Assessment of the learning curve for EUS-guided gastroenterostomy for a single operator

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Background and Aims: EUS-guided gastroenterostomy (EUS-GE) is increasingly used as an alternative to surgery and enteral stent placement to manage gastric outlet obstruction (GOO). However, no data are available on the learning curve (LC) for EUS-GE. Defining the LC is necessary to create adequate subspecialty training programs and quality assurance.

Methods: This study is a retrospective analysis of a prospectively maintained dataset of patients who underwent EUS-GE at 1 tertiary referral center. Primary outcome was the LC for EUS-GE defined by the number of cases needed to achieve proficiency and mastery using cumulative sum (CUSUM) analysis. Moving average graphs and sequential time-block analysis were also performed to assess procedural time. Secondary outcomes included efficacy and safety of EUS-GE.

Results: Eighty-seven consecutive patients underwent EUS-GE, mostly for malignant GOO. For consistency, 14 patients were excluded from analysis (noncautery-assisted EUS-GE, 11; surgical anatomy, 3). The same endoscopist performed all procedures using the same freehand technique. Technical success was achieved in 68 of 73 patients (93%). Immediate adverse events occurred in 4 patients (5.5%), whereas late adverse events occurred only in 1 patient (1%), all managed conservatively or endoscopically. All immediate adverse events occurred during the first 39 cases. Clinical success (defined as resuming at least an oral liquid diet within a week) was achieved in 97% of patients. The mean procedural time was 36 minutes (standard deviation, 24). Evaluation of the CUSUM curve revealed that 25 cases were needed to achieve proficiency and 40 cases to achieve mastery. These results were confirmed with the average moving curve and sequential time-block analysis.

Conclusions: We report, for the first time, data on the LC for EUS-GE. About 25 procedures can be considered as the threshold to achieve proficiency and about 40 cases are needed to reach mastery of the technique. (Gastrointest Endosc 2021;93:1088-93.)

(footnotes appear on last page of article)

Mechanical gastric outlet obstruction (GOO) may result from benign causes, such as peptic/iatrogenic stenosis or benign extrinsic compression, or malignant causes, such as carcinoma of the stomach, duodenum, pancreas, or metastatic disease. Surgical gastrojejunostomy, the traditional cornerstone treatment for patients with mechanical obstruction, has been associated with significant morbidity and mortality.[1] For this reason, minimally invasive alternative approaches have been sought. Enteral stent placement has shown high technical and clinical success rates.[2,3] However, recurrent obstruction, mainly because of tissue ingrowth/overgrowth, is relatively common with enteral stent placement, and enteral stent placement requires more reinterventions and is overall more costly when compared with surgery.[3,4] Thus, enteral stent placement is currently suggested as a means of palliation in patients with poor performance status and/or short life expectancy.[5] These data highlight the need for minimally invasive procedures with high success and low reintervention rates.

The recent advent of lumen-apposing metal stents (LAMSs) and the possibility of their deployment under direct EUS guidance has paved the way for introducing EUS-guided gastroenterostomy (EUS-GE) into clinical practice.[6] This was first successfully attempted in 2012 in animal models,[7] and in 2015 we and others described the first-in-human experiences.[8-11] Since then, EUS-GE has been increasingly used as an alternative to surgery and enteral stenting for the management of GOO.[12-15] However, because EUS-GE is a technically challenging procedure that creates a new communication between anatomically separate organs, it may have serious, and potentially fatal, adverse events (AEs), including perforation from stent misdeployment, peritonitis, and bleeding, in up to 5.6% of cases.[16] As a result, this procedure is currently only performed at tertiary referral centers by operators with expertise in interventional EUS.[17] The numbers of procedures required to reach competency in EUS-GE is currently unknown. It is therefore imperative to define its learning curve (LC) to create adequate subspecialty training programs and quality assurance. Here we aim to provide data on the LC for EUS-GE.

METHODS

This was a retrospective analysis of a prospectively collected dataset. All consecutive patients who underwent EUS-GE for the treatment of GOO by a single interventional endoscopist (M.A.K.) between October 2014 and April 2020 were included. Participant demographics, type and location of the obstruction, and prior treatments for the obstruction (eg, duodenal dilation or stenting) were recorded. Procedural outcomes such as technical success (creation of the GE fistula by placement of a LAMS), clinical success (ability to tolerate at least a full liquid diet within a week from the procedure), length of procedure (time between the beginning and end of the endoscopic procedure), length of hospital stay (initial hospitalization until discharge), EUS-GE–related AEs, GOO recurrence, and reinterventions were recorded. Procedural time included the time from the beginning of the procedure to the end, including the time of gastroscopy with fluid injection.

