Learning curve for peroral endoscopic myotomy

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submitted 20. July 2015
accepted after revision 12. February 2016

Bibliography
DOI http://dx.doi.org/10.1055/s-0042-104113
Published online: 30.3.2016
Endoscopy International Open 2016; 04: E577–E582

E-ISSN 2196-9736

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Background and study aims: Although peroral endoscopic myotomy (POEM) is being performed more frequently, the learning curve for gastroenterologists performing the procedure has not been well studied. The aims of this study were to define the learning curve for POEM and determine which preoperative and intraoperative factors predict the time that will be taken to complete the procedure and its different steps.
Patients and methods: Consecutive patients who underwent POEM performed by a single expert gastroenterologist for the treatment of achalasia or spastic esophageal disorders were included. The POEM procedure was divided into four steps: mucosal entry, submucosal tunneling, myotomy, and closure. Nonlinear regression was used to determine the POEM learning plateau and calculate the learning rate.
Results: A total of 60 consecutive patients underwent POEM in an endoscopy suite. The median length of procedure (LOP) was 88 minutes (range 36–210), and the mean (± standard deviation [SD]) LOP per centimeter of myotomy was 9 ± 5 minutes. The total operative time decreased significantly as experience increased ($P < 0.001$), with a "learning plateau" at 102 minutes and a "learning rate" of 13 cases. The mucosal entry, tunneling, and closure times decreased significantly with experience ($P < 0.001$). The myotomy time showed no significant decrease with experience ($P = 0.35$). When the mean (± SD) total procedure times for the learning phase and the corresponding comparator groups were compared, a statistically significant difference was observed between procedures 11–15 and procedures 16–20 (15.5 ± 2.4 min/cm and 10.1 ± 2.7 min/cm, $P = 0.01$) but not thereafter. A higher case number was significantly associated with a decreased LOP ($P < 0.001$).
Conclusion: In this single-center retrospective study, the minimum threshold number of cases required for an expert interventional endoscopist performing POEM to reach a plateau approached 13.

Introduction

Peroral endoscopic myotomy (POEM) has been established as a minimally invasive endoscopic procedure for the treatment of achalasia, a chronic progressive esophageal motility disorder with significant morbidity. Ortega et al. [1] in 1980 published the first reported endoscopic myotomy performed in 17 patients with achalasia. In 2007, Pasricha et al. [2] described endoscopic submucosal endoscopy followed by esophageal myotomy in a porcine model. Shortly thereafter, Inoue et al. [3] reported the first series of patients who underwent POEM for achalasia. Since then, use of the POEM procedure has been increasing, with more than 5000 cases now performed worldwide amid growing enthusiasm for a procedure that has been proven to be safe and effective [4].

POEM is a complex and technically challenging procedure requiring advanced endoscopic skills and knowledge of the anatomy of the mediastinum and upper abdomen. It is being practiced by both surgeons and advanced interventional gastroenterologists, who typically undergo training on animal models before commencing clinical cases. The rapid dissemination of POEM necessitates a formalized training program to optimize the quality of practice in an efficient manner. There is a paucity of literature describing the learning curve for POEM [5–7]. The aims of this study were to (i) analyze with multiple analytical methodologies the learning curve for POEM when performed by a single interventional gastroenterologist and (ii) assess predictors of procedural times.

Patients and methods

This was a retrospective analysis of prospectively collected data. The study was approved by the Johns Hopkins Hospital Institutional Review Board for Human Research and complied with Health Insurance Portability and Accountability Act (HIPAA) regulations. All patients who underwent POEM performed by a single interventional gastroenterologist (M.A.K.) between May 2011 and September 2014 for the treatment of achalasia or a spastic esophageal disorder refractory to medical therapy were included. The endoscopist examined the POEM literature in depth and reviewed videos of POEM procedures performed by experts. Initial training in POEM consisted of observing two experts, each performing one live POEM procedure and providing verbal instructions on the different steps and principles of the procedure. Following observation, five nonsurvival POEM experiments were performed, then five survival experiments on porcine models.

