

# Lumen-apposing metal stents: How far are we from standardization? An Italian survey

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## ABSTRACT

**Background and Objectives:** EUS-guided transluminal drainage has increasingly developed, especially after the era of lumen-apposing metal stent (LAMS): a fully covered, barbell-shaped, metal stent with anti-migratory properties allowing direct therapeutic interventions through a wide and short channel. The aim of this survey is to investigate the current management of patients undergoing LAMS placement nationwide. **Materials and Methods:** Forty-eight questions were submitted to Italian centers about expertise, peri- and intra-procedural aspects, budget/refund, and future perspectives. Statistical analyzer was SPSS®. **Results:** Thirty-six centers completed the survey. Indications for LAMS positioning are pancreatic fluid collection drainage (PFC, 97.2%), biliary drainage (BD, 80.5%), gallbladder drainage (GBD, 75%), and gastroentero-anastomosis (GEA, 19.4%). A total of 77.7% of the endoscopists perform only on-label procedures and 22.2% both on-label and off-label. 38.8% attended a training preliminary course, 27.7% were just supported by an expert, 22.2% had both the opportunities, and 8.3% none of them. Management of antiplatelets and sedation protocol is very heterogeneous. Only 50% involves a multidisciplinary meeting and 30.5% has a specialized clinic for follow-up. Acid suppression is usually continued after PFC. The type and timing of postprocedural imaging varies widely. 8.3% of the endoscopists work without fluoroscopy. Refund for LAMS is mostly not guaranteed. Main future growing indications appear to be BD, GBD, and GEA (69.4%, 55.5%, and 55.5%, respectively). **Conclusions:** This is the first survey assessing the state of the art on LAMS almost 10 years after their advent. There are currently wide variations in practice nationwide, which demonstrates a pressing need to define technical, qualitative, and peri-procedural requirements to carry out this procedure, toward a standardization.

**Key words:** interventional EUS, lumen apposing metal stent, survey

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## INTRODUCTION

EUS-guided interventional procedures have undergone an exponential increase. In the last decade, a new type of stent, dedicated to EUS interventional procedures, called lumen-apposing metal stent (LAMS), was introduced revolutionizing the panorama of EUS world. LAMS consists of a fully covered, barbell-shaped, self-expandable metal stent with two-side flanges, which provide anti-migratory properties, and a wide and short tubular saddle, which facilitates the creation of a stable fistula between two cavities.<sup>[1]</sup> These stents have different measures, both in length and in diameter, which could vary from 8 to 20 mm and from 6 to 20 mm, respectively. Wider stents, mainly those larger than 15 mm, also allow the introduction of the endoscope into the target cavity to perform direct therapeutic interventions.<sup>[2-6]</sup>

LAMS was invented and patented by Binmoeller and Shah in 2004 and the first report in animal studies dates back to 2011.<sup>[7]</sup> Moreover, thanks to the introduction of the electrocautery-enhanced LAMS, which allows to perform a single-step procedure and without the need of fluoroscopy, the use of these devices has widespread among the endoscopic units.

In the last years, several studies have been published on the technical and clinical outcomes of LAMS<sup>[8-12]</sup> and their use and indication is expanding. To date, LAMS has three on-label indications: pancreatic fluid collection (PFC) drainage (PFCD),<sup>[13,14]</sup> secondary to acute pancreatitis, biliary drainage (BD)<sup>[15,16]</sup> for relieving biliary obstruction after failed ERCP, and gallbladder drainage (GBD)<sup>[17]</sup> for treatment of acute cholecystitis in high-risk surgical patients. Among many off-label indications, gastroentero-anastomosis (GEA) for management of gastric outlet obstruction is the most promising.<sup>[18]</sup>

Although these new devices make easier the stent deployment, adverse events related to the procedure could be severe requiring expertise in interventional endoscopy, especially ERCP, for their management,<sup>[15,19]</sup> moreover, patients who underwent these procedures are usually hard-to-treat patients, in life-threatening conditions, requiring multidisciplinary approaches. Nevertheless, no guidelines or consensus about training and peri-procedural aspects of LAMS placement exist, so that is to date difficult to define the standard of care for the use of this device. The aim of this survey is to investigate the current management of this

setting of patients among most of the Italian centers performing EUS-guided drainage using LAMS, with the purpose to be helpful in understanding practice patterns nationwide, identifying key areas of controversies to guide future research toward a beneficial standardization.

