A Novel Lumen-Apposing Metal Stent with an Electrocautery Tip for Different Indications: Initial Experience in a Referral Center

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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 (3 F; mean age: 75.6 ± 14.6 years) who underwent new EC-LAMS placement for different indications (cholecystitis, malignant biliary obstruction, and malignant gastric outlet obstruction). We described all the procedures of EC-LAMS placement, providing also a video of one of them (see online suppl. material; for all online suppl. material, see www.karger.com/doi/10.1159/000518539). 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 the 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.

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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 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, malignant biliary obstruction, cholecystitis, and gastric outlet obstruction [3–6]. 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, MA, USA) LAMS has...
been used, and only few studies have 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 1 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 free-hand placement with intra-channel release of the new EC-LAMS. The secondary aim was to assess technical and clinical outcome and rate of adverse events (AEs).

**Materials and Methods**

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

**Features of the New EC-LAMS**

The new EC-LAMS (Hot-Spaxus™; Taewoong Medical Ltd.) is a fully covered metal stent with a bi-flange shape, designed to prevent migration and maintain anastomotic conduit between 2 adjacent organs. The flexible flare design helps accommodate 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.

**Case 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 in 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 multiorgan failure due to septic shock, we decided to perform emergently EUS drainage of the gallbladder. Under EUS guidance, a cholecystoduodenostomy with a 10 × 20 mm EC-LAMS was performed. The procedure was carried out without fluoroscopy in the intensive care unit (ICU). No AEs were observed. The patient died 1 week later because of renal failure, after cholecystitis was resolved [9].

**Case 2**

A 65-year-old woman was admitted to our emergency department due to jaundice and a weight loss of 6 kg in the past 3 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 with macroscopic on-site evaluation 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 × 20 mm EC-LAMS. No AEs were experienced during the procedure, and the patient was discharged 3 days after the procedure. No AEs were reported during the 30-day telephone follow-up.

**Case 3**

A 90-year-old man was admitted to our emergency department for fever, jaundice, and a weight loss of 8 kg 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 fine-needle biopsy with macroscopic on-site evaluation was performed, and a CGS with a 16 × 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 the procedure. No AEs were reported during the 30-day telephone follow-up.

**Case 4**

A 63-year-old man was admitted to our emergency department for vomit over the last 2 days. The patient had been recently diag-

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

| Patients | Sex and age | Indication to EC-LAMS | EC-LAMS type, mm | Anastomosis | Note | Follow-up, days |
|----------|-------------|-----------------------|------------------|-------------|------|----------------|
| 1        | F, 63       | Cholecystitis in MOF   | 10 × 20          | GDS         | No X-ray | 7              |
| 2        | F, 65       | Jaundice in pancreatic cancer | 10 × 20 | CGS         | None | 30             |
| 3        | M, 90       | Jaundice in pancreatic cancer | 16 × 20 | CGS         | None | 30             |
| 4        | M, 63       | GOO for pancreatic neoplasia with duodenal infiltration | 16 × 20 | GJS         | Jejunal loop dilation with NBD | 30 |
| 5        | F, 93       | Ampullary cancer       | 8 × 20           | CDS         | None | 30             |

EC-LAMS, electrocautery lumen-apposing metallic stent; MOF, multiorgan failure; GDS, gallbladder duodenostomy; CGS, cholecystogastrostomy; CDS, cholecystoduodenostomy; GJS, gastrojejunostomy; GOO, gastric outlet obstruction; NBD, naso-biliary drainage.
nosed 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 an 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 gastrojejunostomy (GJS). A 7-Fr nose-jejunal drainage was advanced over a wire, as far as possible beyond the stricture. The jejunal loops were irrigated through the nose-jejunal drainage with a mixed solution of contrast medium, methylene 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 × 20 mm EC-LAMS. The patient was discharged after 3 days, and he restarted feeding 48 h after the procedure (online suppl. video). In this case, the procedure was performed with an off-label indication for this LAMS. No AEs were reported during the 30-day telephone follow-up.

Case 5
A 93-year-old woman was admitted to our endoscopy unit for jaundice and a weight loss of 10 kg 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, an LAMS for jaundice palliation. Under EUS guidance, we performed a choledocoduodenostomy with the new 8 × 20 mm EC-LAMS. No AEs were experienced during the procedure, and the patient was discharged 3 days after the procedure. No AEs were reported during the 30-day 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 the freehand technique and intra-channel release. We chose this technique for 2 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 organ’s 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. 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
The authors state that subjects have given their written informed consent. Written informed consent was obtained from the patients for publication of this case report and any accompanying images. This study protocol was reviewed and approved by the local independent ethics committee, Approval No. 35/21 HMD.

Conflict of Interest Statement
The authors declare no conflicts of interest related to this research.

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Author Contributions
Benedetto Mangiavillano performed the cases, ideated, and wrote the manuscript. Francesco Auriemma and Laura Lamonaca edited the video. Alessandro Repici approved the manuscript.

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

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