Patients with surgically altered anatomy and patients who underwent EUS-GE with noncautery-assisted LAMS were excluded from analysis, because the procedure is modified in those cases. Data on some patients included in the current study have been previously used to study the efficacy and safety of the EUS-GE technique[8,13,14,18,19] but not to explore the LC for EUS-GE. The study was approved by the Johns Hopkins Hospital Institutional Review Board for Human Research and complied with Health Insurance Portability and Accountability Act regulations.

Outcomes and definitions

The primary outcome of this study was to define the LC for EUS-GE by assessing the number of cases needed to achieve proficiency and mastery. Cumulative sum (CUSUM) curve analysis was used to assess both proficiency and mastery in terms of procedural time. The overall mean procedure time was used as the target value. Proficiency was defined as the number of procedures at the inflection point in the CUSUM graph, at which point the procedural time begins to become shorter, indicating operator performance refinement. Mastery was defined as the number of procedures at which the average time of procedures was consistently similar to or lower than the target value, as observed with a plateau or descent in the CUSUM graph. Moving average graph and sequential time-block analysis were also used to assess procedural time and thus the LC.

Freehand EUS-GE procedure

Techniques vary for performing the EUS-GE procedure Initially, we used to place noncautery-assisted LAMS over a guidewire, as previously described.[18,20] However, we transitioned to the freehand technique once the electrocautery-tip enhanced LAMS became available. For the sake of data homogeneity (in terms of technique and stent used), we excluded patients who underwent EUS-GE with the use of noncautery-assisted LAMS placed over a guidewire and evaluated the LC only for the freehand EUS-GE procedure.

In brief, the freehand EUS-GE technique entails the creation of a GE with direct deployment of a cautery-enhanced LAMS through the stomach into a small-bowel loop adjacent to the gastric wall under EUS guidance. To facilitate the puncture, a forward-viewing gastroscope is first inserted and advanced to the obstruction site, and fluid is infused through the endoscope therapeutic channel into the small bowel distal to the obstruction. Generally, 500 mL of fluid using a combination of saline solution, contrast, and methylene blue is infused. Then, the forward-viewing gastroscope is withdrawn and a linear echoendoscope is advanced into the stomach. The small bowel adjacent to the stomach can be visualized both under fluoroscopy and US. A standard 19-gauge needle is used as a "finder" needle to puncture and locate a small-bowel loop closest to the stomach by aspiration of blue-tinged fluid confirming the correct puncture site. A cautery-assisted LAMS (AXIOS-EC stent; Boston Scientific, Marlborough, Mass, USA) is then inserted directly across the stomach and into the small bowel followed by stent deployment, forming the GE. Successful stent deployment is confirmed by observing flow of blue-tinged fluid through the stent into the stomach. The LAMS was not balloon dilated after deployment.

All patients received intravenous antibiotics immediately before the procedure. All EUS-GE procedures were performed in an endoscopy unit with patients under general anesthesia. All procedures were performed by an expert therapeutic endoscopist (M.A.K.) with extensive experience in interventional EUS at a tertiary care center (Johns Hopkins Medical Institution).

CUSUM curve analysis

We used the CUSUM curve analysis to assess proficiency and mastery in terms of procedural time, using the overall mean procedure time as the target value. The CUSUM LC analysis, initially used for early detection of out-of-control manufacturing processes, was quickly adapted in the medical literature to asses LC for surgical[21,22] and endoscopic[23-25] procedures. The CUSUM curve is the product of the standardized cumulative difference between each sequential observed procedural time and the target time. Because of a lack of experience at the beginning, the time for each procedure is longer than the target time. As a consequence, the standardized difference between the actual time and the target time is a positive number. Hence, as these positive numbers are added up sequentially, the CUSUM curve will initially ascend. Then, as the operator becomes more experienced and proficiency and mastery of the technique are achieved, he or she will be more confident with rapidly performing the procedure, leading to a shorter procedural time. As procedural time is shortened, it will be either equal to or shorter than the target value; thus, the curve will reach a plateau or descend. The inflection point represents the moment at which proficiency has been achieved, because it indicates that point at which procedural time starts to shorten. Mastery, on the other hand, can be observed once the average time of procedures is consistently similar to or lower than the target value. In that case the difference between the actual procedural time and the target value becomes very small or negligible and is expressed with a plateau or descent in the CUSUM graph. Because each point on the CUSUM graph represents the cumulative sum of the standardized differences from a target value of all prior procedures up to that point, this method is not substantially influenced by single outlier procedural times that can be observed in very challenging or very easy cases.[26] For this reason it is an ideal method to assess complex procedures, such as EUS-GE.