Achalasia and its subtype or a spastic esophageal disorder was diagnosed based on high resolution esophageal manometry. Clinical response was defined as a decrease in symptoms and a decrease in the Eckardt score to 3 or lower. Adverse events were recorded and graded according to the severity grading system of the American Society for Gastrointestinal Endoscopy lexicon [8]. Length of procedure (LOP) was defined as the sum of the times taken to complete the following: mucosal incision with access into the submucosal space, submucosal tunneling, endoscopic myotomy, and closure of the mucosal entry. Times taken to clear the esophagus of food residue and to obtain measurements with an endoscopic functional luminal imaging probe (EndoFLIP; Crospon Medical Devices, Galway, Ireland) were excluded from the LOP calculation. Mucosal entry time was defined as the time taken from starting to finishing the mucosal incision and gaining access to the submucosal space. Submucosal tunneling time was defined as the time taken to create a submucosal tunnel from the esophagus to the gastric cardia. Myotomy time was defined as the time from starting to cut the muscle fibers to completing the myotomy in the gastric cardia. Closure time (closing the mucosal incision) was defined as the time from exit of the first clip from the endoscope into the field of view to completion of the closure.

Peroral endoscopic myotomy technique

POEM procedures were performed in a manner similar to that described by Inoue et al. [3]. A high definition gastroscope (GIF-HQ190; Olympus, Tokyo, Japan) fitted with a straight cap having an outer length of 4 mm (D-201-11804; Olympus) was used. This gastroscope has a slim tip diameter of 9.2 mm and features an integrated water jet channel. Carbon dioxide insufflation was used throughout the procedures. When the lower esophageal sphincter (LES) was identified, a submucosal bleb was created in the mid esophagus. A 1.5-cm longitudinal mucosal incision was made with a triangle tip (TT) knife (KD-640L; Olympus) by using dry cut mode at 50 W, effect 3 (ERBE Electromedizen; Tübingen, Germany). The endoscope was then maneuvered into the submucosal space, and the TT knife was used to dissect the submucosal fibers with spray coagulation mode at 50 W, effect 2 (ERBE Electromedizen). Repeated jet injection of saline mixed with indigo carmine was performed to enhance the demarcation between the submucosal layer and the muscularis propria whenever the submucosal dissection plane became unclear. Care was taken with orientation of the endoscope to ensure that the mucosal layer was not injured during dissection as the submucosal tunnel was extended past the LES and at least 2 cm into the proximal stomach. Subsequently, myotomy of the inner circular muscle bundles was performed starting 2 cm distal to the mucosal entry point. The sharp tip of the TT knife was used to catch single circular muscle bundles and lift them toward the tunnel, followed by cutting with spray coagulation current at 50 W, effect 2 (ERBE Electromedizen). The mucosal entry was then closed with endoscopic clips or endoscopic suturing.

Inverse curve fitting

To define the "learning curve," nonlinear regression was used to fit an inverse curve, with case number used as the independent variable and procedure time as the dependent variable to yield an estimate of *a* (asymptote) and *b* (slope) according to the method described by Feldman et al. [9]. The "learning plateau" is then defined as the procedure time at the asymptote of the learning curve (i. e., the theoretical best score that a subject could achieve with infinite practice). The "learning rate" is defined as the number of trials required to reach 90 % of potential (i. e., the speed at which the subject acclimates to the task). When procedure time = $a + 0.1 \times$ (slowest individual procedure time − a), then learning rate case number = $10 \times b$ / (slowest time − a) [5]. We also performed this analysis on the procedure time per centimeter of myotomy to obtain a standardized measurement of time for all procedures.

