

Endoscopic ultrasound-guided gastroenterostomy using large-diameter (20 mm) lumen apposing metal stent (LLAMS)



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ABSTRACT

Background and study aims Endoscopic ultrasound-guided gastroenterostomy (EUS-GE) using a 15-mm lumen apposing metal stent (LAMS) has emerged as a viable alter-

native to surgical gastrojejunostomy for management of gastric outlet obstruction (GOO). However, given the size of the anastomosis created with a 15-mm LAMS, long-term luminal patency and clinical outcomes may be suboptimal. The aim of this study was to evaluate the technical feasibility, efficacy, and safety of EUS-GE with a large-diameter (20 mm) LAMS (LLAMS).

Patients and methods A retrospective analysis of a prospectively maintained database of all patients undergoing EUS-GE with LLAMS between December 1, 2018 and September 30, 2020 was performed. All EUS-GEs were performed using a cautery-enhanced LLAMS.

Results Thirty-three patients were referred for endoscopic management of GOO. Two patients were excluded due to a lack of an adequate window for EUS-GE. The remaining 31 patients (93.94%) (mean age: 61.35 ± 16.52 years; 54.84% males) underwent EUS-GE using LLAMS for malignant (n = 23) and benign (n = 8) GOO. Technical success was achieved in all patients (100%) with attempted EUS-GE. Complete clinical success (tolerance of regular diet) was achieved in 93.55% of patients (n = 29). Two patients (6.45%) had partial clinical success and died of unrelated causes prior to advancing diet beyond full liquids. Overall mean follow-up was 140.84 ± 160.41 days (median 70, range 4–590). All stents remained patent with no evidence of recurrent GOO symptoms. One patient (3.23%) developed an asymptomatic clean-based jejunal ulcer on 3-month follow-up endoscopy. **Conclusions** EUS-GE with LLAMS is a technically feasible, effective and safe option for patients with GOO allowing for tolerability of regular diet. Future prospective, ideally randomized studies comparing long-term outcomes of EUS-GE with 20- and 15-mm LAMS are required.

Introduction

Gastric outlet obstruction (GOO) presents with nausea, vomiting, and the inability to tolerate enteral nutrition secondary to mechanical obstruction within the gastrointestinal tract as a result of both benign and malignant processes. Regardless of the etiology, bypass or relief of the mechanical obstruction is the key to management. Traditionally, surgical gastrojejunostomy

has been the primary treatment approach for both benign and malignant GOO [1]. However, it is associated with high mortality and an adverse event rate of around 40% [2, 3]. Further it is limited by prolonged recovery times, delaying therapy for malignancy-related obstructions, and substantial cost [2]. These factors led to the development of less-invasive endoscopic alternatives. Endoscopic luminal self-expanding metal stents (SEMS) have demonstrated earlier onset of oral intake and re-

duced length of stay during the index hospitalization in patients with malignant GOO. However, they are associated with poor long-term patency from tumor or tissue-ingrowth, recurrent symptoms and gastrointestinal bleeding, leading to reinterventions [1]. Benign GOO is even more challenging to manage as endoluminal stenting with fully covered SEMs is associated with a higher risk of adverse events (AE) including stent migration and risk of ampullary obstruction [4, 5].

More recently, endoscopic ultrasound-guided gastroenterostomy (EUS-GE) using 15-mm lumen apposing metal stents (LAMS) has emerged as a viable alternative to both surgical gastrojejunostomy and endoluminal stenting. Recent meta-analyses have demonstrated that EUS-GE appears to provide an effective and safe minimally invasive alternative for treatment of benign and malignant GOO [6, 7]. However, given the size of the gastroenterostomy (GE) anastomosis created with a 15-mm LAMS, long-term luminal patency and clinical outcomes may be suboptimal, with a proportion of patients subject to dietary restrictions. The aim of this study was to evaluate the technical feasibility, efficacy, and safety of EUS-GE with a large-diameter (20 mm) LAMS (LLAMS) for benign and malignant GOO.

