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Mangiavillano B, Auriemma F, Lamonaca L, Repici A

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A NOVEL LUMEN APPOSING METAL STENT WITH AN ELECTROCAUTERY-TIP FOR DIFFERENT INDICATIONS: INITIAL EXPERIENCE IN A REFERRAL CENTER

[1,2]Benedetto Mangiavillano, [1]Francesco Auriemma, [1]Laura Lamonaca, [2,3]Alessandro Repici

[1] Gastrointestinal Endoscopy Unit – Humanitas Mater Domini – Castellanza (VA); [2]Humanitas University, Pieve Emanuele, Italy; [3]Digestive Endoscopy Unit, Humanitas Research Hospital, Milan;

Italy

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Corresponding to:

Benedetto Mangiavillano, MD

Gastrointestinal Endoscopy Unit, Humanitas - Mater Domini

Via Gerenzano n.2, 21053– Castellanza (VA)

Tel: 0039 0331 476205 – 381

Email address: bennymangiavillano@gmail.com

Abstract

Background and study aims: Recently, a new electrocautery lumen-apposing metal stent (EC-LAMS) has been launched. The primary aim of our study was to assess the feasibility of the freehand placement, with intra-channel release, of the new EC-LAMS. The secondary aims were to assess technical and clinical outcomes and rates of adverse events.

Patients and Methods: We retrospectively evaluated 5 patients (3F; mean age: 75.6 ± 14.6 ys) who underwent new EC-LAMS placement for different indication (cholecystitis, malignant biliary obstruction and malignant gastric outlet obstruction). We described all the procedures of EC-LAMS placement, providing also an video of one of them (online supplementary material).

Results: Technical and clinical success was achieved in all patients who underwent new EC-LAMS placement, and no AEs were experienced. All of the EC-LAMS were placed using freehand technique with intra-channel release.

Conclusions: Our initial experience with the new EC-LAMS showed a good performance of this device for different indications, especially if the stents are placed freehand and with intra-channel release. Further studies are needed to confirm our preliminary data and first impression about this new EC-LAMS.

Introduction

Endoscopic ultrasound (EUS)-guided drainage procedures are increasing, especially after the development of lumen-apposing metal stents (LAMS). Some authors prefer an initial placement of a wire using a fine needle aspiration (FNA) needle [1]. The use of LAMS has shown to decrease recovery time, costs, and duration of hospital stay, compared to previous treatments [2]. There are several main indications for LAMS placement, such as for the treatment of pancreatic pseudocyst, walled-off pancreatic necrosis (WOPN), malignant biliary obstruction, cholecystitis and gastric outlet obstruction (GOO) [3,4,5,6]. LAMS can be also placed through the meshes of an indwelled duodenal self-expandable metal stent, during the same procedure [7,8]. Until now, in most of the published studies, the Hot-Axios (Boston Scientific, Natick, Mass.) LAMS has been used, and only few studies reported the use of the Spaxus (Taewoong medical, Ltd.) LAMS. Recently, a new electrocautery LAMS (EC-LAMS) (Hot-Spaxus™, Taewoong medical, Ltd.) has been launched, and only one case report and a study with a porcine model [9,10] have been published about the use of this device. The primary aim of our study was to assess the feasibility of the freehand placement with intra-channel release of the new EC-LAMS. The second aim was to assess technical and clinical outcome and rate of adverse events (AEs).

Materials and Methods

From July to December 2020, we retrospectively indentified 5 patients (3F and 2M; mean age: 75.6 ± 14.6 ys) who underwent new EC-LAMS placement for different indications. Clinical and technical features of the EC-LAMS placements are reported in the Table 1.

Features of the new EC-LAMS

The new EC-LAMS (Hot-Spaus™; Taewoong medical Ltd.) is a fully covered metal stent (FCSEMS) with a bi-flange shape, designed to prevent migration and maintain anastomotic conduit between two adjacent organs. The flexible flare design helps accommodative apposition regardless of the wall thickness; the available diameters of the stent are 8, 10 and 16 mm, with a standard length of 20 mm but with an accommodation length from 7 to 20 mm. The diameter of the flange at both ends is 25 mm. The Hot-Spaxus™ is pre-loaded in an electrocautery delivery system. It has an electrocautery-tip which is designed to penetrate the tissue of the target organs. The diameter of the delivery system is 10 Fr with a working length of 180 cm.

Cases reports

Case 1

A 67-year-old severely obese woman was admitted to our emergency room for upper right quadrant pain, fever, hypotension and dyspnea. Biochemical evaluation showed increased WBC. Renal function was impaired and a significant increase of cholestasis and cytolysis enzymes was observed. A fast abdominal ultrasound showed a hydropic gallbladder with thickened walls with sludge and small stones inside. Despite initial resuscitation procedures and broad-spectrum antibiotic therapy, the clinical conditions became increasingly worse. In this context of multi-organ failure (MOF) due to a septic shock, we decided to perform emergently and endoscopic ultrasonographic (EUS) drainage of the gallbladder. Under EUS guidance, a cholecystoduodenostomy (CDS) with a 10 x 20 mm EC-LAMS was performed. The procedure was carried out without fluoroscopy in the intensive care

unit (ICU). No AEs were observed. The patients died one week later for renal failure, after cholecystitis was resolved [9].