Consecutive groupings

Taking into account the ratio of procedure time (minutes) per centimeter of myotomy, we divided consecutive procedures into groups of five. We compared the mean LOP per centimeter of myotomy in each group (the "learning phase") with the mean LOP per centimeter of myotomy in the subsequent group of five consecutive procedures (the "comparator group"); for example, procedures 1 – 5 were compared with procedures 6 – 10. We also performed this analysis on the mean LOP (minutes) without accounting for the myotomy length.

Statistical analysis

Results are reported as mean ± standard deviation (SD) or as median with range for quantitative variables and as percentages for categorical variables. Continuous variables were compared with two-sample Student *t* tests or Mann-Whitney *U* tests, and categorical variables with chi-squared or Fisher's exact tests. Bivariate Pearson's correlation was used for the correlation of continuous variables (age, baseline Eckardt score, length of myotomy, and case number), and univariable linear regression was used to determine the association of categorical variables (gender, achalasia type or jackhammer esophagus, previous therapy, and posterior myotomy) with procedure time. Multivariable linear regression was used to determine predictors of procedure time. Exact chi-squared was used to determine the rate of accidental mucosotomies in four sequential groups. Statistical significance was based on two-sided design-based tests evaluated at $\alpha = 0.05$. Statistical analysis was performed with IBM SPSS Statistics, version 21 (IBM Corporation, Armonk, New York, USA).

Results

A total of 60 patients (30 men, 30 women, mean age 48 years) underwent POEM for the treatment of achalasia (3 type I, 44 type II, 8 type III) or a spastic esophageal disorder (5 jackhammer esoph-

Table 1 Characteristics of 60 patients enrolled in a study of the endoscopist learning curve for peroral endoscopic myotomy.

Preoperative	
Age, y, mean ± SD	48 ± 16.5
Female, n (%)	30 (50)
Type of disease, n (%)	
Type I achalasia	3 (5)
Type II achalasia	44 (73)
Type III achalasia	8 (13)
Jackhammer esophagus	5 (8)
Baseline Eckardt score, median (range)	8 (5 – 11)
Grade II or III dilatation,* n (%)	14 (23)
Duration of symptoms, median (range), y	3 (1 – 15)
Previous therapy, n (%)	24 (40)
Previous botulinum toxin injection, n (%)	13 (22)
Previous pneumatic dilation, n (%)	19 (32)
Previous Heller myotomy, n (%)	6 (10)
Operative	
Approach, n (%)	
Anterior	54 (90)
Posterior	6 (10)
Procedure duration, median (range), min	88 (36 – 210)
Mucosal incision, median (range), cm	2 (1.5 – 2)
Length of submucosal tunnel, median (range), cm	13 (9 – 25)
Length of myotomy, median (range), cm	10 (7 – 22)
Adverse events, n (%)	10 (17)
Mucosotomy	4 (7)
Pneumoperitoneum	3 (5)
Pneumothorax	1 (2)
Pulmonary embolus	1 (2)
Pleural effusion	1 (2)
Postoperative	
Length of hospital stay, median (range), d	1 (1 – 9)
Clinical response (Eckardt score ≤ 3), n (%)	48 (92)

* Esophageal dilatation grade (according to maximum diameter of the esophageal lumen): I, < 3.5 cm; II, 3.5 to 6 cm; III, > 6 cm.

agus) during the study period. POEM was successfully performed and completed in all patients. The preoperative (patient demographics, disease characteristics), operative, and postoperative data are shown in **Table 1**. A total of 10 complications occurred in 10 patients (17 %); 7 were rated as mild, 3 as moderate, and none as severe. For the 52 patients who were followed, the median follow-up period was 364 days (range 180 – 1081). A clinical response was observed in 48 patients (92 %).