## MATERIALS AND METHODS

A 48-questions survey about the practice of LAMS placement was submitted, during a temporal trend of 3 months (November 2019–January 2020), among Italian centers performing interventional EUS and LAMS deployment. The questionnaire was reviewed by three experts (CF, AA, and IT) from the Department of Gastroenterology and Digestive Endoscopy of three different Italian hospitals. For some questions, there was the possibility to choose between just one of the answers, while for others, it was allowed to select multiple options. Data were reported anonymously on a database (Excel, OpenOffice). Consent to the use of data for research purposes only was implicit in the will to join the survey.

### *Design of the questionnaire*

The questions were grouped under several sections:

- Expertise LAMS user: Background demographics, prior experience in advanced endoscopy, and experience in LAMS positioning
- Peri-procedural management: Preprocedural preparation and postprocedural management/follow-up, including fasting, refeeding, and imaging performed for each of the main current indications (PFCD, BD, GBD, and GEA)
- Procedural aspects: Technical considerations about the procedure and the setting
- Budget and refunds: Based on the different geographical regions
- Future perspective: New possible indications, expertise diffusion, and training.

### *Statistical analysis*

Categorical variables were summarized with frequencies and proportions. A subanalysis comparing more experienced endoscopists with less ones was performed using Chi-squared test for categorical data ( $P < 0.05$  as statistically significant). The endoscopists were stratified basing on years of endoscopic experience ( $\geq 15$  years), number of EUS per year ( $\geq 250$ ), or number of LAMS placed per year ( $\geq 10$ ). Therefore, the two groups were compared for several topics: LAMS placement limited to on-label *versus* on- and off-label

indications, perception of the technical complexity of the procedure, and imaging performed after the endoscopic procedure (for each out of four indications evaluated). Statistical analyses were performed using SPSS® 20.0 statistical software (SPSS, Chicago, Illinois, USA).

## RESULTS

A total of 36, out of 40, Italian centers performing interventional EUS and LAMS placement completed the survey.

Only questions answered by at least 50% of the participants were reported in the results.

### Session I: Expertise lumen-apposing metal stent users

The first session of the questionnaire was composed of 15 questions.

The demographic characteristics of the participants are outlined in Table 1.

The majority of endoscopists are gastroenterologists (29/36, 80.5%), 19/36 (52.7%) working in a medical department, and 12/36 (33.3%) in a surgical one.

The experience of participants is variable: 15/36 (41.6%) had more than 15 years of experience in endoscopy, the majority (58.3%) have experience in all kinds of interventional endoscopic procedures (EUS, ERCP, and endoluminal resections), 21/36 (58.3%) perform more than 250 EUS/year, and 19/36 (52.7%) more than 200 ERCP/year. The overall number of LAMS placed was <20 for 22/36 (61.1%) of the endoscopists, while the number per year of LAMS placed was <10/year for 55.5% of the participants. Indications for LAMS positioning are PFCD (35/36, 97.2%), BD (29/36, 80.5%), GBD (27/36, 75%), GEA (7/36, 19.4%), and pelvic abscess (1/36, 2.7%). Considering PFCD, BD, and GBD as on-label indications and GEA or others as off-label indications, 28/36 endoscopists (77.7%) perform only on-label procedures while 8/36 (22.2%) both on-label and off-label.

Concerning the training, 14/36 (38.8%) attended a training course, 10/36 (27.7%) were supported by an expert, 8/36 (22.2%) had both the opportunities, while 3/36 (8.3%) did not do any of them. Only 6/36 (16.6%) respondents consider LAMS

placement as an easy procedure and most of the endoscopists (24/36, 66.6%) reported to be able to double-pigtail stent positioning.