Patients and methods

A retrospective analysis of a prospectively maintained database of all consecutive patients undergoing EUS-GE with LLAMS for GOO from December 1, 2018 to September 30, 2020 was performed. Charts were reviewed for indications, technical and clinical success, adverse events (AEs), and long-term outcomes. Technical success was defined as the successful transmural deployment and placement of LLAMS between the stomach and the target loop of proximal small bowel distal to the site of obstruction, creating an endoscopic GE. Clinical success was defined as the ability to tolerate solid/regular consistency diet at 2 weeks after the procedure. Partial clinical success was defined as the ability to tolerate full liquid diet or diet up to their maximum consistency allowed based on other clinical factors. As part of clinical care, the patients were followed to determine clinical success, recurrence of symptoms, and the development of procedure-related AEs including intraprocedural or delayed bleeding, infection (fever, peritonitis, sepsis), perforation, stent migration and dysfunction. The severity of AEs was defined by the American Society for Gastrointestinal Endoscopy (ASGE) lexicon severity grading index [8]. Descriptive analysis was performed by calculating means and standard deviations for continuous variables and proportions for categorical ones. The study was approved by our Institutional Review Board.

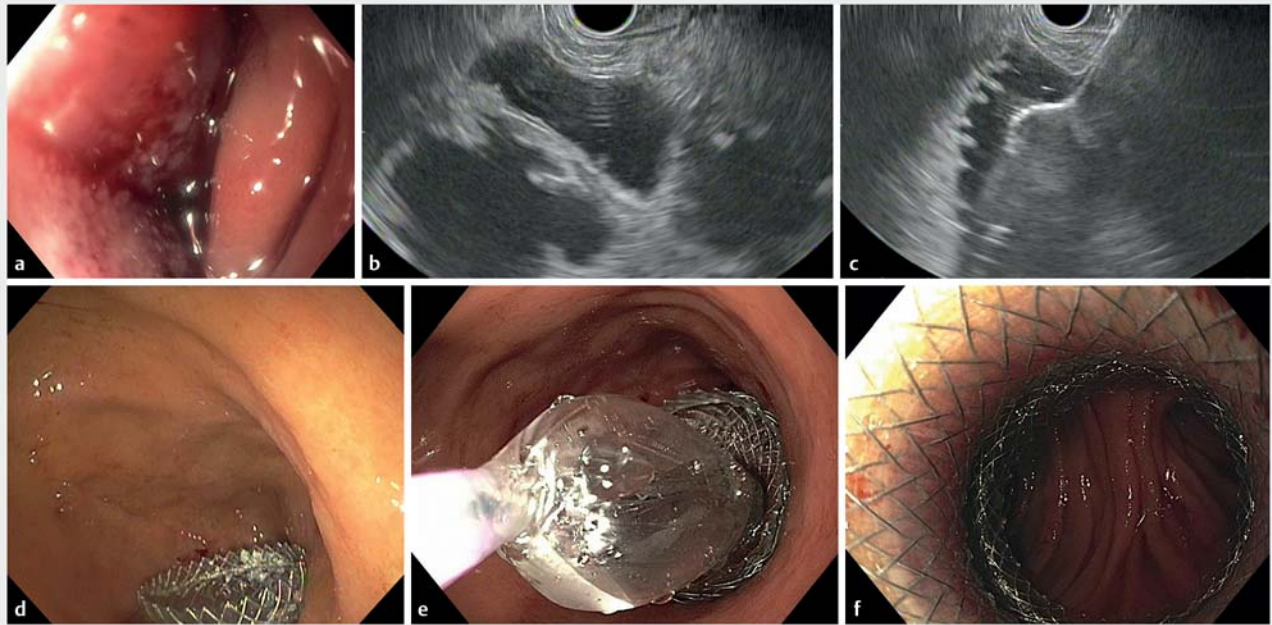
Procedure

All procedures were performed by a single therapeutic endoscopist (TR) with significant experience in interventional EUS and LAMS placement. All patients underwent general anesthesia with endotracheal intubation given the risk of aspiration from underlying GOO. No peri-procedural antibiotics were administered.