Learning plateau and rate

The total operative time (median 88 minutes, range 36 – 210) decreased significantly over the course of consecutive POEM procedures when tested by inverse curve regression ($r^2 = 0.21$, $P < 0.001$), with a learning plateau at 102 minutes and a learning rate of 13 cases (**Fig. 1**). The mucosal entry time (median 5.5 minutes, range 2 – 25) decreased significantly with experience ($r^2 = 0.27$, $P < 0.001$), with a learning plateau at 6 minutes and a learning rate of 16 cases. Similarly, the submucosal tunneling time (median 44 minutes, range 18 – 96) decreased significantly ($r^2 = 0.08$, $P = 0.046$), with a learning plateau at 50 minutes and a learning rate of 14 cases. The endoscopic myotomy time (median 21 minutes, range 9 – 102) did not significantly change with experience ($r^2 = 0.05$, $P = 0.09$). Time for closure of the mucosal entry (median 8 minutes, range 4 – 60) decreased significantly ($r^2 = 0.68$, $P < 0.001$), with a learning plateau at 11 minutes and a learning rate of 16 cases. Endoclips were used for closure of the

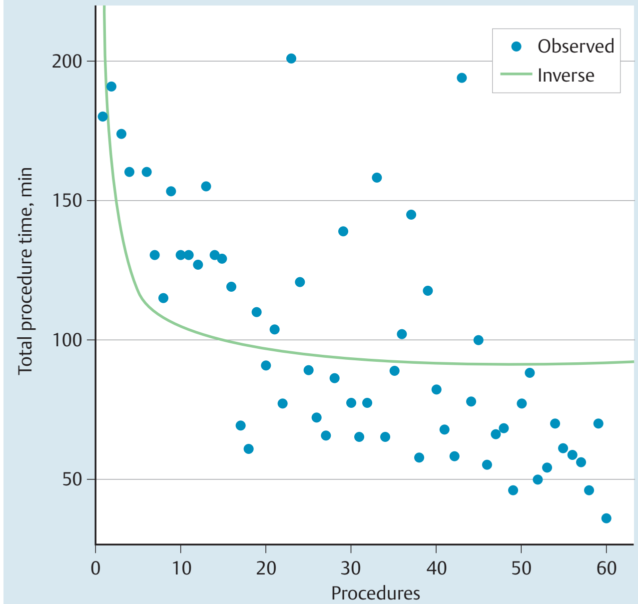

Fig. 1 Total procedure time significantly decreased over the course of consecutive peroral endoscopic myotomy procedures, with a learning plateau at 102 minutes and a learning rate of 13 cases.

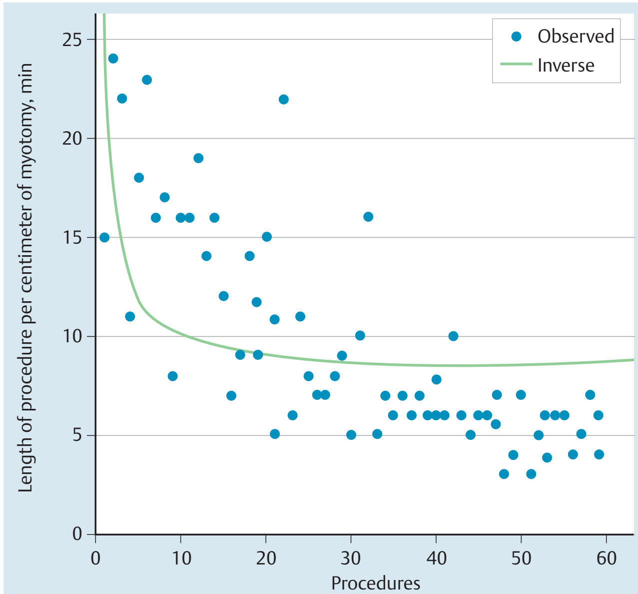

Fig. 2 Total procedure time (minutes) per centimeter of myotomy significantly decreased over the course of consecutive peroral endoscopic myotomy procedures, with a plateau at 10 min/cm and a learning rate of 11 cases.

mucosal entry in all except two cases, in which endoscopic suturing was applied. The number of clips used for closure of the mucosal entry (median 5 clips, range 4 – 12) decreased significantly ($r^2 = 0.11$, $P < 0.001$) with experience.