### Session II: Peri-procedural management

The second session of the questionnaire was composed of nine questions.

Management of antiplatelet therapy is very heterogeneous: one-third of the experts (13/36, 36.1%) always take off ticlopidine maintaining acetylsalicylic acid (ASA), others (10/36, 27.7%) always discontinued ticlopidine maintaining ASA only for secondary prevention, 7/36 (19.4%) have a variable behavior, and 6/36 (16.6%) always take both drugs off before the procedure. There is a univocal trend to manage all the patients (34/36, 94.4%) as inpatients. The participants were also asked if specific, scheduled programs were considered for this setting of patients: only 50.0% (18/36) discuss the case in a multidisciplinary meeting, and only in 30.5% (11/36) of cases, a dedicated follow-up in a specialized clinic is foreseen.

After PFCD, majority of endoscopists does not place double pigtail stents within LAMS lumen (21/35, 60.0%), does not insert a nasoenteral feeding tube after

**Table 1. Demographics of the 36 survey participants**

Demographics	n (%)
Total survey participants	36
Unit type	
UOC gastroenterology	19 (52.7)
UOC surgery	1 (2.7)
UOS endoscopy	11 (30.5)
UOC endoscopy	3 (8.3)
NA	2 (5.5)
Endoscopic experience (yrs)	
0-5	5 (13.8)
6-10	6 (16.6)
11-15	9 (25)
16-20	5 (13.8)
>20	10 (27.7)
NA	1 (2.7)
Experience type	
Diagnostic EUS	2 (5.5)
Diagnostic/ interventional EUS	7 (19.4)
EUS/ERCP	5 (13.8)
EUS + ERCP + endoluminal	21 (58.3)
NA	1 (2.7)

UOC: Complex operative unit; UOS: Simple operative unit; NA: Not available

the procedure (28/35, 80.0%) and carry on with proton pump inhibitor (PPI) therapy (23/35, 65.7%).

Preprocedural fasting for PFCD, BD, GBD, and GEA is reported to be <12 h for 54.3% (19/35), 56.6% (17/30), 51.8% (14/27), and 42.8% (3/7), respectively; postprocedural fasting is reported to be 12–24 h for 57.1% (20/35), 60.0% (18/30), 66.6% (18/27), and 42.8% (3/7), respectively.

Considering the whole spectrum of indications, postprocedural imaging is performed by 51.8%–70.0% of the endoscopists only if there is a suspected adverse event, consisting in an abdominal contrast-enhanced computed tomography (CT) scan by 20.0%–42.8% or an abdominal ultrasonography by 5.7%–22.2%. Postprocedural esophagogastroduodenoscopy is not performed by most of the respondents (82.8%–100%).

We finally compared the responses between the endoscopists grouped in high experienced and less experienced, with regard to LAMS placement for only on-label *versus* on- and off-label indications, perception of the procedural technical complexity, and performing postprocedural imaging examinations (for each of the four indications evaluated). No significant differences were outlined ( $P = 0.35$ ).

### Session III: Procedural management

The third session of the questionnaire was composed of four questions.

In the majority of cases the LAMS placement is performed in a radiologic room (29/36, 80.5%), while in 8.3% (3/36) in a standard endoscopic room; in addition, two out of these three endoscopists perform not only PFC drainage but also GBD. The choice of sedation varies widely among centers: general anesthesia is always performed in 38.8% of the centers (14/36), deep sedation in 30.5% (11/36), conscious sedation in 8.3% (3/36), while a variable behavior dependent on the patient clinical conditions or indication is preferred in 13.8% (5/36) and 8.3% (3/36) of cases, respectively.

### Session IV: Budget and refunds

The fourth session of the questionnaire was composed of 15 questions.

For 16 participants (44.4%) LAMS are provided on consignment stock (it means that the producer retains ownership until the device is used by the endoscopist),

for 13 (36.1%) LAMS are bought from the hospital, in 1 case (2.7%) both. Taking into account whatever form of refund for LAMS, we found it is guaranteed in ten Italian regions (27.7%) for PFCD, in four Italian regions (11.1%) for BD and GBD, while no reimbursement is provided for GEA in all of them.

