of a duodenal SEMS is mandatory before proceeding to ERCP. After SEMS placement, if ERCP fails, EUS-BD using LAMS can be considered. Draining the CBD or the gallbladder through the duodenal stent mesh is technically feasible and clinically successful. Larger prospective studies are warranted to confirm our promising data.

Competing interests

The authors declare that they have no conflict of interest.

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