With the procedure time per centimeter of myotomy (mean ± SD = 9 ± 5 min/cm) taken into account, the curve estimate showed a significant decrease over time ($r^2 = 0.25$, $P < 0.001$), with a learning plateau at 10 min/cm and a learning rate of 11 cases (**Fig. 2**).

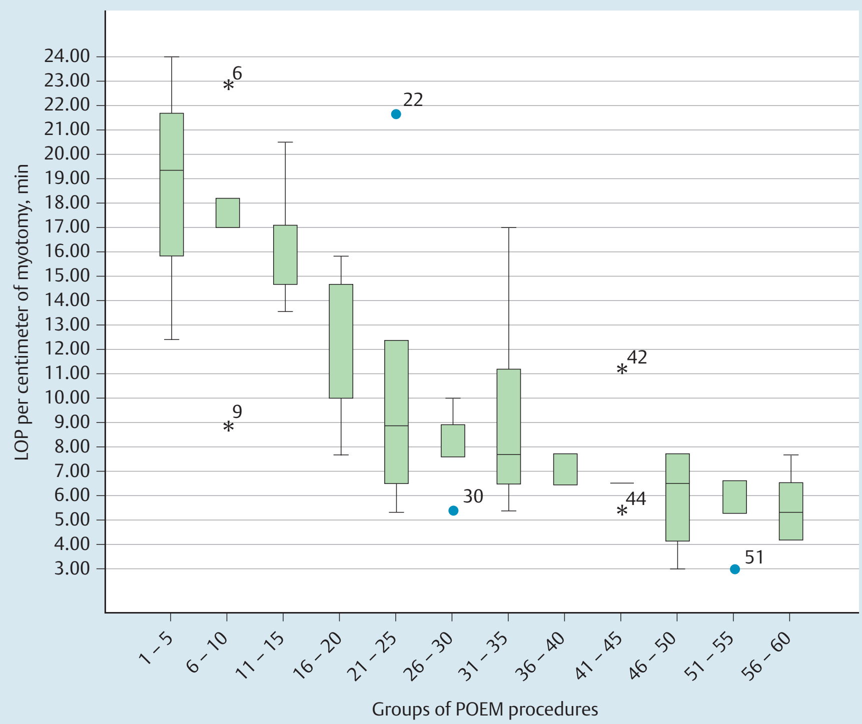

Fig. 3 Box plot of peroral endoscopic myotomy (POEM) procedures divided into sequential groups of five procedures demonstrating the median length of procedure (LOP) per centimeter of myotomy for each group within 25 % and 75 % interquartile range. Significance was observed when the mean (± standard deviation [SD]) LOP per centimeter of myotomy in procedures 11 – 15 was compared with the mean (± SD) LOP per centimeter of myotomy in procedures 16 – 20 (15.5 ± 2.4 min/cm vs 10.1 ± 2.7 min/cm, $P = 0.01$). No significance was observed in comparisons of groups 16 – 60. Asterisk, outlier.

Mean time grouping

When the mean (± SD) LOPs (minutes) for consecutive procedures were compared, no significance was observed with procedures 1 – 5 and procedures 6 – 10 (176.25 ± 12.91 and 147.60 ± 25.52, $P = 0.08$) and with procedures 6 – 10 and procedures 11 – 15 (147.60 ± 25.52 and 134.20 ± 11.65, $P = 0.31$). Comparison of the mean (± SD) LOPs (minutes) showed marginal significance with procedures 11 – 15 and procedures 16 – 20 (134.20 ± 11.69 and 90.00 ± 25.11, $P = 0.07$), suggesting a possible learning plateau at about 15 cases. There was no significance for comparisons of the mean (± SD) LOPs (minutes) of groups 16 – 60.