The results of the CUSUM curve analysis were confirmed with 2 methods, the moving average graph[23,24] and the sequential time-block analysis.[27,28] The moving average graph is a method for observing overall long-term trends by reducing the influence of single outlier fluctuations. This is done by incorporating each value to the mean of a predetermined number of previous procedures. We set the moving average length at 15 procedures; thus, at each point in the graph we observe the mean time of the previous 15 procedures. The sequential time-block analysis compares the mean procedural time of consecutive groups of procedures. We compared 3 groups: before proficiency, after proficiency but before mastery, and after mastery.

Statistical analysis

Results are reported as mean ± standard deviation or as median with interquartile range for continuous variables and as percentages for categorical variables. Continuous variables were compared with the 2-sample Student *t* test or Mann-Whitney U test and categorical variables with χ^2 or Fisher's exact tests. Linear regression was used to compare procedural time for sequential time-block analysis. A 2-sided $P < .05$ was considered statistically significant. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC, USA).

TABLE 1. Baseline characteristics

Characteristic	Value
Mean age, y (standard deviation)	60 (15)
Female	37 (51)
Mean body mass index, kg/m^2 (standard deviation)	24 (5)
Type of gastric outlet obstruction*	
Benign	9 (12)
Malignant, pancreatobiliary	44 (60)
Malignant, other	20 (27)
Site of obstruction*	
Antrum/pylorus	7 (10)
Bulb/second duodenal portion	51 (70)
Distal duodenum or proximal jejunum	15 (21)
Prior duodenal stent/dilation	5 (7)

Values are n (%) unless otherwise defined.
*Percentages may not add up to 100 because of rounding.

RESULTS

Baseline characteristics

Overall, 87 consecutive patients underwent EUS-GE at our center during the study period. To study exclusively the LC for the freehand EUS-GE in patients with native anatomy, 14 patients were excluded from analysis. Of these, 11 had undergone EUS-GE with noncautery-assisted LAMS over a guidewire and 3 had surgically altered anatomy. Thus, 73 consecutive patients (50% women, mean age 60 years) were included in this study. EUS-GE was mostly performed for malignant GOO (88%). Further baseline characteristics of these patients are summarized in Table 1.

Procedural outcomes

Technical success was achieved in 68 patients (93%). Clinical success was achieved in 66 of 68 patients (97%) with technically successful EUS-GE. Immediate AEs occurred in 4 patients (6.5%) patients: 3 cases of LAMS misdeployment and 1 case of self-limiting hemoperitoneum that did not require blood transfusion and was managed conservatively. All immediate AEs occurred during the first 39 cases. The composite outcome of technical failure and/or immediate AEs occurred in 8 patients (11%). Late AEs occurred only in 1 patient (distal stent migration nearly 9 months after EUS-GE, managed by replacement LAMS via the same track). Further procedural outcomes are detailed in Table 2.

LC analysis

The mean procedural time was 36 minutes (standard deviation, 24) (Table 2). Evaluation of the CUSUM curve revealed that 25 cases were needed to achieve proficiency and 40 cases were needed to achieve mastery of the technique (Fig. 1). Starting at 25 cases, we observed an inflection of the CUSUM curve, which means that from this point forward, procedural time began to shorten

TABLE 2. Procedural characteristics and outcomes

Characteristics and outcomes	Values
Mean procedural duration, min (standard deviation)	36 (24)
Size of LAMS*	
10 mm	0
15 mm	64 (94)
20 mm	4 (6)
Dilation of LAMS	24 (35)
Technical success†	68 (93)
Clinical success‡	66 (97)
Immediate adverse events§	4 (6)
Composite outcome¶	8 (11)
Late adverse events‖	1 (1)
Recurrence of nausea/vomiting during follow-up**	11 (15)
Median length of hospital stay, days (interquartile range)	3 (2-7)
Mean length of follow-up, days (standard deviation)	86 (139)
Alive at end of follow-up	43 (59)

