








Clinical and technical outcomes of patients undergoing endoscopic ultrasound-guided gastroenterostomy using 20-mm vs. 15-mm lumen-apposing metal stents

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ABSTRACT

Background Most studies on endoscopic ultrasound (EUS)-guided gastroenterostomy (EUS-GE) for palliation of malignant gastric outlet obstruction (GOO) utilized a 15-mm lumen-apposing metal stent (LAMS). More recently, a 20-mm LAMS has become available. This study aimed to compare rates of technical and clinical success and adverse events (AEs) in patients undergoing EUS-GE using a 20-mm vs. 15-mm LAMS.

Methods Patients who underwent EUS-GE with 15-mm or 20-mm LAMS for malignant GOO during the period from January 2018 to October 2020 were included. The primary outcome was clinical success, defined as an increase in the gastric outlet obstruction score (GOOS) by at least 1 point during follow-up. Secondary outcomes were technical success, maximum tolerated diet, re-intervention rate, and rate/severity of AEs.

Results 267 patients (mean age 67 years, 43% women) with malignant GOO from 19 centers underwent EUS-GE. Clinical success rates were similar for the 15-mm and 20-mm stents (89.2% [95%CI 84.2%–94.2%] vs. 84.1%

[77.4%–90.6%], respectively). However, a significantly higher proportion of patients in the 20-mm group tolerated a soft solid/complete diet at the end of follow-up (91.2% [84.4%–95.7%] vs. 81.2% [73.9%–87.2%], $P=0.04$). Overall, AEs occurred in 33 patients (12.4% [8.4%–16.3%]), with similar rates for 15-mm and 20-mm stents (12.8% [7.5%–18.2%] vs. 11.8% [6%–17.6%]), including incidence of severe/fatal AEs (2% [0.4%–5.8%] vs. 3.4% [0.9%–8.4%]).

Conclusions The 20-mm and 15-mm LAMS show similar safety and efficacy for patients undergoing EUS-GE for malignant GOO. The 20-mm LAMS allows a more advanced diet and is, thus preferred for EUS-GE.

Introduction

Endoscopic ultrasound (EUS)-guided gastroenterostomy (EUS-GE) has become an established technique for palliation of malignant gastric outlet obstruction (GOO). Malignant GOO is a consequence of an advanced cancerous disease, most commonly pancreatic or gastric, causing mechanical obstruction at the level of the pylorus or duodenum. EUS-GE is also used, albeit less frequently, in cases of GOO due to benign conditions, such as strictures from pancreatitis, surgical anastomosis, or peptic ulcer disease [1, 2]. The traditional endoscopic approach to treat these cases has been through enteral stenting, where a duodenal stent is placed across the obstruction site. However, this procedure is associated with a considerable rate of symptom recurrence in patients who survive more than 6–12 months. This is due to the uncovered nature of the duodenal stent, which is subject to tumor ingrowth [3].

EUS-guided gastroenterostomy using a lumen-apposing metal stent (LAMS) was developed to potentially eliminate the risk of tumor ingrowth as the fully covered stent is placed away from the tumor site [4]. When compared with duodenal stents, results showed that although both procedures had similar technical and clinical success, the rate of symptom recurrence/re-intervention was less frequent in patients undergoing EUS-GE [5]. Historically, the 15-mm LAMS has been utilized for EUS-GE. The literature shows that EUS-GE with this stent has high technical success rate and efficacy, and an acceptable safety profile [6–8].

More recently, however, a 20-mm LAMS (AXIOS; Boston Scientific, Marlborough, Massachusetts, USA) has become available as an alternative stent for the bypass anastomosis. Although the larger stent provides an increase of 77% of luminal area, it is unknown how the two stents compare in terms of efficacy and safety. Theoretically, one would expect the 20-mm LAMS to be more difficult to deploy and to increase the risk for adverse events. At present, however, there is no available literature comparing these stents in EUS-GE. The aim of this study is to compare the use of 20-mm vs. 15-mm LAMS for EUS-GE in the treatment of patients with malignant GOO, in terms of efficacy, safety, and adverse events (AEs).