Case 2

A 65-year-old woman was admitted to our emergency department due to jaundice and weight loss of 6kg in the past three months. A CT scan showed a 4 cm neoplasia of the pancreatic head, with mesenteric vein involvement, common bile duct (CBD) dilation till 15 mm and dilated gallbladder. An EUS plus fine needle biopsy (FNB) with macroscopic on-site evaluation (MOSE) was performed and, after an unsuccessful ERCP procedure with failure to cannulate the CBD, we decided to perform a cholecystogastrostomy (CGS) with the new 10 x 20 mm EC-LAMS. No AEs were experienced during the procedure and the patient was discharged 3 days after procedure. No AEs were reported during the 30 days telephone follow-up.

Case 3

A 90-year-old man was admitted to our emergency department for fever, jaundice and weight loss of 8kg in the past 8 months. A CT scan showed a 5 cm neoplasia of the head of the pancreas, with mesenteric vessels involvement, and with a 20 mm CBD dilation with gallbladder empyema. An EUS plus FNB with MOSE was performed and a CGS with a 16 x 20 mm EC-LAMS was directly performed, without a prior attempt of ERCP. No AEs were experienced during the procedure and the patient was discharged 5 days after procedure. No AEs were reported during the 30 days telephone follow-up.

Case 4

A 63-year-old man was admitted to our emergency department for vomit over the last two days. The patient had been recently diagnosed with gastric antral adenocarcinoma with invasion of the duodenum and of the pancreatic head, but without peritoneal involvement. The patient was judged unfit for surgery and no chemotherapy was started. The CT scan showed gastric outlet obstruction due to the gastric neoplasia with a 8 cm neoplastic stenosis of the duodenum. Due to his poor clinical conditions, the long neoplastic stricture and his limited survival expectancy, we decided to perform directly an EUS-guided gastro-jejunostomy (GJS). A 7 Fr nose-jejunal drainage (NJD) was advanced over a wire, as far as possible beyond the stricture. The jejunal loops were irrigated through the NJD with a mixture solution of contrast medium, metilen blue and saline solution with the intent to dilate as much as possible the loops. After identifying the closest target point to one of the jejunal loops, the GJS was performed using a 16 x 20 mm EC-LAMS. The patient was discharged after three days and he restarted feeding 48 hours after the procedure (video). In this case the procedure was performed with an off label indication for this LAMS. No AEs were reported during the 30 days telephone follow-up.

Case 5

A 93-year-old woman was admitted to our endoscopy unit for jaundice and weight loss of 10kg in the past 8 months. A CT scan showed a 35 mm ampullary cancer with upstream dilation of the CBD up to 30 mm. We decided to place, as first intention, a LAMS for jaundice palliation. Under EUS guidance we performed a choledochoduodenostomy (CDS) with the new 8 x 20 mm EC-LAMS. No AEs were experienced during the procedure and the patient was discharged 3 days after procedure. No AEs were reported during the 30 days telephone follow-up.

Discussion

In our series we observed an excellent feasibility of the placement of the new EC-LAMS, with an easy intra-channel release. The technical and clinical success was achieved in all patients who underwent EC-LAMS

placement, and no AEs were experienced. All EC-LAMS were placed with freehand technique and intra-channel release. We chose this technique for two reasons: the first is that the freehand technique allows to avoid a possible guide-wire displacement, diminishing possible AEs and avoiding that, during the introduction of the tip in the targeted organ, the tip could penetrate in a different axis, compared to the axis of the guide-wire; the second is that, with the intra-channel release, the scope remains strictly attached to the organs' wall, allowing a perfect control of the device, during the stent release. During the placement of the new EC-LAMS we observed, differently to other types of LAMS with blocked steps in the handle, a better control of the distal flange, especially when the targeted organ is not too dilated, as during GJS or during choledocoduodenostomy (CDS). In these particular and challenging cases, during the distal flange opening, it is possible to move the device, maintaining the opened flange in the same position of the tip when the stent is closed. Further studies are needed to confirm our preliminary data and first impressions about this new EC-LAMS.

Statement of Ethics:

Authors state that subjects have given their written informed consent. Written informed consent was obtained from the patient for publication of this case report and any accompanying images.

This study protocol was reviewed and approved by local Independent Ethic Committee, approval number 35/21 HMD.

Conflict of interest statement:

The Authors declare no conflicts of interests related to this research.

Author Contributions:

Benedetto Mangiavillano: Performed the cases, ideated and wrote the paper

Francesco Auriemma and Laura Lamonaca: Edited the video

Alessandro Repici: Approved the paper

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Data Availability Statement:

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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Patients	***Sex and Age***	***Indication to EC-LAMS***	**EC-LAMS type**	***Anastomosis***	***Note***	***Follow-up***
1	F, 63	Cholecystitis in MOF	10x20 mm	GDS	No X-ray	7 days
2	F, 65	Jaundice in pancreatic cancer	10x20 mm	CGS	None	30 days
3	M, 90	Jaundice in pancreatic cancer	16x20 mm	CGS	None	30 days
4	M, 63	GOO for pancreatic neoplasia with duodenal infiltration	16x20 mm	GJS	Jejuna loop dilation with NBD	30 days
5	F, 93	Ampullary cancer	8x20 mm	CDS	None	30 days

Table 1: Features and EC-LAMS type of the enrolled patients

Acronyms:

EC-LAMS: electocautery lumen-apposing metal stent

GDS: gallbladder duodenostomy

CGS: cholecystogastrostomy

CDS: choledoco-duodenostomy

GJS: gastrojejunostomy

GOO: gastric outlet obstruction

NBD: naso-biliary drainage