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The safety and efficacy of a new 20-mm lumen apposing metal stent (lams) for the endoscopic treatment of pancreatic and peripancreatic fluid collections: a large international, multicenter study

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Abstract

Background Lumen apposing metal stent (LAMS) allows an easy access to peripancreatic fluid collections (PPFCs) and the possibility of performing direct endoscopic necrosectomy (DEN). The aim of our study was to evaluate the safety and efficacy of a new 20-mm LAMS in the management of PPFCs. This novel stent represents the largest diameter LAMS available on the market to date.

Methods This is an international, multicenter retrospective study involving 20 centers. Consecutive patients who underwent EUS-guided PPFC drainage using a 20-mm LAMS were included. Primary outcomes were technical and clinical success. Secondary outcomes were rate and the severity of adverse events.

Results A total 105 patients underwent PPFC drainage using the new 20-mm LAMS and 106 LAMS were placed. Technical success was 100% (106/106). 7/105 patients died due to causes not related to the stent. Clinical success was achieved in 92/98 patients (93.9%). Significant adverse events occurred in 8/98 patients (8.16%): 4 cases (4.08%) of bleeding, 3 cases (3.06%) of suprainfection, 1 case of gastric outlet obstruction.

Conclusions This multicenter study demonstrated acceptable rates of technical and clinical success using a new 20-mm LAMS for PPFC, including walled-off pancreatic necrosis (WOPN). The results of our study suggest that a new 20-mm LAMS is non-inferior in terms of safety, efficacy, and adverse events as compared to smaller diameter LAMS in the management of PPFCs, including pancreatic psuedocysts (PP) and WOPN. Randomized controlled studies will be needed to determine the ideal size of LAMS need to achieve the greatest clinical benefit with the minimized risk exposure for this high-risk patient population.

Keywords Pancreatic fluid collection · Lumen apposing metal stent · EUS-guided drainage · Walled-off pancreatic necrosis

Lumen-apposing metal stents (LAMS) have been commercially available for several years, but their widespread use for the access and drainage of pancreatic and peripancreatic fluid collections (PPFCs), including pancreatic pseudocysts (PP) and walled-off pancreatic necrosis (WOPN), is only recent [1]. LAMS have been utilized to treat PPFCs in a variety of single-center and multicenter prospective and retrospective studies with favorable results and an acceptable safety profile [2–5].

When compared to plastic stents and fully covered metal biliary stents used for drainage of PPFCs, published data suggest that the use of LAMS may result in earlier resolution of PPFCs, although they are associated with increased costs and, in early series, to increased risk of adverse events, most notably being pseudoaneurysm-related bleeding [6]. Other studies have shown more favorable results of LAMS without an increased rate of adverse events as compared to more traditional modalities [1–9]. In particular, a recent study by Bang et al. suggested that earlier removal of LAMS, within

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3 weeks from stent placement, significantly reduces the prevalence of bleeding complications, with a rate of adverse events comparable to plastic stents [10]. Although this study did not demonstrate the superiority of LAMS over plastic stents in the treatment of WOPN [10], data from the literature supports the use of LAMS for these types of PPFCs. This may be related to the fact that in some cases the use of LAMS makes possible the use of a standard gastroscope to access the WOPN cavity coaxially to the LAMS in order to perform lavage and direct endoscopic necrosectomy (DEN) [8, 9, 11, 12]. Variability in outcomes may be due to differences in PPFC drainage and debridement technique, which remains largely non-standardized [12, 13]. Moreover, the diameter of LAMS (until recently, the largest one being 16 mm) sometimes prevents the removal of larger pieces of necrotic tissue. The need for repeated intubations with the endoscope and challenges in the removal of large necrotic fragments may influence the outcome of the procedure, leading to necrosectomy failure, to traumatic bleeding or even to the unintentional displacement of the LAMS. We hypothesize therefore that a larger diameter LAMS may be useful in overcoming these issues.

To date, a variety of LAMS sizes have been commercially available, with the previous largest one being 16 mm in diameter. Since a limited commercial release in October 2016, a LAMS with 20-mm lumen diameter has been available (Fig. 1). This device, known commercially as the electrocautery-enhanced Axios stent (Boston Scientific, Marlborough, MA, USA) is supplied preloaded in an electrocautery-enhanced delivery device and catheter, which is used to both access the PPFC utilizing endoscopic ultrasound (EUS) guidance as well to deploy the stent. This is currently the largest diameter LAMS available on the market.

