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Safety of teaching endoscopic ultrasound-guided gastroenterostomy (EUS-GE) can be improved with standardization of the technique*

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ABSTRACT

Background and study aims Endoscopic ultrasound-guided gastroenterostomy (EUS-GE) is a novel technique developed to manage gastric outlet obstruction (GOO). It involves creating a fistula between the stomach and the proximal small bowel using an electric cautery-enhanced lumen-apposing metal stent (ECE-LAMS) with EUS guidance. We aimed to publish our experience in improving teaching of this technique to practicing endoscopists with a wide range of experience by comparing the outcomes before and after standardization of procedural steps.

Methods All EUS-GEs performed for inoperable GOO at a single institution from 2014 to 2021 were retrospectively analyzed. The technique was taught by one experienced endoscopist with prior expertise. Five advanced endoscopists with prior EUS and ECE-LAMS placement experience participated. The impact of standardization on outcomes (clinical and technical success, length of stay [LOS], procedure time, and adverse events [AEs]) was compared.

Results A total 41 EUS-GEs were performed (5 before and 36 after standardization) by endoscopists with practice experience ranging from 2 to 13 years. The patient population was similar in age and sex. Standardization was associated with significantly higher rates of technical success (100 % vs 60 %, $P=0.01$) and lower peri-procedural AEs (2.8 % vs 40 %, $P=0.03$). Two AEs in the pre-standardized group were gastric perforation and gastrocolic fistula creation. One AE in the post-standardized group was gastric perforation. Procedure time, clinical success, and LOS showed improvement, although it was not statistically significant.

Conclusions Teaching EUS-GE after standardizing the procedure was associated with a significant increase in technical success and a decrease in AEs irrespective of prior total experiences.

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Introduction

Gastric outlet obstruction (GOO) is a clinical condition in which patients present with abdominal pain, nausea, and postprandial vomiting due to a mechanical blockage of the upper gastrointestinal tract. GOO is a misnomer, however, as the obstruction can involve the duodenum or even be caused by tumors causing extrinsic compression of the bowel lumen. Before the 1970 s, most GOO cases were due to benign causes, with peptic ulcer disease (PUD) consisting of 90 % of the cases. With the decline in PUD, it is now estimated that 50 % to 80 % of GOO cases are attributable to malignancy [1].

Until recently, surgical gastroenterostomy has been the standard of care for patients with GOO. Despite its quite high technical success rates, the adverse event (AE) rates are significant, with some studies reporting up to 41 % [2]. A common issue following a technically successful, conventionally done bypass surgery is prolonged ileus, which poses major issues in worsening malnutrition and delayed initiation of oncologic treatment [3]. Moreover, patients with malignant GOO are dealing with advanced stages of their cancer and, therefore, are poor surgical candidates. For nonsurgical patients, the options had been limited to endoscopic placement of an uncovered metal luminal stent. These uncovered enteral stents, however, were prone to occlusion from tissue ingrowth and often required repeated procedures [4].

Endoscopic ultrasound-guided gastroenterostomy (EUS-GE) is a new endoscopic technique developed to manage GOO. The technique was first introduced in an animal model by Fritscher-Ravens et al. in 2002, but necessitated endoscope exchange and needed special devices, and thus, was deemed too complicated to be translated into clinical practice [5]. However, with the invention of the new generation of electric cautery-enhanced (ECE)-LAMS, creating a new fistula tract became much simpler. The advantage of this procedure over duodenal stenting is that there is significantly less risk of tissue ingrowth and secondary stent restenosis and stent-induced biliary obstruction [6]. EUS-GE involves creating a fistulous connection between the stomach and the proximal small bowel using an electric cautery-enhanced (ECE)-LAMS with EUS guidance. Several studies indicated that EUS-GE showed high efficacy and low AE rates, compared to surgical gastroenterostomy [7]. A recent meta-analysis also confirmed the high technical (92.9 %) and clinical success (90.11 %) rates, and low AE rate (5.61 %) of EUS-GE [8]. Our internal studies comparing EUS-GE with uncovered metal stents have shown improved tolerance for oral diet and medications with fewer patients requiring nutrition support for EUS-GE. Nonetheless, this is a technically complex procedure, and when performed suboptimally, serious complications, such as stent misdeployment leading to bowel perforation and peritonitis, may occur.