### Session V: Future perspectives

The fifth session of the questionnaire was composed of five questions.

Future indications of growing resonance are PFCD for 44.4% (16/36), BD for 69.4% (25/36), GBD for 55.5% (20/36), GEA for 55.5% (20/36), benign strictures for 22.2% (8/36), and others for 5.5% (2/36), such as vascular and bariatric indications. Half of the participants believe that future LAMS use should be reserved only to few referral centers (17/36, 47.2%), while for minority, it should be extended to all endoscopic units for every indication ( $n = 5$ , 13.8%) or only for some specific indications ( $n = 6$ , 16.6%).

There is a variable perception about training of future LAMS users: 50.0% (18/36) think that they should perform all kinds of interventional endoscopic procedures (EUS, ERCP, and endoluminal resections), 19.4% (7/36) believe that an experience in EUS and ERCP is needed, while 13.8% (5/36) think that expertise in EUS associated with a course or training with an expert is sufficient.

## DISCUSSION

To our knowledge, this is the first survey aimed to assess the state of the art on “LAMS experience” almost 10 years after their introduction in interventional EUS practice. In 2017, it was published a worldwide multi-institutional consensus on how to perform EUS-guided PFCD and endoscopic necrosectomy among members of the EUS Journal Editorial Board, concluding that there were wide variations in practice and randomized studies were urgently needed to establish the best approach for management of this condition, establishing a best practice consensus.<sup>[20]</sup>

Despite the increasingly widespread use of LAMS among endoscopy units and the ever-increasing extension of indications in therapeutic field, it looks clear the currently considerable heterogeneity of this approach. For this reason, we thought it would have been necessary to take stock of the current situation

in order to assess the key points which can represent a starting point for a standardization of the procedure, therefore the possible future drafting of guidelines and above all, to light out those gray areas which may be objects of future studies.

In this setting of patients, that include both malignant and benign conditions burdened by high mortality, the main goal needs to go beyond the mere technical aspects but should be considered as crucial both pre- and postprocedural management in order to optimize the patient clinical outcome. Therefore, it looks pivotal a multidisciplinary approach involving all the specialists dedicated to pancreatic and biliary diseases, as we are dealing with increasingly old and fragile patients with multiple comorbidities.

With regard to the existence of a dedicated pathway scheduled/protocol for this class of patients, both in a preprocedural decision phase and during follow-up, only half of the centers (50%) discuss the case in a multidisciplinary meeting, regardless of indication, and a specific follow-up is planned in a specialized clinic only in 30.5% of the cases.

In our opinion, because of the complexity of these clinical conditions, it looks essential a multidisciplinary approach in all these patients, involving particularly radiologists and surgeons which could represent the further key players in this scenario, in order to reach a common agreement on the treatment strategy and to be already alert on the potential development and management of adverse events. Indeed, it is crucial to keep in mind that many patients which are candidate for EUS-guided procedures are affected by benign diseases in which EUS-guided procedure could be pivotal in their clinical improvement towards recovery. This is in contrast with the role of EUS-guided procedure in oncological patients, often with poor life expectancy, who are nevertheless object of multidisciplinary meeting although often our interventions are only palliative without healing intent. This is also true for patient's follow-up, which is fundamental for the long-term outcome definition, with the assessment of late adverse events. Hot topic regarding LAMS, indeed, is represented by the patency, which is still to date a debated issue because of the scarceness of data available in literature. Standing to most of the published data, largely characterized by a follow-up of no more than 6 months, concerns are still present in leaving LAMS in place for a long time as the

rate of buried stent, food impaction, and bleeding are not well assessed, especially for PFC.<sup>[19]</sup> This means that it is necessary to regularly update the clinical status of the patient even doing radiological check, to evaluate longterm results after stent placement and to define the best timing of its removal, if indicated.