No significance was observed when the mean (± SD) LOP (minutes) per centimeter of myotomy for the first five procedures was compared with that for the subsequent five procedures (18.00 ± 5.2 min/cm and 16.1 ± 5.6 min/cm, $P = 0.56$). Similar results were obtained when the mean LOP per centimeter of myotomy for procedures 6 – 10 was compared with that for procedures 11 – 15 (16.1 ± 5.6 min/cm and 15.5 ± 2.4 min/cm, $P = 0.83$). We observed statistical significance when comparing the mean LOP per centimeter of myotomy for procedures 11 – 15 with that for procedures 16 – 20 (15.5 ± 2.4 min/cm and 10.1 ± 2.7 min/cm, $P = 0.01$), which again identifies a learning plateau at 15 cases (**Fig. 3**). No significance was observed for comparisons of groups 16 – 60.

Variables associated with procedural times

Operator experience (as measured by case number) was significantly correlated with decreased total procedure time ($r = -0.70$, $P < 0.001$). Also, operator experience was significantly correlated with decreased times for all four procedure steps (all $P < 0.001$). There was no significant association between the other variables (i.e., patient age, type of achalasia, previous therapy, and length of myotomy) and procedure times (**Table 2**). Operator experience was not significantly correlated with the postoperative Eckardt score ($r = -0.10$, $P = 0.46$) and rate of accidental mucosotomies ($P = 0.19$). Inadvertent mucosotomies occurred in four patients, and all were successfully closed endoscopically without consequences. These mucosotomies occurred during procedures 2, 15, 23, and 38. No mucosotomies occurred after procedure 38. Only the case number was negatively correlated with the LOP per centimeter of myotomy ($r = -0.8$, $P < 0.001$).

Multivariable analysis was also performed to adjust for relevant variables such as patient age, gender, type III achalasia/jackhammer esophagus, baseline Eckardt score, previous therapy, and posterior approach. After adjustment, only the case number was significantly associated with total procedure time ($P < 0.001$).

Discussion

We report the learning curve for POEM performed by an expert interventional endoscopist after initial adequate and extensive preclinical training. We observed that the total procedure time decreased significantly with increasing experience and calculated a learning rate of 13 procedures and a learning plateau at 102 minutes. In addition, we separated the procedure into its four steps and calculated the learning curve for each. We observed that with increasing experience, the time required for mucosal entry, submucosal tunneling, and closure of the mucosal entry decreased significantly, with different learning rates and learning times for each. The learning plateau was attained at 16 cases for mucosal entry, at 14 cases for submucosal tunneling, and at 16 cases for mucosal closure. The myotomy time did not decrease as the operator's experience increased. When we used the mean time grouping method, a possible learning plateau was also observed at about 15 cases. When we accounted for the myotomy length in the total procedure time as time per centimeter of myotomy, to accounting for the variability in myotomy length between procedures, learning rates of 11 cases with the inverse curve regression model and 15 cases with the mean time grouping model were observed. Overall, our results suggest that a gastroenterologist with expertise in therapeutic endoscopy and

Table 2 Associations of preoperative and operative patient factors with procedure, submucosal entry, submucosal tunneling, myotomy, and closure times.

	Total procedure time		Submucosal entry time		Submucosal tunneling time		Myotomy time		Mucosal closure time	
	r	*P* value	*r*	*P* value	*r*	*P* value	*r*	*P* value	*r*	*P* value
Preoperative factors										
Age	0.02	0.86	−0.05	0.82	0.05	0.74	0.16	0.27	−1.10	0.46
Gender	–	0.68	−0.13	0.37	–	0.75	–	0.99	–	0.19
Type III achalasia or jackhammer esophagus	–	0.24	0.23	0.11	–	0.29	–	0.05	–	0.32
Baseline Eckardt score	0.03	0.83	−0.03	0.85	−0.06	0.67	0.07	0.63	0.12	0.41
Previous therapy	–	0.67	–	0.18	–	0.18	–	0.99	–	0.67
Operative factors										
Length of myotomy	−0.12	0.34	−0.12	0.41	−0.06	0.66	−0.003	0.99	−0.14	0.34
Posterior myotomy	–	0.97	–	0.14	–	0.78	–	0.50	–	0.74
Case number	−0.70	<0.001	−0.57	<0.001	−0.48	<0.001	−0.37	<0.001	−0.50	<0.001

proper POEM training achieves proficiency in POEM at about 16 cases.