Many different technical approaches to EUS-GE have been described in the literature [9, 10]. This includes multiple different ways to fill the jejunum with fluid, special double balloon catheters to help stabilize the jejunum prior to gastrostomy (EPASS), and different ways to puncture the stomach including a freehand technique, over a guidewire, and using a balloon catheter to create a target in the jejunum. Given different ways to perform this procedure as well as the daunting task of creating a controlled iatrogenic perforation in the stomach, often the procedure is deferred only to the hands of the "experts."

In this study, we show that standardization of the EUS-GE procedure can significantly increase the technical success rate and decrease AEs. The standardized procedure can be easily taught and safely performed even in the hands of the most junior endoscopists with <2 years of total experience.

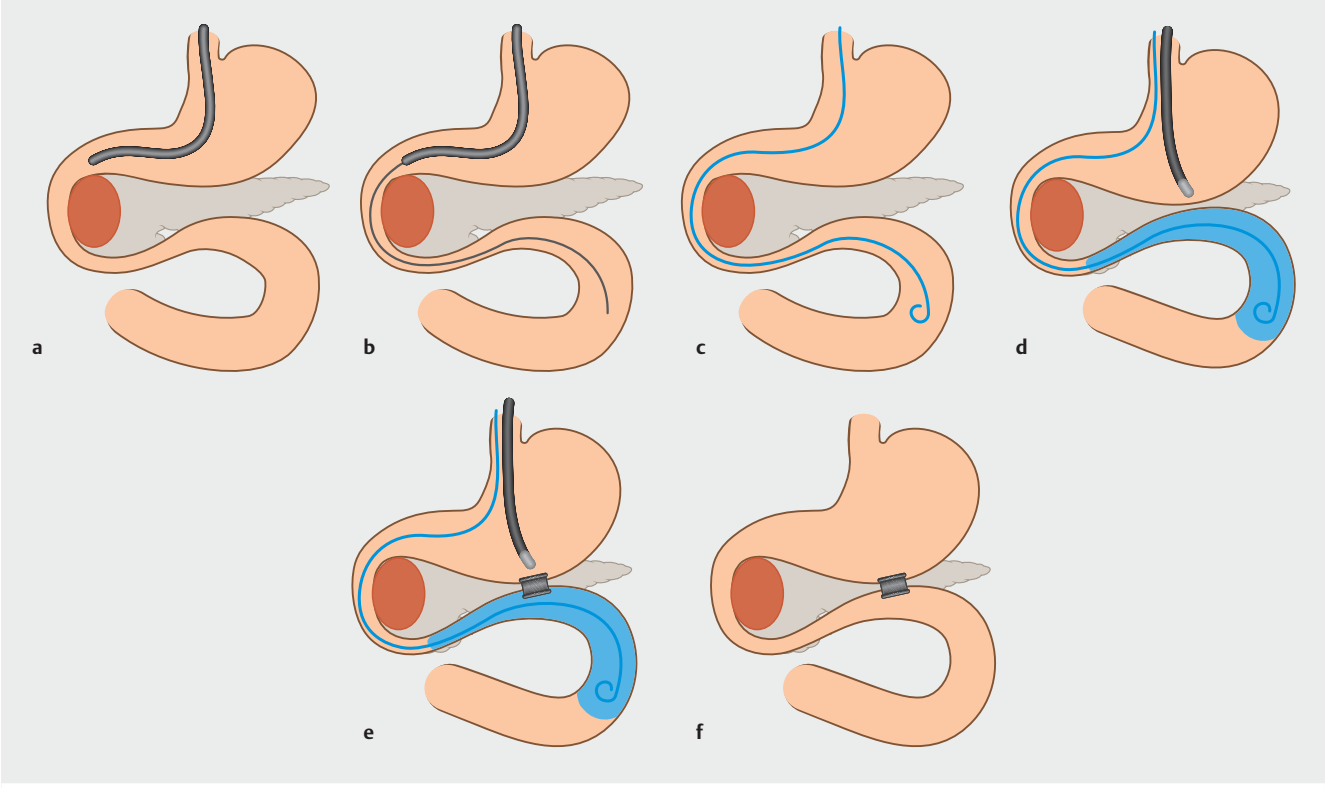
Methods

A retrospective analysis was done of all EUS-GE performed for inoperable GOO at Cedars-Sinai Medical Center from 2014 to 2021. The protocol to carry out a retrospective study of the cases performed was approved by the Institutional Review Board (IRB) at our institution. All the endoscopists in this study were, in addition to being competent in EUS and ECE-LAMS placement, experienced in endoscopic suturing (OverStitch, Apollo) and placement of over-the-scope clips (OTSC, Ovesco). All patients gave their informed consent before the procedure, including for EUS-GE. All the patients were intubated before the procedure, given concern for aspiration in the setting of GOO and given pre-procedure administration of intravenous antibiotics (levofloxacin 500 mg and metronidazole 500 mg).

One senior endoscopist with the most clinical experience and prior proficiency in EUS-GE taught and supervised other advanced endoscopists trained in EUS and ECE-LAMS placement. The senior endoscopist only trained one individual at a time and only moved on to the next trainee if he felt that the current endoscopist was adequate at performing the procedure on his own (average 2–3 procedures).

Prior to standardization, various pre-procedure and peri-procedure techniques were utilized, including both prone and supine patient positioning, varying volumes, and mixtures of media to fill the small bowel (water, normal saline, radiopaque contrast, and methylene blue), different types of catheters (nasobiliary, stone extraction, dilation balloon), and different EUS-guided puncturing methods (wire-guided, water-inflated balloon targeted, and freehand). After standardization, all patients were placed in the