Values are n (%) unless otherwise defined.
LAMS, Lumen-apposing metal stent.
*Among the 68 technically successful procedures.
†Technical failure observed in 5 patients, because of LAMS misdeployment in 1 patient and inability to visualize a safe window for LAMS deployment in 4 patients (because of large mass, insufficient dilation of the small bowel, hypermobility of small bowels and large amount of ascites, and interposition of the colon). These patients were treated with duodenal stents.
‡Ability to tolerate any type of oral feeding within a week from the procedure. Calculated only among the 68 patients with technical success.
§These include 3 cases of stent misdeployment (all managed endoscopically) and 1 case of hemoperitoneum (managed conservatively).
¶The composite outcome of technical failure and/or immediate adverse events.
‖This includes 1 case of stent migration 9 months after initial placement (treated with new LAMS placement).
**These include 1 case of stent migration (treated with new LAMS placement), 3 patients with progressive metastatic disease (treated with percutaneous endoscopic transgastric jejunostomy for venting and feeding purposes), and 7 patients with functional nausea/vomiting related to chemotherapy and treated conservatively with medical therapy (endoscopic and/or radiologic evaluations showed a patent gastrojejunostomy in these patients).

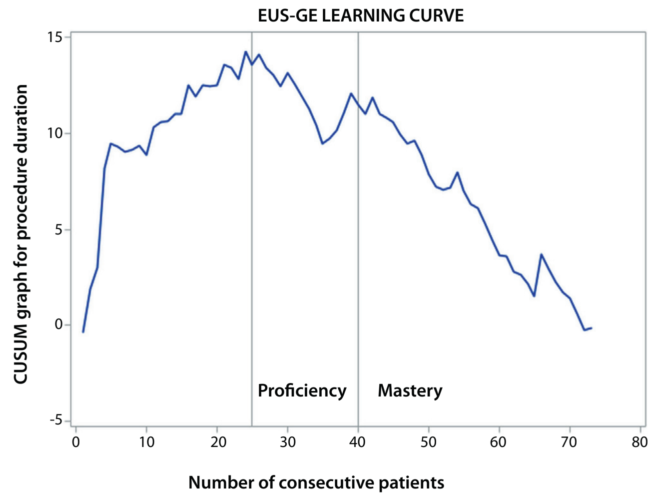

Figure 1. Cumulative sum curve on the number of procedures needed to achieve proficiency and mastery of the technique.

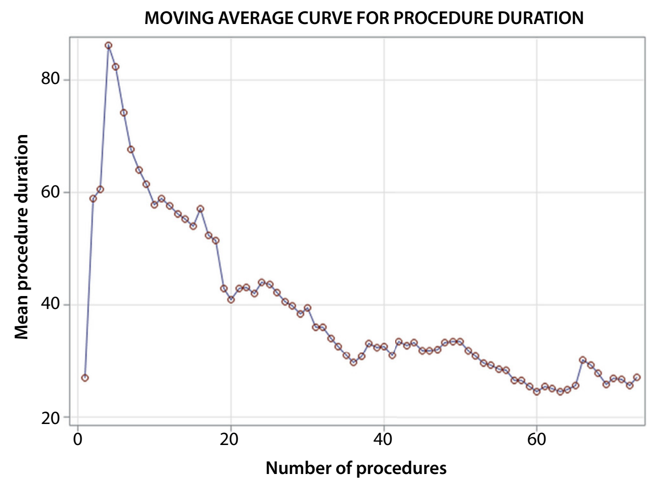

Figure 2. Moving average curve on the number of procedures needed to achieve proficiency and mastery of the technique.

compared with the target value, indicating that the operator had acquired proficiency. Starting at 40 cases, we observed a consistent descent of the graph, which means that procedural time was consistently similar to or lower than the target value, denoting that the operator had acquired mastery of the technique (Fig. 1).

Similar overall results were also observed with the average moving curve, where the plateau of the curve began at about 20 to 30 cases and was ultimately achieved at about 40 to 50 cases (Fig. 2). These results were also confirmed by comparing sequential time blocks. The mean procedural times for patients 25 to 39 (proficiency period) and for patients 40 to 73 (mastery period) were significantly lower compared with the first 24 procedures (nonproficient period): –19 minutes (95% confidence interval, –33 to –5; $P = .01$) and –23 minutes (95% confidence interval, –35 to –12; $P = .0002$), respectively (P-trend = .0003) (Table 3, Fig. 3).