Methods

This multicenter, international, retrospective study involved 19 tertiary care centers (12 USA and 7 Europe). Patients who underwent EUS-GE for malignant GOO with a 15-mm LAMS or with a 20-mm LAMS during the period from January 2018 to October 2020 were included. The patients were divided into two groups based on whether a 15-mm or 20-mm LAMS was used. Primary and secondary outcomes were compared between the two groups.

A total of 109 of the cases, from 4 centers, had been included in previously published literature on EUS-GE [7, 9–13]. These studies mainly involved patients who underwent EUS-GE using the 15-mm LAMS, with some using the 20-mm LAMS, but none of them were comparative trials that looked at the difference in outcomes for the two stent sizes.

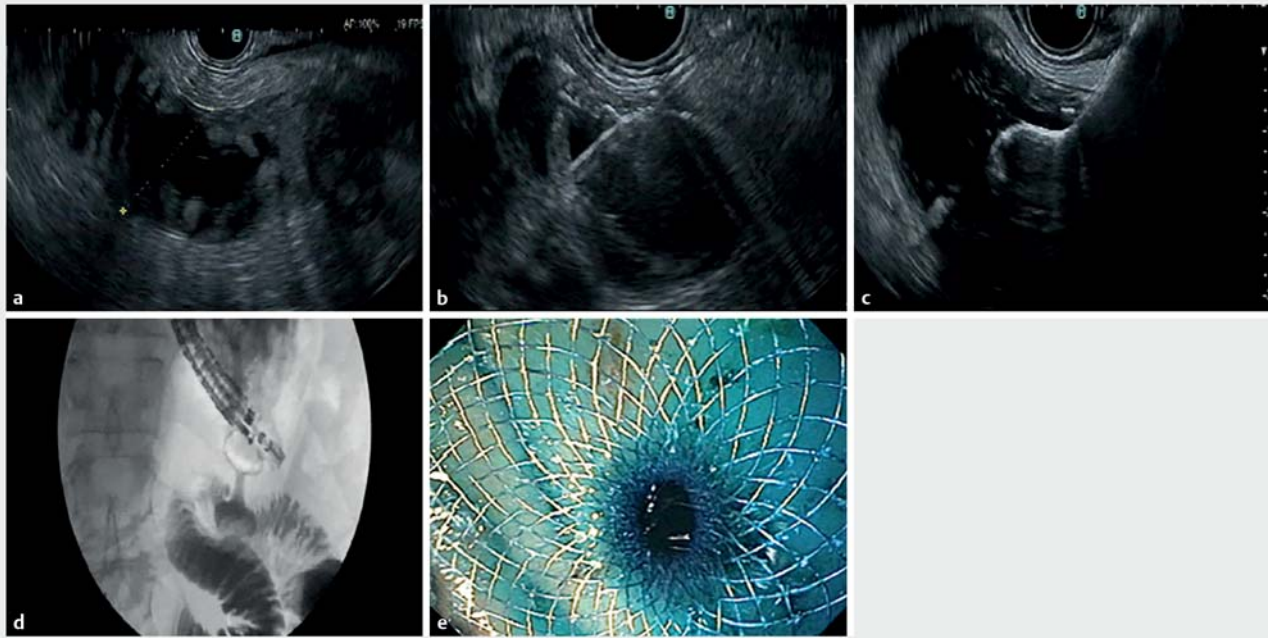
The study was approved by the local institutional review board for each of the participating centers. Data on de-identified patients were shared securely with the lead center, the Johns Hopkins Hospital, for data analysis.

EUS-GE procedure technique

Informed consent was obtained from all patients before EUS-GE was performed. All EUS-GEs were carried out by therapeutic endoscopists with patients under deep sedation or general anesthesia. The procedure was done with one of two different techniques, either direct or balloon-assisted EUS-GE, as previously described by our group [7, 10, 14–16].

In the direct EUS-GE, the gastroscope was advanced to the site of GOO. If the obstruction was traversable, a mixture of saline, dye, and methylene blue was infused downstream to distend the duodenum and jejunum. However, if the obstruction was nontraversable, the fluid mixture was injected at the site of obstruction. Then, using endoscopic ultrasound and fluoroscopy, a loop of small bowel adjacent to the stomach and distal to the obstruction was identified. Next, a puncture of the small-bowel loop was performed transgastrically using a 19-gauge needle. The correct placement of the needle was confirmed with aspiration of blue dye. This was followed by the direct deployment of a 15-mm or 20-mm cautery-enhanced LAMS (► Fig. 1).