prone position and water immersion technique was performed via a 7F nasobiliary catheter, instilling at least 500 mL of sterile water, methylene blue, and radiopaque contrast (enough contrast to be visible on fluoroscopy). Glucagon (0.5 mg to 1 mg) was given to reduce bowel motility and a freehand GE was performed with ECE-LAMS. The standardized protocol for performing the EUS-GE procedure is summarized in ▶ **Fig. 1**.

The outcomes of interest, including clinical and technical success rates, procedure time, hospital length of stay (LOS) (calculated as the number of days in the hospital after the procedure performed), and AEs, were compared between the groups of patients who received EUS-GE before or after standardization of the procedure. Technical success was defined as creation of a gastroenterostomy tract using the LAMS and clinical success was defined as improvement in GOO score as well



▶ **Fig. 1** Standardization of EUS-GE procedural steps. **a** 1. Intubate and place the patient in a semi-prone position on the fluoroscopy table. Give one dose of peri-procedural broad-spectrum IV antibiotics. 2.Perform EGD and identify the exact location, length, and diameter of the luminal stricture. **b** 3. Place a guidewire across the luminal stricture and advance a 7Fr nasobiliary catheter over the guidewire (through the scope) into the jejunum. **c** 4. Exchange the scope out, leaving the tip of the oro-jejunal (OJ) tube near the ligament of Treitz or where you intend to create the gastroenterostomy. 5. Attach a water pump with a foot pedal to the OJ tube to allow the endoscopist to actively control when and how much water to be flushed. 6. Pass down a therapeutic linear EUS scope alongside the OJ tube into the stomach. 7. Using the foot pump, fill the jejunum with approximately 500 mL of sterile water mixed with radiopaque contrast and methylene blue to distend the small bowel so a target bowel can be easily identified on EUS and fluoroscopy. 8. On EUS, identify the target jejunum where water turbulence can be visualized while the water is actively being pumped in (via the foot pedal). Give 0.5–1 mg of glucagon intravenously to minimize bowel motility. **d** 9. Using electrocautery enhanced LAMS, puncture the stomach and jejunal wall freehand under EUS guidance in one swift motion. **e** 10. Once the distal tip of the catheter is confirmed to be within the jejunum on EUS, deploy the stent appropriately. **f** 11. Once proper deployment of the stent is confirmed on both endoscopy and fluoroscopy, dilate the stent tract with a dilation balloon (depending on the size of the LAMS used) to maximize the size of the stent lumen.