Fig. 1 The Hot-AXIOS™ stent, preloaded in an electrocautery-enhanced delivery device and catheter, made up of braided nitinol and fully covered with silicone, with wide flanges on both ends

The aim of our large international, multicenter study was to retrospectively evaluate the safety and efficacy of the new 20-mm LAMS in the management of PPFCs.

Materials and methods

This international, multicenter retrospective study involved 20 centers with experience in using the 20-mm LAMS. An Excel spreadsheet (Microsoft, Redmond WA, USA) containing 38 parameters for each employed device was sent to all the 20 centers involved. Between October 2016 and May 2018, all consecutive patients who underwent EUS-guided PPFC drainage using 20-mm LAMS were included. The indications for endoscopic treatment listed in recent guidelines [14] are the presence of symptoms such as nausea, vomiting, abdominal pain, gastric or duodenal obstruction, the presence of suspected or proven infected necrosis, jaundice, and persistent organ failure. All the collections were drained after four weeks from the onset of the pancreatitis.

Patients younger than 18 years of age, pregnant, or belonging to special groups of patients, such as patients affected by dementia, coagulopathy, or decompensated cirrhosis, were excluded from the study. Informed consent to the procedure was obtained in all patients.

The spreadsheet was used to gather anonymized data including but not limited to patient demographics, morphological characteristics of the PPFCs, the type of PPFC access and drainage, the need for DEN, the number of DEN sessions until the resolution of the PPFC, the need for additional non-endoscopic treatments (surgery, interventional radiology drainage, etc.), LAMS patency, the timing of stent removal, adverse events and their management, the PPFCs recurrence rate and a space for special comments or concerns regarding each use of the device by their operators. All data were collected and were subject to statistical analysis.

LAMS placement could be performed both over guidewire or using a freestyle technique and the deployment of the second flange could be done under endoscopic view or intrachannel.

Primary outcomes were technical success, defined as the ability to successfully place the stent and drain the fluid collections, and clinical success, defined as WOPN or pseudocyst < 2 cm visible with axial imaging 3–6 months after stent insertion without need for additional radiological, endoscopic, or surgical intervention, respectively. Secondary outcomes were the rate and the severity of adverse events (AEs), as per the ASGE lexicon [15]. IRB approval was obtained for this study.

Results

Patient demographics

One hundred and five (105) patients underwent PPFC drainage using 20-mm LAMS. 106 stents were placed (in one patient, 2 stents were used due to the need to drain a large-volume fluid collection). The mean age of patients was 57 years old (SD 15,25). 28 patients were female (26.7%), and 77 patients were male (73.3%). The etiology of pancreatitis was as follows: biliary 46/105 (43.81%), alcohol 37/105 (35.24%), idiopathic 10/105 (9.52%), trauma 2/105 (1.9%), post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis 5/105 (4.76%), hypertriglyceridemia 2/105 (1.9%), and others 3/105 (2.86%).

Patient and clinical characteristics are outlined in Table 1.

The stents were deployed using a freestyle technique in 96/106 (90.6%) cases (Fig. 2) or over a previously placed guide-wire using a 19 G needle in 10/106 (9.4%) and all the stents were deployed using the intrachannel stent release technique [16].

PPFCs were located in the head of pancreas in 8/105 patients (7.62%), in the body/tail in 66/105 patients (62.86%), and the entire pancreas was involved in 32/105 patients (30.48%). The mean long-axis measurement of the PPFC was 109 (±49.45) mm. The mean short-axis measurement of the PPFC was 71 (±33.24) mm. Excluding 4 collections, all the treated PPFCs in this study contained some degree of solid debris when observed using EUS: 17/101 had an estimated percentage of necrosis < 25%, while 84/101 had an amount of necrosis > 25%; with a mean estimated percentage of solid debris within the cyst of 42.4% (range: 10–80% of solid debris).