Concerning peri-procedural management, a considerable variability was observed in handling antiplatelet therapy. Although LAMS placement could be considered a high-risk procedure, ESGE guidelines<sup>[21]</sup> do not mention EUS-guided drainage with LAMS positioning in the risk stratification of the different endoscopic procedures and no recommendation has been stated from scientific societies on how to manage these drugs in these patients. Evidences are arising that bleeding events appear to be infrequent among patients who undergo EUS-guided drainage while continuing antiplatelets or anticoagulants.<sup>[22,23]</sup> Regarding the execution of postprocedural radiologic examinations in order to check the correct LAMS positioning or the occurrence of peri-procedural adverse events, for all the indications considered, a range of 51.8%–70% of the responders reported to perform an imaging technique only in case of suspected complication, otherwise a contrast-enhanced CT scan (20%–42.8%) or an abdominal ultrasonography (5.7%–22.2%) is routinely requested. This behavior looks heterogeneous and clear advices from literature on this attitude are lacking; the only study which reported a standard protocol for postprocedural imaging after LAMS placement is the study by Bang on PFC:<sup>[24]</sup> authors, indeed, suggested to perform a CT scan 3 weeks after LAMS placement in order to evaluate the stent positioning, the appearance of the cystic cavity, and the formation of pseudoaneurysm in order to guide LAMS removal reducing the occurrence of late bleeding.

To verify if a possible explanation of this variability can originate from the personal expertise on the technique, we compared the practice of more or less experienced endoscopists with regard to the performance of off-label indications, perception of the procedural technical complexity, and execution of postprocedural imaging tests, but no significant differences for all these variables were revealed.

An issue regarding postprocedural medications in PFC is acid suppression. In 2016, Thompson *et al.*<sup>[25]</sup> demonstrated that, among sixty patients who underwent necrosectomy, discontinuing PPI therapy may encourage

autodigestion of the necrotic tissue by physiologic gastric acid production and further address potential infectious complications. The most recent published guidelines on management of pancreatic necrosis<sup>144</sup> assessed that, despite endoscopists with experience in managing walled off-necrosis (WON) have recommended avoidance of PPI after transmural drainage given the potential for autodebridement from secreted gastric acid, data are lacking to support this practice. In our survey, only 34.2% of the endoscopists discontinue PPIs in patients who underwent LAMS placement, while the majority of them (65.7%) carry on with PPI.

However, regardless to the indication for LAMS, we believe that this could be a key point for further discussions. It is known, indeed, that PPI may induce modifications of gastric microbial communities,<sup>126</sup> which could act a role in late complications such as superinfections after PFCD or ascending cholangitis after biliary tree drainage or GBD.

The expertise of participants in this survey, as we described, was very heterogeneous. With regard to the training process prior to performing LAMS placement on their own, our survey highlights an extreme variability between the endoscopists, as 3/36 LAMS users (8.3%) did not attend a prior training course neither a support by an expert. Since there is no consensus on the minimum experience required to gain an adequate expertise in LAMS placement, these data reveal how it is important to define a standard training (*e.g.*, minimum standard of annual EUS and/or ERCP performed) and a threshold of LAMS placement in order to reach the correct expertise for approaching such a sophisticated and expensive technique. Besides, this consideration is strengthened by the fact that all the published guidelines underline how the available expertise should drive the choice of performing the EUS-guided approach rather than the percutaneous one, although no definition of the expertise is to date available.<sup>116,17,27</sup> Above all, what looks crucial to define is the adequate working setting, the essential need of a radiologic room, and a specialized team of interventional radiologists and pancreatobiliary surgeons. It is known, indeed, that LAMS placement has a not negligible rate of intraprocedural adverse events, such as technical failure, misdeployment, bleeding, and perforation<sup>19</sup> to manage whom fluoroscopy is needed, as well as radiological and surgical facilities.