as evaluating for nausea, vomiting, and moderate to severe abdominal pain (as defined on the numeric rating scale, NRS-11) [11]. At our center, patients were advised to only advance their diet to a semisolid/low residue diet post-procedure. Endoscopist total years in practice, total years of EUS experience, and total years of ECE-LAMS experience were also noted.

Statistical analysis was done by using an unpaired *t*-test for continuous variables and Fisher's exact test for categorical variables. Statistical significance was defined as $P<0.05$. Graph Pad Prism 9.0 was used to perform all statistical analyses.

Results

A total of 41 consecutive EUS-GE procedures were performed during this study period. Five procedures were performed prior to standardization and 36 procedures were performed after the standardization (▶ **Table 1**). Detailed individual patient characteristics and outcomes are detailed in **Supplemental Table 1**.

The procedures were performed by six different interventional endoscopists with a wide range of clinical (2–33 years) and ECE-LAMS (2–5 years) experiences. The pre-standardized and post-standardized patient populations were similar in age (pre- 63.2 vs post- 70.8 years old) and sex (pre- 60 % vs post- 50 % male). Standardization of the EUS-GE procedure was associated with a significantly higher technical success rate (100 % vs 60 %, $P=0.01$) and lower peri-procedural AE rate (2.8 % vs 40 %, $P=0.03$) (▶ **Table 1**). The overall procedure time was lower and the clinical success rate was higher in the post-standardization group, but these differences were not statistically significant. Prior to EUS-GE, all patients had either no/inadequate oral intake or were limited to some form of a liquid diet. Post-procedure, 60 % of patients (3 of 5) in the pre-standardization group were able to advance their diet to a semisolids/low residue diet prior to discharge, and in the standardization group, 89 % of patients (32 of 36) were able to advance their diet to a semisolids/low residue diet prior to discharge (GOO mean score pre- 1.40 vs

▶ **Table 1** Patient characteristics and outcome.

	Pre-standardization	Post-standardization	*P* value
Total cases	5	36	
Mean age (years)	63.2	70.8	0.15
Sex (male)	60 %	50 %	>0.99
Technical success	60 %	100 %	**0.01**
Peri-procedural Adverse event rate	40 %	2.8 %	**0.03**
Procedure time (mins)	89.8	80.0	0.60
Clinical success	60 %	83.3 %	0.25
Hospital length of stay after procedure (days)	6.6	7.8	0.76

▶ **Table 2** Experience of different endoscopists performing EUS-GE.

Endoscopist	Experience in practice (yr)	Experience with EUS (yr)	Experience with ECE-LAMS (yr)	Total EUS-GE performed	Adverse events
1	33	26	5	8	1
2	13	13	2	1	0
3	12	12	5	4	1
4	9	9	3	8	1
5	5	5	4	6	0
6	2	2	2	14	0

EUS-GE, endoscopic ultrasound-guided gastroenterostomy; ECE-LAMS, electric cautery-enhanced lumen-apposing metal stent.

post- 1.83, $P=0.08$). Endoscopist total years of clinical, EUS, and LAMS experience did not impact either the technical success rate or the rate of AEs (▶ **Table 2**).