Table 1 Patients and clinical characteristics

Patients	105
Sex	
Male	28/105 (26.7%)
Female	77/105 (73.3%)
Mean age (yrs)	57 (range 21–86)
Etiology of pancreatitis	
Biliary	46/105 (43.81%)
Alcohol	37/105 (35.24%)
Idiopathic	10/105 (9.52%)
Trauma	2/105 (1.9%)
Post-ERCP	5/105 (4.76%)
Hypertriglyceridemia	2/105 (1.9%)
Others	3/105 (2.86%)
Location of PPFCs	
Head	8/105 (7.62%)
Body/tail	66/105 (62.86%)
Entire pancreas	32/105 (30.48%)
Mean axis (mm)	
Long	109 (±49.45)
Short	71 (±33.24)
Mean estimated percentage of solid debris	42.4% (range: 10–80%)
Patients underwent ERCP	19/105 (18.09%)
Placement of PS during ERCP	14/105 (13.3%)

yrs years, *ERCP* endoscopic retrograde cholangiopancreatography, *PPFCs* pancreatic and peripancreatic fluid collections, *PS* plastic stent

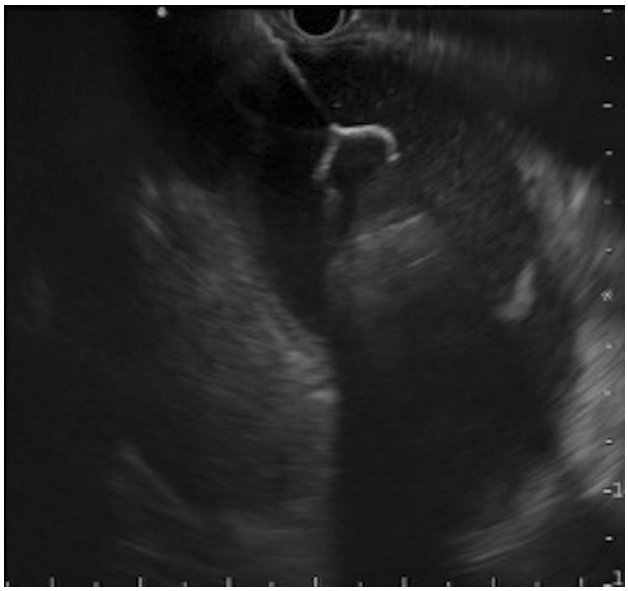

Fig. 2 Endoscopic ultrasonography (EUS) view of the first flange deployment of the lumen apposing metal stent (LAMS) in a walled-off pancreatic necrosis (WOPN)

Technical and clinical success

All 106 (100%) LAMS placements were technically successful. 103/106 (97.16%) LAMS were transgastric, while 3/106 (2.84%) were transduodenal. After deployment and stent placement, dilation of the LAMS was performed in 68/106 cases (64.16%) and double pigtail plastic stents were placed through the LAMS after deployment in 23/106 (21.69%). Only in 5/106 (4.71%) cases a nasocystic tube was placed into the WOPN cavity after the deployment of the LAMS.

DEN was performed in 65/105 (61.9%) patients because of the presence of large amount of solid necrosis, while in 41/105 patients (39.05%) there was no need for DEN to achieve PPFC resolution. The mean number of DEN sessions after initial LAMS placement was 2 per patient (range 1–8). Stent occlusion was observed only in 3/106 cases (2.83%) and was resolved by endoscopic debridement in all cases.

Mean follow-up after the procedure was 81.81 (±95.15) days. 7/105 patients died due to causes not directly attributable to the LAMS or endoscopic procedure(s), namely multiorgan failure in 4 patients, heart attack in 1 patient, severe pulmonary infection in 1 patient, and systemic complications in which a relation with the stent was excluded in one case. The mean indwelling time for LAMS was 42.6 days (±34.77). Clinical success, calculated after excluding those 7 patients who died from causes unrelated to the stent, was achieved in 92/98 patients (93.9%) (Fig. 3), while in 6/98 (6.1%) patients a resolution of the PPFCs was not achieved. In those cases where endoscopic treatment failed, surgical necrosectomy (3/6 patients) or percutaneous drainage (3/6 patients) was the choices of treatment.

Only 3/98 (3.06%) patients had a recurrence of WOPN after LAMS removal. One patient was treated successfully with the placement of second LAMS and the placement of a 7 Fr plastic stent into the pancreatic duct (PD). One patient died after 58 days after LAMS removal because of sepsis, while the third patient underwent to a dual approach using percutaneous drainage and percutaneous necrosectomy but died 42 days after because of sepsis.

Adverse events

Adverse events following LAMS placement occurred in 12/98 patients (12.24%): 5 cases of stent migration (5.1%), 4 cases of bleeding (1 moderate and 3 severe) (4.08%), and 3 cases of infection (1 severe and 2 mild) (3.06%).