To date, three published studies have analyzed the learning curve for POEM [5 – 7]. Two of them analyzed the performance of surgeons [5, 6]. Kurian et al. [6] showed that mastery of technique (evidenced by a decrease in length of procedure, variability of minutes per centimeter of myotomy, and incidence of inadvertent mucosotomies) was attained at 20 cases; however, data on the learning plateau or rate were not reported. Teitelbaum et al. [5] studied the learning curve for POEM performed by two surgeons with extensive experience in laparoscopic Heller myotomy. The two operators conducted 36 POEM procedures conjointly, and it was reported that the total procedure time for POEM did not significantly decrease with experience; however, a learning rate of 8 procedures and a plateau at 97 minutes were observed after 2 outlier cases that required unusually prolonged times for mucosal entry closure had been excluded.

Patel et al. [7] reported the only study that analyzed the POEM learning curve when procedures were performed by a gastroenterologist. Using cumulative sum (CUSUM) analysis, they found that efficiency was attained after 40 POEM procedures and mastery after 60 POEM procedures. Efficiency was defined as the point in the learning curve at which the operator started engaging in performance refinements that led to a gradual decrease in procedure time, and mastery was defined as the point at which procedure time became consistent and no further change in mean procedure time was observed. There are several possible explanations for the significant difference between the results reported by this study and those of the current study and the others discussed above. Patel et al. [7] studied procedural mastery and efficiency, whereas the current study aimed to evaluate the learning plateau. Moreover, learning curves vary among operators, being influenced by innate ability, previous experience, motivation, available technology, task complexity, case mix, operative findings, and institutional factors [10, 11].

We did not observe any preoperative or intraoperative factors that affected the total procedure time on univariable and multivariable analysis, except for the case number. Specifically, patient age, previous therapy, type of achalasia, and myotomy length did not affect total procedure time. We also assessed predictors of the times that would be taken for the four steps of the POEM procedure, which were not reported in any of the previous studies of POEM learning curves. Mucosal entry, submucosal tunneling, myotomy, and mucosal closure times were not affected by preoperative or intraoperative factors. Therefore, operator experience, rather than patient or procedural factors, is the major determinant of procedural time. As in the current study, Patel et al. [7] demonstrated that no preoperative or operative factors influenced the procedure time after adjustment for case number. In contrast, Teitelbaum et al. [5] reported that prior treatment, symptom duration, and esophageal width had a significant influence on the total procedure time, even after adjustment for case number.

The current study has the following limitations. First, the learning curve for POEM performed by a single gastroenterologist with extensive experience in therapeutic endoscopy was analyzed, and so the results may not be generalizable. Furthermore, all procedures were performed with the assistance of experienced anesthesia, nursing, and endoscopy teams, and these have a direct but unmeasurable effect on procedural times. Lastly, procedure time may not be the best measure of competence to assess the learning curve for POEM. Nonetheless, it is considered a surrogate measure of operator proficiency. The clinical response rate of patients after POEM is high, and adverse events are uncommon. Therefore, these outcomes may not be suitable for measuring learning curves.

In conclusion, we estimate that an advanced gastroenterologist with proper training in POEM before undertaking clinical procedures and with prior experience in therapeutic endoscopy will perform approximately 13 cases to reach a learning plateau.

Competing interests: Mouen A. Khashab is consultant for Boston Scientific, Olympus America, and Xlumena. Anthony Kalloo is a founding member, equity holder, and consultant for Apollo Endosurgery. Kathryn A. Carson's support for statistical consulting was from the National Center for Research Resources and the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health through grant No. 1UL1TR001079. None of the other authors have any relevant conflicts of interest to disclose.

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