An esophagogastroduodenoscopy (EGD) was performed using an upper endoscope (GIF 190; Olympus America, Center Valley, Pennsylvania, United States) in the same setting to confirm and evaluate the obstruction prior to proceeding with gastroenterostomy. An angled 0.025-inch Visiglide 2 guidewire (Olympus Medical, Center Valley, Pennsylvania, United States) was passed across the stricture and allowed to coil in the jejunum. A 10 Fr orojejunal tube (Cook Medical, Bloomington, Indiana, United States) or a 12- to 15-mm Controlled Radial Expansion (CRE) balloon dilator (Boston Scientific Incorporated; Marlborough, Massachusetts, United States) was passed over a guidewire into the jejunum distal to the site of obstruction. The jejunal lumen was subsequently distended using a mix of dilute contrast, saline and methylene blue using the water irrigation pump attached to the external end of the orojejunal tube (Cook Medical, Bloomington, Indiana, United States). EUS was performed using a therapeutic curved linear-array echoendoscope (UCT 180, Olympus America, Center Valley, Pennsylvania, United States). With the EUS scope in the distal gastric lumen, a distended loop of distal duodenum or proximal jejunum was identified in close proximity to the gastric wall, using fluoroscopic assistance if needed. Color Doppler imaging was used to identify any major blood vessels within the stent path. We accessed the target loop of intestine using a 22g fine-needle aspiration needle via a transgastric approach under endosonographic and fluoroscopic guidance. Aspiration of methylene blue fluid confirmed small bowel limb. Next a transgastric-transenteric 20 mm × 10 mm cautery-enhanced biflanged fully covered LAMS (AXIOS, Boston Scientific Corporation; Marlborough, Massachusetts, United States) was placed under endosonographic guidance using the recommended ERBE (ERBE Elektromedizin GmbH; Tübingen, Germany) settings (Effect 5; 100 W Autocut) (► Fig. 1). The distal and proximal flanges of the stent were deployed creating an endoscopic gastroenterostomy. Position of the stent was confirmed by noting dilute methylene blue flowing across the stent. Contrast injection via the stent was used to further confirm free flow into the intestine without extravasation into the peritoneal cavity. The angled 0.025-inch Visiglide 2 guidewire was passed through the gastroenterostomy-LLAMS and allowed to coil in the jejunum under fluoroscopic guidance. The gastroenterostomy-LLAMS was then serially dilated from 10 mm to 15 mm using CRE Balloon dilators over the guidewire. The upper endoscope or an ultraslim XP 190 gastroscope (Olympus Medical, Center Valley, Pennsylvania, United States) was passed through the stent to confirm adequate positioning of the distal flange and to evaluate opposing wall for any injury (► Fig. 1).

Post-procedure protocol

Post-procedure, the patients were kept Nil Per Os (NPO) for 4 hours. The diet was subsequently advanced in a stepwise fashion: clear liquid diet for 24 hours, full liquid diet for the following 72 hours, and then soft diet for the next 7 days. After this gradual advancement they were encouraged to eat a regular diet. For outpatient EUS-GE procedures, the patients came to the endoscopy suite the day of the procedure and were discharged on the same day. Detailed written instructions includ-



► **Fig. 1** **a** Endoscopy showing high-grade malignant obstruction of the duodenum. **b, c** EUS showing distended fluid-filled proximal jejunal limb aligned near vertically **c** with deployment of distal flange of the LLAMS under endosonographic guidance. **d** Endoscopy showing successful LLAMS placement in distal stomach **e** followed by dilation of the LLAMS-GE using a CRE balloon. **f** Endoscopy showing afferent and efferent jejunal lumen visualized across the LLAMS.

ing diet protocol and for monitoring signs and symptoms of AEs were provided to the patients. Telephonic follow-up was conducted on the evening of the procedure, at 24 hours, and within 1 week, followed by close outpatient clinic visits.

Results

A total of 33 patients were referred for endoscopic management of GOO. An adequate window for EUS-GE could not be identified in two patients and EUS-GE was not attempted. One of these patients had a large ulcerated tumor infiltrating the gastric wall precluding EUS-GE, and was managed with placement of a duodenal stent, in the same session. The second patient had extensive peritoneal carcinomatosis and a proximal small bowel limb could not be identified in close proximity to the gastric wall despite adequate fluid distension of the proximal small bowel.