In the balloon-assisted EUS-GE, a wire was passed through the obstruction and a balloon catheter was passed over the



► **Fig. 1** Endoscopic ultrasound (EUS)-guided gastroenterostomy using the 20-mm lumen-apposing metal stent (LAMS). **a** EUS view of the distended duodenum and jejunum after injection of contrast and methylene blue. **b** Puncture of the small-bowel loop distal to the obstruction with a 19-gauge finder needle with aspiration of blue dye. **c** Deployment of the distal flange under EUS guidance. **d** Fluoroscopic visualization of the fully deployed LAMS. **e** Endoscopic view of the deployed LAMS.

wire. The balloon was inflated with fluid when positioned in the duodenum or jejunum. Using EUS, the balloon was localized and punctured transgastrically using a 19-gauge needle. If the balloon burst, then the correct positioning of the needle tip within the small bowel had been confirmed. Finally, a guidewire was passed through the needle, with immediate deployment of a 15-mm or 20-mm LAMS over the wire, creating the gastroenterostomy (► **Fig. 1**).

Study outcomes and definitions

For each patient, we recorded their baseline characteristics, symptoms, and diet tolerated, according to the gastric outlet obstruction score (GOOS) system [17]. In this scoring system, 0 represents no oral intake, 1 represents a liquid diet, 2 represents semi-solids/low-residue diet, and 3 represents an unmodified diet. The primary outcome of this study was clinical success, which was defined as an increase in the GOOS by at least 1 point at the last follow-up after the procedure.

Secondary outcomes included technical success (defined as adequate positioning and deployment of the stent as determined endoscopically or radiographically), maximum tolerated diet (absolute GOOS), rate of re-intervention, and rate of adverse events (AE severity graded according to the American Society for Gastrointestinal Endoscopy [ASGE] lexicon [18]).

Statistical analysis

Statistical analysis was performed using SPSS software (SPSS 25.0; Chicago, Illinois, USA). Continuous variables were reported as mean (SD) or median (interquartile range [IQR]), while ca-

tegorical variables were reported as percentages. Comparisons between the two LAMS groups were analyzed using the Fisher exact test or chi-squared test for categorical variables, and with the *t* test or Wilcoxon sum rank test for continuous variables.

A multivariate logistic regression analysis was performed with regard to the primary outcome (clinical success) by including variables that differed at baseline between the two cohorts. *P* values of <0.05 were considered statistically significant. All other analyses were considered exploratory, so no correction for multiple testing was done.

Results

A total of 267 patients (mean [SD] age, 67.3 (12.1) years; women, 43%) with malignant GOO underwent EUS-GE at the participating centers during the study period. Of those patients, 148 (55.4%) underwent EUS-GE using the 15-mm LAMS, and 119 (44.6%) with the 20-mm LAMS. The baseline characteristics of the two groups, including age, gender, preoperative body mass index (BMI), preoperative diet tolerated, history of radiotherapy, history of chemotherapy, and history of previous stent or dilation, were equivalent (► **Table 1**). The most common etiology for malignant GOO in both groups was pancreatic cancer (*n* = 142, 53.2%). The most common presenting symptoms at the time of the procedure were nausea/vomiting (91.4%), abdominal pain (41.6%), and early satiety (37.5%).

*With respect to the preoperative diet tolerated, the majority (58.1%) of patients in both groups presented with an inability

► Table 1 Comparison of 15-mm and 20-mm lumen-apposing metal stents (LAMSs) for endoscopic ultrasound-guided gastroenterostomy (EUS-GE) in patients with malignant gastric outlet obstruction (GOO): baseline characteristics of study groups.