The two peri-procedure AEs in the pre-standardization group were gastric perforation and gastrocolic fistula creation. The gastric perforation was repaired using endoscopic suturing and OTSC. The gastrocolic fistula required a surgical repair. EUS-GE was not reattempted in either of these two patients. The single peri-procedure AE in the post-standardization group was a gastric perforation due to a failed puncture of the small bowel wall due to dislodgement. The gastric wall defect was repaired using an OTSC and a second attempt led to a successful EUS-GE during the same procedure.

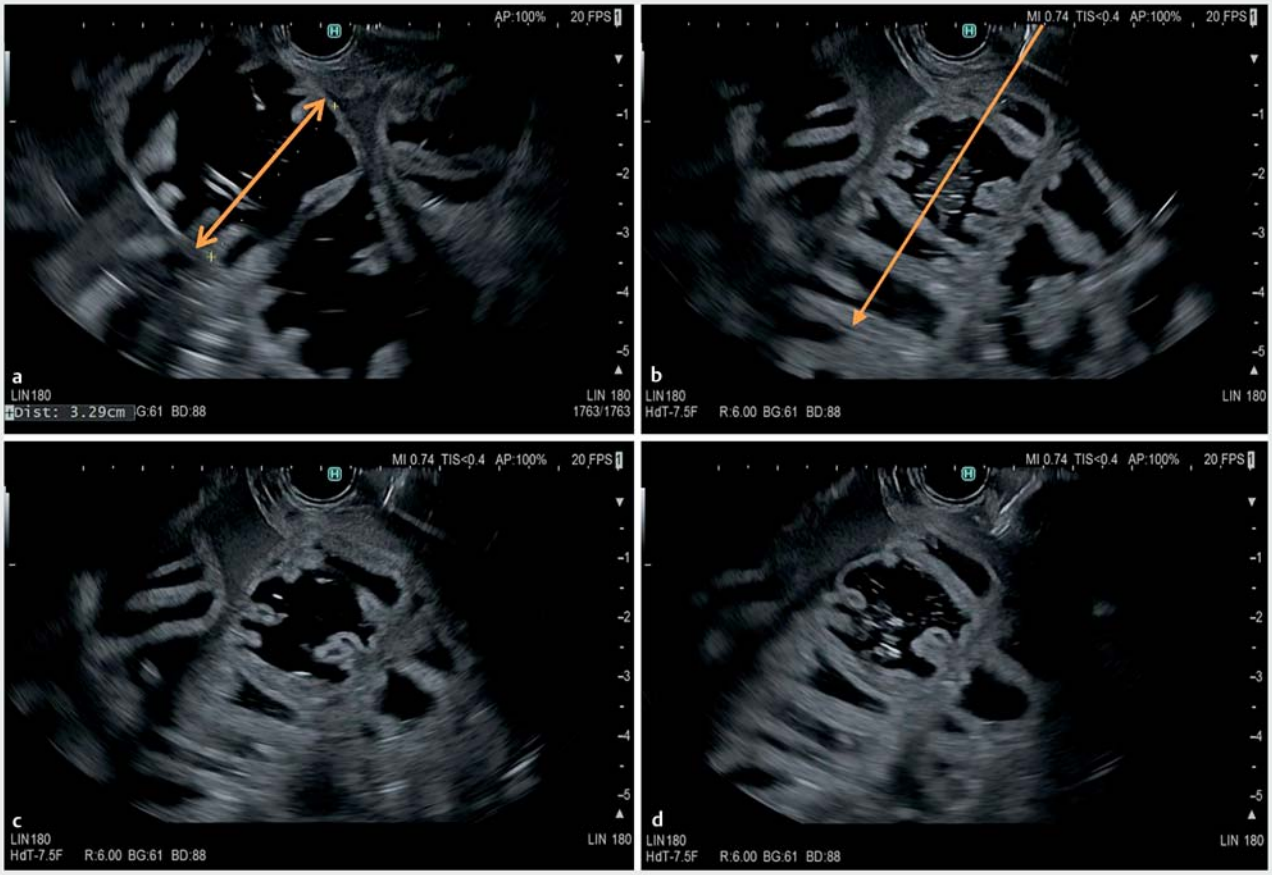
Of the 41 patients who had EUS-GE performed at our center, 14 patients were deceased at 6 months follow-up due to their underlying malignancy; nine of them died while enrolled in a hospice program. Overall, four patients (all in the post-standardization group) experienced a complication outside of the peri-procedure period. One patient experienced gastrointestinal bleeding suspected due to the stent, and three patients experienced stent occlusion due to food debris, which was removed during repeat esophagogastroduodenoscopy.