The remaining 31 of 33 patients (93.94%) underwent EUS-GE for malignant (n=23) and benign (n=8) GOO (► **Table 1**). All patients with benign GOO were refractory or not amenable to conventional endoscopic therapy (► **Table 1**). All EUS-GEs were performed using LLAMS. The mean age of patients was 61.35 ± 16.52 years with 54.84% (n=17) being male. Twelve patients (38.71%) had prior endoscopic therapy with dilation, SEMS or both. Technical success was achieved in all 31 patients (100%) in whom EUS-GE was attempted (intention to treat analysis 93.94%). One patient required two attempts as an adequate window was not available given large volume ascites on the first attempt; an adequate window was identified on a re-

peat attempt after therapeutic paracentesis. Complete clinical success was achieved 93.55% of patients (n=29); partial clinical success was achieved in two patients (6.45%) who died of unrelated causes prior to advancing diet beyond full liquids. One patient died on post-procedure day 4 in a hospice facility, secondary to suspected biliary sepsis. The second patient died on post procedure day 12 due to acute respiratory failure secondary to pulmonary edema.

Nine patients (29%) had EUS-GE as an outpatient procedure without any AEs. Overall mean follow-up was 140.84 ± 160.41 days (median 70, range 4–590). All stents remained patent with no evidence of recurrent GOO. Of the 23 patients with malignant obstruction, 17 died of non-procedure-related causes as a result of their advanced malignancy during the mean follow-up duration of 88.35 ± 98.51 (median 54, range 4–395). The eight patients with benign GOO had a mean follow-up of 291.75 ± 211.40 days (median 290, range 66–590).

Based on the American Society for Gastrointestinal Endoscopy Lexicon of AEs mild procedure-related AEs were noted in one patient (3.23%) who was noted to develop a clean-based jejunal ulcer noted on routine 3-month follow-up EGD. One patient presented 5 weeks after EUS-GE with severe upper gastrointestinal bleeding not related to the EUS-GE. EGD showed an actively bleeding ulcer secondary to erosion from a previously placed duodenal stent. The GE-LLAMS was in adequate position and patent with no other source of bleeding identified. The patient underwent interventional radiology-guided angiography which showed active hemorrhage from multiple branches of

► **Table 1** Summary of patients undergoing EUS-GE with LLAMS.

	Overall (n = 31)	Malignant (n = 23)	Benign (n = 8)
Age (years)	61.35 ± 16.52	67.13 ± 10.77	44.75 ± 19.51
Male	54.84% (17)	56.52% (13)	50% (4)
Etiology		Pancreatic 43.4% (10)	Peptic stricture 50% (4)
		Duodenal 17.39% (4)	
		Metastatic 17.39% (4)	Chronic pancreatitis 25% (2)
		Gallbladder 13.04% (3)	
		Cholangiocarcinoma 4.35% (1)	SMA syndrome 25% (2)
		Gastric 4.35% (1)	
Technical success	100% (31)	100% (23)	100% (8)
Mean follow-up (days)	140.84 ± 160.41	88.35 ± 98.51	291.75 ± 211.40
Median follow-up (days)	70	54	290
Clinical success	93.55% (29)	91.30% (21)	100% (8)
Adverse events	3.23% (1)	0% (0)	12.5% (1)
Prior therapy (any)	38.71% (12)	21.74% (5)	87.5% (7)
Prior dilation	16.13% (5)	–	62.5% (5)
Prior SEMS	16.13% (5)	17.39% (4)	12.5% (1)
Prior dilation and SEMS	6.45% (2)	4.35% (1)	12.5% (1)

EUS-GE, endoscopic ultrasound-guided gastroenterostomy; LLAMS, lumen apposing metal stent; SMA, superior mesenteric artery; SEMS, self-expanding metal stent

the gastroduodenal artery into the duodenum and was successfully treated with Gelfoam and coil embolization.

Discussion

GOO is a challenging entity; with surgical gastrojejunostomy being the primary therapeutic modality, however, this is associated with a high rate of AEs. Endoscopic therapy for benign intraluminal strictures with dilation often requires multiple sessions over time before the patient is able to tolerate a regular diet and has a high risk of AEs including bleeding and perforation. Endoscopic luminal stenting is an effective endoscopic option for malignant GOO; however, stent dysfunction from tumor/tissue ingrowth with recurrent GOO is an issue, particularly with increasing survival rates/life expectancy in many cancer patients from newer oncologic therapies. EUS-GE originally performed in a porcine model by Fritscher-Ravens et al in 2002 appears to bridge surgical and endoscopic modalities [9]. Given the cumbersome and technically challenging nature of the originally described procedure along with the need for special devices it was difficult to adopt in clinical practice [9, 10]. The development of LAMS, with the ability to safely appose two juxtaposed luminal structures and form an endoscopic anastomosis brought new insights into development of EUS-GE [10, 11].