	15-mm LAMS (n = 148)	20-mm LAMS (n = 119)	Total (n = 267)	P value
General characteristics				
▪ Female, n (%)	62 (53.9)	53 (46.1)	115 (43)	0.71
▪ Age, mean (SD), years	67.9 (11.3)	66.7 (13)	67.3 (12.1)	0.52
▪ Previous radiotherapy; n (%)	28 (18.9)	14 (11.8)	42 (15.7)	0.13
▪ Previous chemotherapy; n (%)	48 (32.4)	53 (44.5)	101 (37.8)	0.06
▪ Preoperative BMI, mean (SD), kg/m ²	22.8 (4.0)	23.5 (5.1)	23.1 (4.5)	0.39
▪ Previous duodenal stenting or dilation; n (%)	26 (17.6)	15 (12.6)	41 (15.3)	0.31
Symptoms, n (%)				
▪ Nausea/vomiting	130 (87.8)	114 (95.8)	244 (91.4)	0.03
▪ Abdominal pain	77 (52.0)	34 (28.6)	111 (41.6)	>0.001
▪ Weight loss	15 (10.1)	6 (5.0)	21 (7.9)	0.17
▪ Early satiety	61 (41.2)	39 (32.8)	100 (37.5)	0.16
▪ Other	12 (8.1)	8 (6.7)	20 (7.5)	0.82
Preoperative diet, n (%)				
▪ No oral intake	89 (60.1)	66 (55.5)	155 (58.1)	0.74
▪ Liquid diet only	43 (29.1)	38 (31.9)	81 (30.3)	
▪ Soft solids	16 (10.8)	15 (12.6)	31 (11.6)	
BMI, body mass index.				

to tolerate any oral intake (GOOS 0) (15-mm vs. 20-mm: 60.1% vs. 55.5%), while 30.3% of patients presented with an ability to tolerate only a liquid diet (GOOS 1) (15-mm vs. 20-mm: 29.1% vs. 31.9%).

Clinical outcomes

► **Table 2** summarizes the outcomes in the two study groups. Technical success was achieved in the vast majority of the patients (n = 255, 95.5% [95%CI 93%–97.9%]) and was found to be similar for the two groups (15-mm vs. 20-mm: 96% [92.3%–99.1%] vs. 95% [91%–98.9%]). Median (IQR) follow-up duration was 72 (23–160) days and was similar for both groups (15-mm vs. 20-mm: 72 [23–159] days vs. 74 [26–165] days).

Clinical success, defined as an improvement in the GOOS by at least 1 point at last follow-up, was also achieved in the vast majority of the patients (n = 232, 87% [82.8%–90.9%]). This was also similar for the two groups, being achieved in 89.2% (84.2%–94.2%) in the 15-mm group versus 84.1% (77.4%–90.6%) in the 20-mm group. Over a median follow-up duration of 72 (23–160) days, 59.6% (53.7%–65.7%) of patients (n = 154) reached a complete diet (GOOS 3); 26% (0.6%–31.3%) (n = 67) tolerated a soft solid diet (GOOS = 2); 12.8% (8.7%–16.9%) (n = 33) tolerated a liquid diet (GOOS = 1); and 1.6% (0%–3%) (n = 4) did not tolerate oral intake. A higher proportion of patients in the 20-mm group vs. the 15-

mm group were able to tolerate a soft solid or complete diet (GOOS ≥ 2) at their last follow-up (91.2% [84.4%–95.7%] vs. 81.2% [73.9%–87.2%], *P* = 0.04).

The rate of reintervention was 8.1% (3.7%–12.5%) in the 15-mm group vs. 4.2% (0.6%–7.8%) in the 20-mm group; however, the difference was not statistically significant.

Considering that patients in the two groups differed at baseline with regard to nausea/vomiting and abdominal pain, we performed a multivariate analysis incorporating these variables. There was no statistically significant difference between the two types of stents at multivariate analysis with regard to clinical success (univariate odds ratio [OR] 0.64 [95%CI 0.29–1.47], *P* = 0.30; multivariate OR 0.51 [0.21–1.21], *P* = 0.13).