Discussion

In this study, we describe a method in which learning a complex and difficult procedure such as EUS-GE can be made safer by standardizing the procedure steps and developing a peri-procedure checklist irrespective of total clinical practice years. In our center, immediately after implementing such changes, we observed a drastic improvement in technical success and AE rates.

With advances in endoscopic technology, more and more opportunities for minimally invasive and nonsurgical therapies have become available to patients. EUS-GE is one such technology that is expected to become more widely accepted as the standard of care for patients with GOO who are not candidates for surgery [12]. Compared to luminal stents, EUS-GE may provide quicker resolution of obstructive symptoms and decrease the need for supplemental nutrition support. In addition, it eliminates a longer-term concern for tumor infiltration and stent restenosis, or biliary obstruction related to the stent traversing across the ampulla.

Despite the many potential benefits of EUS-GE, this technology currently belongs only in expert centers, as its key limitation has been the concern for safety and difficulty acquiring the skills outside of the few highly experienced endoscopists. In addition, despite the low published rates of peri-procedure complications of around 5 % [7], the complications can be quite



▶ **Fig. 2** Checklist immediately prior to gastric puncture. 1. Check on fluoroscopy that the tip of the EUS scope is positioned appropriately. An ideal position would be the tip positioned along the greater curvature of the stomach aimed caudally toward the target small bowel near the ligament of Treitz. **a** 2. Make sure the target small bowel is close to the stomach wall (< 10 mm) and that the distended small bowel has adequate room (> 30 mm) for stent delivery. **b** Ideally the scope tip should be positioned so that the target small bowel is aligned lengthwise with the trajectory of the LAMS catheter to allow for safer puncture. **c** versus **d** 3. Check on EUS that you can immediately see water turbulence when stepping on the foot pedal to infuse water via the OJ tube in the target bowel (before and immediately after the infusion). If not, the bowel segment you are seeing may not be a good target bowel (either too far downstream/upstream or even a colon).

morbid, and those low numbers reflect rates from a few specialized tertiary centers in the hands of experts. These additional concerns add to the absolute need for a method to teach the EUS-GE technique safely and effectively.

We believe that our systematic approach to performing the EUS-GE has allowed us to safely introduce the methodology to all our experienced endoscopic interventionalists with minimal prior exposure to the technique itself. Our prerequisites to learning to practice this procedure were: 1) proficiency in EUS-guided LAMS for treatment of pancreatic fluid collections or gallbladder; and 2) proficiency in endoscopic suturing and OTSC for perforation and fistula repairs. Expertise with both endoscopic closure techniques was felt to be important, as one methodology may be better suited, depending on the size and location of the perforation. This is especially true given that all three patients in our cohort with gastric perforations were managed using OTSC or endoscopic suturing without encountering additional morbidities or the need for emergent surgery. Having fulfilled these criteria, all of our interventionists that were guided to perform EUS-GE had equivalent safety and efficacy outcomes regardless of their years of endoscopy or EUS experience. We believe that our model practiced in this study may be generally applicable to a training situation in other institutions.