Currently EUS-GE is performed at high-volume centers with three major techniques for identification of a target limb [12]. The direct EUS-GE technique where the target intestinal lumen is identified using EUS and confirmed with contrast injection

using a 19 or 22G needle. In the balloon assistance technique, a dilating balloon is advanced beyond the stricture and filled with contrast serving as a target for EUS needle puncture, wire passage, and deployment of the LAMS. The third technique (EPASS) involves a proprietary double balloon enteric tube (Create Medic Co., Ltd., Yokohama, Japan) which is advanced over a guide wire beyond the ligament of Trietz. The balloons are inflated and the space between them is distended with contrast serving as a target [13]. Once target limb is identified, there are two methods for LAMS placement for EUS-GE: freehand puncture using cautery-enhanced LAMS delivery system; and 19G needle puncture with passage of guidewire and stent placement over the guidewire. There appears to be a high rate of technical success regardless of the technique applied. In our study we used a modified direct EUS-GE technique with tube-assisted fluid instillation method to distend the intestinal lumen to create a target followed by free-hand puncture using CE-LAMS.

Two recent meta-analyses have been performed looking at EUS-GE for benign and malignant GOO. Both reported similar combined technical success of 92.90% (95% CI; 88.26 to 95.79; $I^2=0.00\%$) and 92% (95% CI 88–95%; $I^2=0.00\%$) respectively [6, 7]. In our study, technical success was achieved in all patients in whom the procedure was attempted. As stated earlier two patients did not have an adequate window and EUS-GE was not attempted. One patient required two attempts as an adequate window was not available given large volume ascites on the first attempt. We reattempted after a large volume para-

centesis and were successful in finding an adequate window for EUS-GE.

A major technical limitation and prerequisite is the availability of a distended limb of small bowel that is distal to the site of obstruction and in close proximity to the stomach. Distension of the small bowel with fluids allows some repositioning bringing it into close proximity with the distended stomach. Additionally, this enables clear identification of target small bowel loop and easier placement of the LAMS. However, in a small subset of patients an adequate window may not be available despite such maneuvers, especially in patients with limited mobility of the proximal small bowel (secondary to adhesions, carcinomatosis or post-surgical anatomy), or increased distance between the stomach and target limb (as a result of intervening ascites, lymph nodes, tumor masses, peritoneal carcinomatosis or omental implants). Further as seen in one of our patients, tumor invasion of the gastric wall with ulceration along the greater curvature-posterior wall in gastric body may also preclude placement of stent. Careful review of pre-procedure imaging with our radiology colleagues may be able to identify some of these cases.

In the above meta-analyses pooled clinical success rates were 90.11% (95% CI; 84.64 to 93.44; $I^2=0.00\%$) and 90% (95% CI 85–94%; $I^2=0.00\%$) [6, 7]. Clinical success as determined by improvement in the gastric outlet obstruction scoring system (GOOSS) was only reported by Itoi et al with a median post-GOOSS score significantly higher than the pre-GOOSS score (0.00 versus 3.00; $P<0.001$) [14]. The meta-analysis by Iqbal et al including 12 studies with 285 patients reported recurrence or unplanned reintervention in 9% of patients (95% CI 6–13%; $I^2=0.00\%$). AEs were noted in 12% of patients (95% CI 8–16%) [7].

Although prior EUS-GE studies using 15 mm LAMS have reported high clinical success rates, a significant proportion of patients in those studies have been restricted to liquid or soft diet. In a study of 26 patients with benign GOO undergoing EUS-GE using 15 mm LAMS, with clinical success rate of 84%, only 56% patients were able to tolerate a regular diet [15]. Similarly, a study of 45 patients undergoing EUS-GE for malignant GOO, predominantly (73%) using 15-mm LAMS, reported technical and clinical success rates of 86.7% and 73.3%, respectively. However, 45% of patients with clinical success were restricted to a soft diet [16]. Another long-term study evaluating 22 patients with benign GOO reported recurrent GOO in five patients (23.8%) while the stent was in place; four of them were secondary to occlusion of the stent by food residue [17]. This maybe attributable to the narrower diameter of the smaller size (15 mm) LAMS. Using LLAMS may be beneficial as the larger lumen is comparable in size to the physiological gastric outlet of 20 to 23 mm. Further, this is comparable to the diameter of endoluminal stents (20–22 mm) and surgical anastomosis with a prestricturing anastomosis between 21 to 28 mm for circular anastomosis and 20 to 30 mm for linear anastomosis.