Adverse events

Overall, adverse events occurred in 12.4% (8.4%–16.3%) of patients (n = 33). The majority of these were misdeployment of stents (n = 23, 8.6% [5.5%–12.6%]), followed by aspiration pneumonia (n = 3, 1.1% [0.2%–3.3%]), postoperative infection (n = 3, 1.1% [0.2%–3.3%]), and small-bowel perforation (n = 2, 0.75% [0.1%–2.7%]) (► **Table 3**). Of these 33 adverse events, and according to the ASGE lexicon, 16 were mild (48.5% [31.4%–65.6%]); 10 were moderate (30.3% [14.6%–50%]); 4 were severe (12.1% [0.1%–23.2%]); and 3 were fatal (9.1% [0%–18.9%]). The 3 fatality cases were caused by: pulmonary

► **Table 2** Procedure outcomes in comparison of 15-mm and 20-mm LAMSs in patients with malignant GOO.

	15-mm LAMS (n = 148)	20-mm LAMS (n = 119)	Total (n = 267)	P value
Clinical success				0.30
▪ n	132	100	232	
▪ % (95%CI)	89.2 (84.2–94.2)	84.1 (77.4–90.6)	87 (82.8–90.9)	
Technical success				0.77
▪ n	142	113	255	
▪ % (95%CI)	96 (92.3–99.1)	95 (91–98.9)	95.5 (93–97.9)	
Time from operation until oral intake, mean (SD), days	1.2 (0.7)	1 (0.2)	1.1 (0.5%)	0.004
Re-intervention for GOO recurrence				0.22
▪ n	12	5	17	
▪ % (95%CI)	8.1 (3.7–12.5)	4.2 (0.6–7.8)	6.4 (3.4–9.3)	
Follow up duration; median (IQR)	70 (23–159)	74 (26–165)	72 (23–160)	0.48
BMI at last follow up, mean (SD), kg/m ²	22.7 (4.7)	23.4 (5.2)	23 (4.9)	0.58
Diet tolerated at last follow-up¹				
No oral intake				
▪ n	4	0	4	
▪ %, 95%CI	2.8 (0–5.3)	0 (0–0)	1.6 (0–3)	
Liquid diet only				
▪ n	23	10	33	
▪ %, 95%CI	16 (9.7–21.8)	8.8 (3.4–13.4)	12.8 (8.7–16.9)	
Soft solids				
▪ n	39	28	67	
▪ %, 95%CI	27 (19.2–33.5)	24.6 (15.9–31.2)	26 (20.6–31.3)	
Complete diet				
▪ n	78	76	154	
▪ %, 95%CI	54.2 (44.7–60.7)	66.6 (55.2–72.5)	59.6 (53.7–65.7)	0.04 ²

IQR, interquartile range; BMI, body mass index.

¹ Information missing in 9 (3%) patients.

² Comparison between 15-mm and 20-mm group for combined “Soft solids” and “Complete diet” categories.

embolism, following surgery to manage a misdeployed stent; atrial fibrillation leading to severe hypotension and shock; and aspiration pneumonia following the procedure.

The adverse event rates were found to be similar for the 15-mm and 20-mm groups (12.8% [7.5%–18.2%] vs. 11.8% [6%–17.6%]), including the rate of severe/fatal AEs (2% [0.4%–5.8%] vs. 3.4% [0.92%–8.4%]) and the need for surgical intervention (0.7% [0%–3.7%] vs. 2.5% [0.5%–7.2%]). The rate of stent misdeployment was also comparable between the 15-mm and 20-mm groups (8.7% [4.8%–14.6%] vs. 8.4% [4.1%–14.9%]).

Discussion

With continuous advancements in the field of interventional EUS, palliative treatment of patients with malignant GOO has become more successful. With the introduction of large-caliber, dumbbell-shaped LAMS, EUS-GE has become a relatively safe and established technique for the treatment of these patients. The 15-mm LAMS has always been used as the majority of studies have showed its technical feasibility, clinical efficacy, and safety [6–8]. However the 20-mm LAMS has recently been made available, on the hypothesis that a wider lumen may theoretically lead to better clinical results. To the authors' knowledge, there are no studies in the literature that have assessed

► **Table 3** Adverse events related to endoscopic ultrasound-guided gastroenterostomy (EUS-GE) procedures with 15-mm and 20-mm LAMSs in patients with malignant (GOO).