LAMS migration occurred after a mean time of 50 days (range 5–90 days) after stent placement. All of the LAMS migrations were into the lumen of the stomach, rather than into the collection and in all the cases occurred spontaneously after resolution of PPFC. As per ASGE Lexicon [15], LAMS migration is considered as mild severity AEs.

Four patients developed bleeding (1 moderate and 3 severe) after a mean time of 11.25 days (range 1–21 days) following LAMS placement. In one case bleeding was due to a mucosal laceration at the level of the gastric fundus and was resolved endoscopically with mechanical hemostasis. One patient, whose intracystic bleeding occurred during the third DEN session, underwent surgery after several attempts of interventional radiological embolization. In a third patient bleeding occurred during LAMS extraction and, after endoscopic attempts, it was resolved with interventional radiological treatment. The fourth patient developed bleeding days after stent insertion because of the presence of a pseudoaneurysm that was successfully treated with radiological coiling.

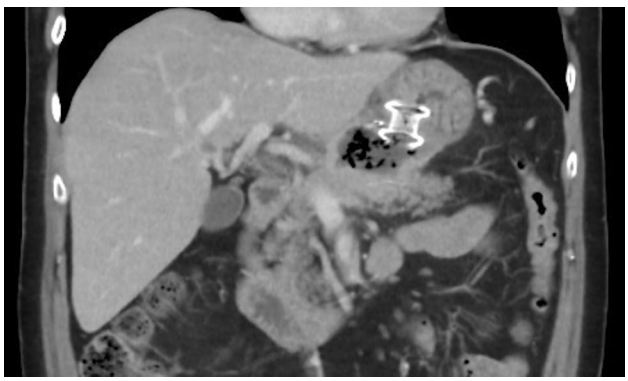

Fig. 3 CT scan appearance of LAMS with WOPN resolution after 3 weeks of placement

Three patients (3.06%) developed infection (2 moderate and 1 severe) after a mean period of 24 days (range 2–43 days) and the approach to the management of this particular adverse event varied widely. In one patient, symptom resolution was simply achieved by removing the stent. In another patient, a conservative approach with systemic and intracavitary instillation of antibiotics was preferred, while the last patient underwent surgical necrosectomy.

No case of death related to stent insertion is reported in this study.

Discussion

This study is a large, international, multicenter study regarding the use of a new 20-mm-diameter LAMS for management of PPFCs including WOPN.

LAMS are now widely employed for PPFC drainage [2–8]. In addition, LAMS are increasingly used for a variety of indications including bile duct drainage, gallbladder drainage and gastrojejunostomy creation, among other indications [12, 13, 17–21]. In the recent past, LAMS have been available in sizes ranging from 6–16 mm wide, with a 15-mm LAMS being widely employed throughout Europe and the USA, mainly for PPFC drainage. Although there is still much debate in the literature on the ideal use of LAMS versus plastic stents for management of pseudocysts, the data available on WOPN drainage support the use of LAMS, mainly due to the improved results achieved by the opportunity to entering the WOPN cavity with a standard endoscope, thus facilitating lavage and/or direct necrosectomy [1–9, 11, 12]. Moreover, the larger diameter of LAMS, compared to single or multiple plastic stents, potentially allows for spontaneous resolution of WOPN without the need for further invasive procedures (such as necrosectomy) in a significant proportion of patients. Despite these characteristics and the larger stent diameter, limitations still exist with the current devices available, and so a larger diameter stent is theorized to improve the procedure. Hence, a larger diameter LAMS (20 mm) has recently come onto the market as a possible solution to this problem.

The increased the stent diameter translates into a significant increase in the cross-sectional area for PPFC drainage. A 15-mm-diameter LAMS has a cross-sectional area (for drainage, necrosectomy, etc.) of 176.71 mm^2, while a 20-mm-wide LAMS has a cross-sectional area of 314.16 mm^2. Hence, the difference of 5 mm in diameter translates into a 77.7% larger cross-sectional area, without a difference in the length of the stent. For this reason a larger diameter LAMS is of clinical interest, both for on-label and off-label usage throughout the GI tract. It is believed that a larger diameter LAMS would allow PPFCs to resolve more quickly and with higher clinical success, as well as better facilitating DEN. A more rapid resolution of PPFCs is desirable from a clinical point of view, as some PPFCs are a life-threatening condition for many patients. Furthermore, a more rapid resolution would also allow for earlier removal of LAMS, which the latest guidelines recommend removing within 4 weeks due to the risk of late bleeding from pseudoaneurysm formation [15].