In our study, clinical success was defined as the ability to tolerate regular diet. This goal was achieved in 93.55% of our patients ($n=29$). Two patients (6.45%) tolerated full liquid diet but died from unrelated causes prior to advancing diet beyond full liquids and therefore complete clinical success could not be

assessed in two patients. We assume the larger diameter of the LLAMS allows for tolerance of regular consistency solid diet, and is less likely to become obstructed by residual food particles and tissue ingrowth within the stent [18]. The larger luminal diameter of the 20-mm LAMS provides approximately 300% and 78% greater cross-sectional area compared with the 10-mm and 15-mm LAMSs, respectively, which has been found to be beneficial for drainage of large walled-off necrosis [19, 20] and EUS-directed transgastric ERCP (EDGE) [19, 23].

Although the technique of EUS-GE remains similar when placing 15-mm and 20-mm LAMS, placement of LLAMS may be technically more challenging with increased risk of maldeployment of the stent given the increased distance required in intestinal lumen for correct deployment of the distal flange within the enteral lumen during placement of LLAMS. This requires careful selection of the intestinal (distal duodenal or proximal jejunal) limb and is typically facilitated by adequate distension of the small bowel with orojejunal tube-assisted fluid instillation and advancing the LAMS delivery system into the small bowel along the longitudinal axis as much as possible to provide longer safe distance for deployment of the distal flange of the stent. Pushing the stent instead of retracting the hub might also allow for safer placement of stent in cases where less than optimal distance is attained despite above maneuvers. We had a low AE rate (1 patient with clean-based jejunal ulcer) with no serious procedure- or stent-related AEs, comparable to AE rate reported with 15 mm EUS-GE studies [6, 17].

Currently LAMS is not considered a permanent prosthesis; however, in patients with advanced malignancy, it is considered an adequate destination therapy. This may be further extended to patients with significant comorbidities and limited life expectancy. The challenge in patients with benign GOO is determining the optimal time and criteria for removal of the LAMS, especially given reports of delayed perforation occurring 6 months after creation of EUS-GE [24]. Considering the relatively recent adaptation of this technique long term data is not yet available. In a recent series on benign GOO by James and colleagues, the LAMS were electively removed after a mean dwell time of 270 ± 273 days in 18 patients. In their study, as discussed previously, five patients developed recurrent GOO while the LAMS was in place; further three patients had recurrence after removal of the LAMS. Of the patients with recurrence after removal of the LAMS one underwent surgery and two underwent placement of a second LAMS as they were deemed poor operative candidates [17]. Long-term follow-up of these selected patients may help provide data regarding the permeance of LAMS in the future.

We present the first and largest series on the exclusive use of LLAMS for EUS-GE in the management of benign and malignant GOO. However, our study has several limitations. Although we have a prospective database, the study was a retrospective analysis with the inherent limitations of a retrospective case series including heterogeneity in patient population. Most studies on EUS-GE are currently limited to case series from high volume centers limiting generalizability. Furthermore, EUS-GE is a complex and highly skilled procedure which has a steep learning

curve and requires significant technical expertise. Lastly, as all patients with GOO referred for endoscopic management during the study period underwent EUS-GE with LLAMS, there is a lack of comparison group with EUS-GE using 15-mm LAMS or enteral stents; however, this adds to the strengths of the study by reducing the risk of selection bias.

Conclusions

In our experience, EUS-GE with LLAMS for benign and malignant GOO is an effective and safe option with high rates of technical and clinical success. The large diameter of the stent allows for tolerance of regular-consistency diet. Further studies comparing long-term outcomes of EUS-GE with 20- and 15-mm LAMS are required.

Competing interests

Dr. Rustagi is a consultant for Boston Scientific.

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