	15-mm LAMS (n = 148)	20-mm LAMS (n = 119)	Total (n = 267)	P value
Adverse event				
Misdeployment of stent				0.91
▪ n	13	10	23	
▪ % (95%CI) ¹	68.3 (47.5–89.3)	71.6 (47.8–95)	70 (54–85.3)	
Aspiration pneumonia				0.25
▪ n	3	0	3	
▪ % (95%CI) ¹	15.8 (0–32.2)	0 (0–0)	9 (0–18.9)	
Small-bowel perforation				0.87
▪ n	1	1	2	
▪ % (95%CI) ¹	5.3 (0–15.3)	7.1 (0–20.6)	6 (0–14.2)	
Shock/bacteremia				0.87
▪ n	1	1	2	
▪ % (95%CI) ¹	5.3 (0–15.3)	7.1 (0–20.6)	6 (0–14.2)	
Peritonitis				0.36
▪ n	1	0	1	
▪ % (95%CI) ¹	5.3 (0–15.3)	0 (0–0)	3 (0–8.9)	
Other				0.45
▪ n	0	2	2	
▪ % (95%CI) ¹	0 (0–0)	14.2 (0–32.6)	6 (0–14.2)	
Total				0.60
▪ n	19	14	33	
▪ % (95%CI) ²	12.8 (7.5–18.2)	11.8 (6–17.6)	12.4 (8.4–16.3)	
Adverse events according to ASGE lexicon score				0.60
Mild				
▪ n	10	6	16	
▪ % (95%CI) ¹	52.7 (30.2–75)	42.9 (16.9–68.8)	48.5 (31.4–65.6)	
Moderate				
▪ n	6	4	10	
▪ % (95%CI) ¹	31.6 (10.7–52.5)	28.6 (4.9–52.2)	30.3 (14.6–50)	
Severe				
▪ n	1	3	4	
▪ % (95%CI) ¹	5.3 (0–15.3)	21.4 (0–42.9)	12.1 (0.1–23.2)	
Fatal				
▪ n	2	1	3	
▪ % (95%CI) ¹	10.4 (0–23.3)	7.1 (0–20.6)	9.1 (0–18.9)	

ASGE, American Society for Gastrointestinal Endoscopy.

¹ Percentage of the total number of complications in the group.

² Percentage of the total number of patients in the group.

the clinical outcomes of using the 20-mm LAMS in EUS-GE. Therefore, this multicenter, international, study is the first to assess the use of the novel 20-mm LAMS and compare it with the traditional 15-mm LAMS in EUS-GEs for palliative treatment of malignant GOO, in terms of efficacy, safety, and adverse events.

The first published use of the 20-mm LAMS for an EUS-GE was a case report by Madanat et al. [19]. The patient initially had a duodenal stricture for which an EUS-GJ was done using a 15-mm LAMS. After 6 months, the patient developed recurrent nausea/vomiting due to tissue ingrowth within the previously placed stent. A 20-mm LAMS was then deployed through the previous stent, and the patient's symptoms resolved after the procedure.

In two recent systematic reviews and meta-analyses [6, 8], it was shown that the EUS-GE procedure had a clinical success rate of 90% (85%–94%) in the first review and 90.1% (84.6%–93.4%) in the second. The technical success rates were 92% (88%–95%) and 92.9% (88.3%–95.8%), respectively. In our study, we included a total of 267 patients who underwent EUS-GE for treatment of malignant GOO. Clinical success was achieved in 87% of patients (n = 232), which is within the confidence interval of both systematic reviews, and technical success was achieved in 95.5% of patients (n = 255), which is within the confidence interval of the second systematic review.

Although clinical success was similar for the two groups (89.2% [84.2%–94.2%] for 15-mm and 84.1% [77.4%–90.6%] for 20-mm LAMSs), the type of diet tolerated at follow-up was different. A higher proportion of the patients in the 20-mm LAMS group tolerated a soft/complete diet (GOOS \geq 2) compared to those in the 15-mm group (91.2% [84.4%–95.7%] vs. 81.2% [73.9%–87.2%], $P=0.04$). This supports the idea that a larger luminal diameter of LAMS may result in better clinical outcomes and allow patients to eventually reach a better tolerated diet.