In this survey, there is a paucity of awareness about training of future LAMS users and data are

lacking regarding the learning curve for EUS-guided interventional procedures. Varadarajulu *et al.* demonstrated that, as a high-volume advanced endoscopist (over 500 EUS procedures yearly), technical proficiency for performing PFCD took 25 cases,<sup>128</sup> but this result was prior to the advent of LAMS. The number of cases needed to achieve technical ability may be lower now given the better handling of LAMS but still requires competence in diagnostic and basic therapeutic EUS. In an Asian survey by Teoh *et al.* on EUS-guided PFCD, a minimum number of ten procedures (with no details on the type of stent used) was proposed by 68% of the participants to gain competency.<sup>129</sup> Tyberg *et al.* recently tried to define the learning curve for EUS-GBD using LAMS (in 52% of the cases), SEMS, or plastic stents, with a prospective study including 48 patients, reporting that efficiency (measured in terms of procedure time and adverse event occurrence) was reached at 41 min with a learning rate of 19 cases, which is similar to aforementioned findings but still needs additional studies.<sup>130</sup> Apart from the Asian survey, in which it is reported that possession of the skills of ERCP was recommended and beneficial before embarking on learning EUS-guided drainage, there are no data about the need of experience in fluoroscopic-guided procedures during the learning process for EUS-guided interventions with LAMS positioning. As previously LAMS placement was a multistep procedure which needed fluoroscopy, to date new electrocautery-enhanced LAMS (EC-LAMS) is available, changing the paradigm of the stent deployment that can be performed as X-ray-free procedures. For all these reasons, the use of LAMS could be widespread among endosonographers without experience in X-ray-guided endoscopic procedures. However, we feel that this will be one of the key points in the future for the definition of the standard of practice, as fluoroscopy remains pivotal to face the adverse events related to LAMS placement, as previously mentioned. Therefore, it will be mandatory in the near future to define the adequate training, the correct threshold of procedure per year to maintain the acquired skills, and not least, the standard of setting in which these procedures should be done.

Moreover, the participants were asked to indicate which they believed to be growing future indications for LAMS placement. The majority of them believe that all the current on-label indications represent the field of development. Among off-label indications, indeed, GEA seems very promising, probably due to the

weakness of the currently available treatment of gastric outlet obstruction, as surgery is burdened by high rate of adverse events and mortality and endoscopic stenting is characterized by a variable rate of clinical success (65%–100%) and rate of reintervention at 6 months up to 60%.<sup>[31–33]</sup>

Nowadays, indeed, palliation is not only a short-term issue as the increased incidence of tumors is leading to a greater number of ill patients and the innovative oncological therapies has lengthened the patients survival, so interventional procedures may lead to a shift of route in the patient's clinical history. Therefore, this will probably change the way of thinking palliation, in which the use of LAMS is consolidated, as well as bridge-to-surgery strategy (both for malignant and benign diseases), in which evidences are initial but promising.<sup>[34,35]</sup>

Finally, it is not negligible the economic burden that goes along this kind of innovative accessories and procedures. There are an increasing number of studies which analyze cost and cost-effectiveness,<sup>[24,36–38]</sup> in particular Chen *et al.*<sup>[38]</sup> in 2018 compared LAMS with PS for WON drainage, demonstrating that LAMS was more efficacious, with a success rate of 92% *versus* 84% for PS; in addition, rates of unplanned endoscopy and surgery were both lower with LAMS approach that was, however, more costly. Our results, however, suggest that further efforts are needed to make EUS-guided interventional procedures a standard of care throughout the Italian endoscopic units and particularly to define an unanimous modality of refund, which is still lacking.

## CONCLUSIONS

This survey provides important preliminary data on the state of the art of LAMS following almost 10 years of studies on the topic and introduction of the method in the current clinical practice. Based on our results, there is a pressing need to define qualitative indicators to carry out this procedure but not least the peri-procedural requirements which may contribute to defining the patient's clinical outcome, drawing up guidelines for standardization of the procedure.

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Nil.

### *Conflicts of interest*

Carlo Fabbri is an Editorial Board Member of the journal. The article was subject to the journal's standard

procedures, with peer review handled independently of this editor and his research groups.

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## \*APPENDIX 1

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