DISCUSSION

In this study we explored for the first time the LC for direct EUS-GE. We found that 25 cases were needed to achieve proficiency and 40 cases were needed to achieve mastery of the technique. These results were confirmed by the average moving curve and by comparing sequential time blocks. In addition, we found that all immediate AEs happened during the first 39 cases, in line with the conclusion that about 40 cases are required to achieve mastery with this procedure. With regard to secondary outcomes, we found a high technical and clinical success rate, with low AE rates, compatible with prior data from the literature.[6,16]

The EUS-GE procedure is part of an expanding and broader field of interventional EUS that includes complex procedures such as EUS-guided drainage of pancreatic fluid collections, EUS-guided biliary drainage, EUS-guided

TABLE 3. Sequential time-block comparison*

	Difference in the mean procedural time (min)	*P* value	*P* trend
Procedures 1-24	Reference		.0003
Procedures 25-40	−19 (−33 to −5)	.01	
Procedures 40-73	−23 (−35 to −12)	.0002	

Values in parentheses are 95% confidence intervals.
*Lack of proficiency (procedures 1-24), proficiency (procedures 25-40), and mastery (procedures 40-73).

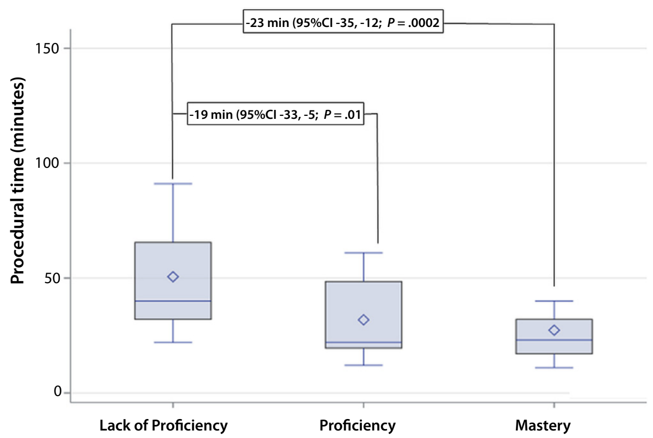

Figure 3. Sequential time blocks showing the mean procedural times for patients 25 to 39 (proficiency period) and for patients 40 to 73 (mastery period).

pancreatic duct drainage, and EUS-guided celiac plexus neurolysis, among others.[17] Additional complexity is added to these procedures in cases of altered anatomy.[29] Most interventional EUS procedures are relatively new and are currently performed only at a few specialized centers. As the demand for advanced therapeutic EUS grows and the breadth of procedures that are feasible increases, there is continued debate on how training in these procedures should be delivered and how competency should be assessed.[30,31] At present there is no mandatory curriculum for training in advanced EUS and, to date, no agreed minimum standards of competency.[30,31]

Our study is the first to report on the LC for EUS-GE for a single operator with prior extensive experience in diagnostic and interventional EUS at a tertiary referral center. This represents the ideal setting for studying the number of procedures needed to achieve proficiency and mastery of this technique. A better understanding of the minimum number of procedures required to obtain proficiency and mastery in EUS-GE will help formulate training programs and postfellowship training pathways going forward.[32]

We also recognize several limitations of our study. First, this is a retrospective study and as such unmeasured factors may have confounded our results. However, procedural time is an objective measure that should not be substantially affected by this design. Second, the endoscopist had experience with 11 cases of EUS-GE with noncautery-assisted LAMS before performing freehand EUS-GE with cautery-assisted LAMS. Hence, our analysis may underestimate the number of procedures needed for proficiency and mastery of the freehand EUS-GE for operators with no prior EUS-GE experience. Third, even though ours is one of the largest single-center experiences with EUS-GE, the sample size is still relatively small, which limited our ability to perform multivariable analyses for secondary outcomes. In addition, follow-up of these patients was relatively short. However, although these factors could influence secondary outcomes, the main outcome of the study, that of defining procedural proficiency and mastery, was not affected by follow-up time. Fourth, there are no established standard techniques for EUS-GE.[20] Although our approach is relatively common, it is certainly not the only approach. Our results are thus applicable only to the freehand technique and do not necessarily apply to other techniques. Finally, we acknowledge that our results reflect the LC for freehand EUS-GE in the setting of GOO only. Although some technical aspects of freehand EUS-GE are similar to other procedures (eg, the creation of gastrogastrostomy for EUS-directed transgastric ERCP [EDGE]) or other indications (eg, EUS-GE for afferent limb syndrome), these results may not be extrapolated to those contexts.

In conclusion, when learning to perform EUS-GE, about 25 procedures can be considered the threshold to achieve proficiency and about 40 cases are needed to reach mastery for operators with prior competence in diagnostic and interventional EUS. Future efforts focused on creating adequate training programs for EUS-GE can use these results as a quality benchmark for independent practice.

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Abbreviations: AE, adverse event; CUSUM, cumulative sum; EUS-GE, EUS-guided gastroenterostomy; GOO, gastric outlet obstruction; LAMS, lumen-apposing metal stent; LC, learning curve.

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