Because of its wider luminal diameter and larger flange size, one would expect more difficulty in deploying the 20-mm LAMS compared to the 15-mm LAMS and also a higher rate of adverse events. However, the results in our study showed otherwise. Technical success was similar between both groups (96% [92.3%–99.1%] for 15-mm vs. 95% [91%–98.9%] for 20-mm LAMS) as well as the rate of stent misdeployment (8.7% [4.8%–14.6%] for 15-mm vs. 8.4% [4.1%–14.9%] for 20-mm LAMS). Overall, adverse events were reported in 33 procedures (12.4% [8.4%–16.3%]) which was similar to the overall adverse events seen in a recent systematic review and meta-analysis of 12 studies (12% [8%–16%]) [6]. The total rate of adverse events in the 20-mm LAMS group was comparable to that in the 15-mm group (11.8% [6%–17.6%] vs. 12.8% [7.5%–18.2%]). The most common adverse event was stent misdeployment and the rate was equivalent in the two groups (8.7% [4.8%–14.6%] vs. 8.4% [4.1%–14.9%]).

Although this is a large international multicenter study, it has some limitations related to its retrospective design. Variability in endoscopic techniques and the procedure itself as well as differences in protocols related to patient care and follow-up periods across the centers are some of these expected limita-

tions. Another notable limitation is the lack of data from both groups about peritoneal tumor dissemination, which might be a factor that contributes to the higher rate of abdominal pain in the 15-mm group. As with any observational study, unmeasured residual confounding is always possible. However, when we performed a multivariate analysis by including factors that differed between groups at baseline, we did not observe a substantial modification of the primary outcome (clinical success), compared to univariate analysis. Also, the secondary outcomes in our study are to be considered as exploratory in nature, and will need to be confirmed in future studies. However, our study is the first to assess and compare the 20-mm vs. the 15-mm LAMS in a large retrospective design. The relatively large cohort size as compared to other studies in the literature is a major strength of our study. Also, the inclusion of centers from many different countries adds an element of generalizability to this study and illustrates the worldwide usage of the 20-mm LAMS in EUS-GE procedures.

In conclusion, the 20-mm LAMS is similar to the 15-mm LAMS in terms of safety and efficacy for patients undergoing EUS-GE for malignant GOO. The 20-mm LAMS allows a more advanced diet and is, thus, the preferred LAMS during EUS-GE, according to our study.

Competing interests

A. Anderloni is a consultant for Boston Scientific, Medtronic and Olympus. J.R. Aparicio is a consultant for Boston Scientific. J.M. Buscaglia is a consultant for Abbvie. B. Confer is a consultant for Boston Scientific. D.L. Diehl is a consultant for Boston Scientific. C.J. DiMaio is a consultant for Boston Scientific, Covidien, and SafeHeal; and a speaker for AbbVie, Mauna Kea, and STERIS. A. Fugazza is a consultant for Boston Scientific and Olympus. M.T. Huggett is a consultant for Boston Scientific, Olympus America, and Cook Medical. M.A. Khashab is a consultant for Boston Scientific, Olympus, Medtronic, GI Supply, MicroTech, and Apollo. H.S. Khara is a consultant for Boston Scientific. T.E. Kowalski is a consultant for Boston Scientific and Medtronic. N.A. Kumta is a consultant for Boston Scientific, Apollo Endosurgery, Intuitive Surgery, Medtronic, and Olympus. D. Loren is a consultant for Boston Scientific, Olympus, and Pinnacle Biologics; and receives research support from Medtronic. J.M. Nieto is a consultant for Boston Scientific. B. Paranandi is a consultant for Boston Scientific and Olympus America. K. D-C. Pham is a consultant for Boston Scientific; he is a speaker for Boston Scientific, Cook Medical, Olympus America and Taewoong Medical; and he is on the advisory board of Ambu. D.K. Pleskow is a consultant for Boston Scientific, Olympus America, and FujiFilm. D.V. Sejal is a consultant for Boston Scientific and Olympus America. R.Z. Sharaiha is a consultant for Boston Scientific, Cook Medical, Olympus, and Lumendi. A.J. Trindade is a consultant for Pentax Medical and Olympus America. R.R. Watson is a consultant for Boston Scientific. The remaining authors declare that they have no conflict of interest.

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CORRECTION

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In the above-mentioned article, the name of Umair Iqbal has been corrected. This was corrected in the online version on March 16, 2022.