Currently, there are many ways to safely perform EUS-GE, yet no studies exist showing the superiority of one approach over the other [9]. Such a wide selection of possible techniques, however, can potentially make the task of performing this procedure seem more daunting. Each institution or group should have a collective endorsement of a particular endoscopic strategy based on local expertise and experience as well as availability of additional tools, such as the double balloon catheters needed for the EPASS technique. Whichever EUS-GE technique is utilized, established criteria for skill acquisition as well as a standard of operation (SOP) and a safety checklist such as the one that we used (▶ **Fig. 2**) should be used. Our study clearly shows results that should address both aspects and it even underscores the relative ease of safely learning how to perform the standardized procedure irrespective of years of practice

with a good outcome. We believe that adoption of a uniform approach to this complex procedure will standardize procedure preparation, eliminate confusion, and facilitate coordination between the endoscopist and support staff, which will lead to safer and better outcomes.

Having simultaneous multimodal imaging (endoscopic, endosonographic, and fluoroscopic) is important in stressing redundancy to ensure the intended outcome. Several important key steps that were adopted and facilitated our version were: 1) placing the patient in the prone position to minimize gastric and intestinal motility [13]; 2) using fluoroscopy and radiopaque contrast to assess the location of the stricture and the target small bowel; 3) using the oro-enteric tube across the obstruction to allow for a dynamic water infusion (via a foot pedal) to confirm in real-time the target bowel by seeing turbulence on EUS); and 4) infusing up to 500 mL of water and contrast mixture to properly distend and allow adequate room for gastroenterostomy.

Two complications prior to standardization (gastrocolic fistula and gastric perforation) could have been avoided with the measures discussed previously. The gastrocolic fistula could have been avoided by utilizing the dynamic water infusion to confirm the correct target bowel on EUS prior to puncture. The gastric perforation possibly could have been avoided with adequate distension of the target jejunum and decreasing bowel motility with prone positioning and glucagon use.

There are several limitations to this study. First, it was a single-center retrospective study with a small sample size. The sample size was largely limited by the natural caseload of GOO and the fact that EUS-GE is a more recent and emerging technique for management of GOO. Second, this was not a randomized controlled study comparing the two techniques, so there is bound to be bias and other factors that may skew the data. For example, one can argue that the statistically significant increase in the technical success rate of the procedure is solely due to the early learning curve of the procedure.

In support of our conclusion, however, the senior endoscopist teaching the technique was already proficient in performing EUS-GE prior to training the first endoscopist. In addition, considering that all five of our interventional endoscopists were novices in this technique, the “learning curve” theory does not explain why there was such a drastic improvement immediately after implementing the new standardized procedure steps. One would expect a more gradual improvement over a longer period if the learning curve was the major factor. In addition, given the retrospective nature of this study, long-term outcomes may be difficult to fully assess in situations in which data may be incomplete or unavailable due to a patient continuing oncologic care at a different medical center, or being admitted at a different medical center for complications related to their cancer. Finally, because this paper focuses solely on the effect of standardization and its effect on improving the safety and efficacy of teaching a complex new technique, it in no way claims superiority of this described technique over other previously published techniques.

Future research should continue to focus on the safety and clinical efficacy of EUS-GE, as well as the comparative efficacy of this procedure, duodenal self-expanding metal stents, and surgical GE. Another area of future research may highlight the methodological differences and outcomes between different centers.

Conclusions

Teaching EUS-GE after standardizing the procedure steps was associated with a significant increase in technical success and a significant decrease in AEs irrespective of prior total EUS or LAMS experience.

Competing interests

Kenneth Park – Received lecture fees from Boston Scientific
Kapil Gupta – Currently employed by Boston Scientific
Simon Lo – Consultant for Olympus
Christopher Thompson – Consultant for Apollo Endosurgery, BostonScientific, Covidien/Medtronic, EnVision Endoscopy, Fractyl, GIDynamics, Olympus/Spiration, and USGI Medical
All other authors disclosed nofinancial relationships.

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