This study demonstrates favorable efficacy and safety of a 20-mm LAMS for EUS-guided transluminal drainage of PPFCs including PP and WOPN. The mean percentage of solid debris in the PPFCs in this study was 42%, suggesting that the majority of patients in this study had WOPN and not simple PP.

The technical and clinical success rates for resolving PPFCs in this study were 100% and 93.8%, respectively. These results are comparable to other published studies and meta-analysis of LAMS usage for PPFCs [2, 3, 22–25].

A total of 12/98 patients (12.24%) patients experienced adverse events following placement of a 20-mm LAMS. According to the ASGE Lexicon, two of these adverse events (2.04% of all patients, 16,67% of total adverse events) were severe and both required surgery, in one case due to massive bleeding and due to severe infection in the other case. In 5 patients (5.1% of all patients, 41.67% of total adverse events) the adverse events were moderate in severity, requiring endoscopic or radiological procedures.

In 5 cases (5.1% of all patients, 41.67% of total adverse events) the adverse events were mild in severity, as the stent migration occurred into the gastric lumen without the need for intervention since they were expelled spontaneously. Other studies including smaller diameter LAMS showed similar or even higher rates of this adverse event [2, 5–7, 26].

Two smaller case-series in the use of 20-mm LAMS were recently published highlighting the effectiveness and good safety profile of this device [27, 28].

The high number of patients enrolled and the multicenter design are not negligible advantages of this study, minimizing bias toward individual operators who had exceptionally good or poor outcomes with this device. It is important to note that the 20-mm LAMS used in this study wasn't fully commercially available, but was reserved for those centers with high expertise and with operators experienced in the use of electrocautery-enhanced LAMS devices.

The possible wider employment of this larger diameter LAMS in current clinical use raises several additional questions. It is unknown whether there is an upper limit to the size of a LAMS with regard to clinical utility. Several questions remain. Is the use of larger stents inherently more dangerous or not? Does the shape of LAMS relate to the risk for bleeding, pseudoaneurysm formation, or other adverse events and is this risk size-dependent? Would a larger diameter LAMS improve other LAMS procedures such as gallbladder drainage or the creation of gastrojejunal anastomosis?

These and other questions are likely to be answered in the coming years, when longer follow-up and the data for wider use of LAMS both for on-label and off-label indications will become available.

These data may suggest that the larger diameter and the bigger cross-sectional area of LAMS are not a disadvantage, but, on the contrary, represent a big advantage in the management of PPFCs, especially WOPN. Probably, it is important to consider that the length of the 20-mm stent is 10 mm, namely the same as 15- and 10-mm LAMS, so that the risks of adverse events, above all late bleeding, could be mainly influenced by this measurement.

In conclusion, the results of our study suggest that a 20-mm LAMS is non-inferior in terms of safety, efficacy, and adverse events as compared to smaller diameter LAMS in the management of PPFCs, including PP and WOPN. Larger randomized studies will be needed to determine the ideal size of LAMS to achieve the greatest clinical benefit with the minimized risk exposure for this high-risk patient population.

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Compliance with ethical standards

Disclosures Dr. Andrea Anderloni is consultant for Boston Scientific and Olympus. Dr. Carlo Fabbri is consultant for Boston Scientific. Dr. Manuel Perez-Miranda is consultant for Boston Scientific, MI Tech and is on the speakers' bureau of Teawoong. Dr. Alessandro Repici is consultant for Boston Scientific and Fuji. Dr. Mouen A. Khashab is consultant for Boston Scientific, Olympus and Medtronic. Dr. Rastislav Kunda is consultant for Boston Scientific, Olympus and Apollo Endosurgery. Dr. Jose Nieto, Dr. Will Uwe, Dr. Markus Dollhopf, Dr. José Ramón Aparicio, Dr. Ilaria Tarantino, Dr. Alexander Arlt, Dr. Frank Vleggaar, Dr. Geoffrey Vanbiervliet, Dr. Jochen Hampe, Dr. Michel Kahaleh, Dr. Juan J Vila, Dr. Barham K. Abu Dayyeh, Dr. Andrew C. Storm, Dr. Alessandro Fugazza, Dr. Cecilia Binda, Dr. Antoine Charachon, Dr. Sergio Sevilla-Ribota, Dr. Amy Tyberg, Dr. Moran Robert, Dr. Sachin Wani, Dr. Amrita Sethi have no conflicts of interest or financial ties to disclose.

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