Original article

Thieme

Pilot prospective study on formal training in per-oral endoscopic myotomy (POEM) during advanced endoscopy fellowship

OPEN ACCESS

Authors

Salmaan Jawaid[1,2], Peter V. Draganov[1], Hiroyuki Aihara[3], Mouen A. Khashab[4], Dennis Yang[1]

Institutions

1   Division of Gastroenterology and Hepatology, University of Florida, Gainesville, Florida, United States
2   Division of Gastroenterology and Hepatology, Baylor College of Medicine, Houston, Texas, United States
3   Division of Gastroenterology and Hepatology, Brigham and Women's Hospital, Boston, Massachusetts, United States
4   Division of Gastroenterology and Hepatology, Johns Hopkins Medicine, Baltimore, Maryland, United States

Corresponding author
Dennis Yang, Division of Gastroenterology and Hepatology, University of Florida, Gainesville, Florida, United States, 1329 SW 16th, Street, Room #5252, Gainesville, FL 32608, United States
Fax: +1-352-627-9002
dennis.yang@medicine.ufl.edu

🌐 Supplementary material is available under
https://doi.org/10.1055/a-1610-8962

ABSTRACT

Background and study aims Gastroenterology societies have recently proposed core curricula for training in per-oral endoscopic myotomy (POEM) based on expert opinion with limited data on its applicability for advanced endoscopy fellowship (AEF) trainees. We prospectively evaluated the feasibility of a structured POEM training curriculum during a dedicated AEF and the trainee's performance during independent practice.

Methods This was a single-center prospective study evaluating a trainee's performance of POEM using a structured assessment tool (POEMAT) to assess core cognitive and technical skills. The trainee's performance was then prospectively assessed during the first 12 months of independent practice.

Results The trainee, who had not prior background in submucosal endoscopy, first observed 22 POEM cases followed by 35 hands-on procedures during his advanced endoscopy fellowship. Based on the POEMAT, submucosal entry and mucosal incision closure were the most challenging technical aspects, while cognitive skills were uniformly attained early in training. Overall, the trainee was able to cross the threshold for competence in his POEMAT performance score in 15 of his last 18 cases (83.3%). The trainee performed 16 POEMs (baseline mean Eckardt 7.2) in his first 12 months of independent practice. Mean procedural time was 79.8 minutes (interquartile range: 67–94 minutes minutes) with no adverse events. Clinical success (Eckardt score<3) was achieved in 100% of the cases at a median follow-up of 20 weeks.

Conclusions Results from this pilot study support the adoptability of the recently proposed core curricula for POEM training within the context of a dedicated AEF and provide a potential blueprint for future studies of performance in POEM among trainees.

Introduction

Per-oral endoscopic myotomy (POEM) is an established endoscopic technique for treatment of achalasia and other selected esophageal motility disorders [1–3], with recent high-quality studies supporting its efficacy and safety when performed by expert endoscopists [4, 5]. In spite of the increasing adoption of this technique worldwide, data on training for POEM remain relatively scarce. Importantly, the literature on training for POEM is conflicting, with a wide discrepancy in the learning

curve plateau reported, ranging anywhere from seven to up-wards of 100 cases, as recently reported by Liu et al [6–11]. This substantial variability is partly due to differences in study design, with many of these reporting data from animal models or retrospective analysis of single-center experiences, rather than studies designed with the main intent of assessing training and competency in POEM. More recently, Schlachterman et al reported results of a pilot study specifically aimed at developing a POEM training and skills evaluation tool [12]. Although this small study was limited by only three trainees and the inclusion of both animal explant (n = 8) and human cases (n = 10), it provided a potential blueprint for integration of a tool for POEM training assessment.

Many advanced endoscopy fellows are seeking additional training in procedures such as POEM. Nonetheless, it should come to no surprise that comprehensive training in POEM within the constraints of a standard 12-month advanced endoscopy fellowship can be challenging, particularly when most of the fellows have limited experience with submucosal endoscopy [13]. Indeed, while many programs may offer exposure to POEM, most trainees are not ready for independent practice and end up pursuing additional training opportunities in POEM on completion of their advanced endoscopy fellowship [14].

The American Society of Gastrointestinal Endoscopy (ASGE) recently introduced a core curriculum for POEM with the goal of highlighting core concepts and skills required for the safe and effective performance of the procedure [15]. The recommendations outlined in this document are primarily based on expert opinion and it remains unclear whether they can be adopted within the context of an advanced endoscopy fellowship. The aims of this prospective pilot study were to evaluate the feasibility of a structured POEM training curriculum during an advanced endoscopy fellowship, assess hands-on competence using an assessment tool, and evaluate one trainee's performance at the onset of independent practice.

Methods

Study subject

This was a prospective, pilot, single-center study conducted at the University of Florida. The advanced endoscopy trainee was enrolled in this study from July 2018 to December 2019. The trainee had completed a standard Accreditation Council for Graduate Medical Education (ACGME) accredited 3-year gastroenterology fellowship in the United States prior to his advanced endoscopy fellowship. Informed consent was obtained from the participating trainee. The study was approved by the Institutional Review Board at the University of Florida.

Advanced endoscopy fellow training background

A baseline survey questionnaire (**Supplement 1**) was given to the trainee to assess his exposure to submucosal endoscopy (i. e. POEM and endoscopic submucosal dissection [ESD]) prior to the start of his advanced endoscopy fellowship.
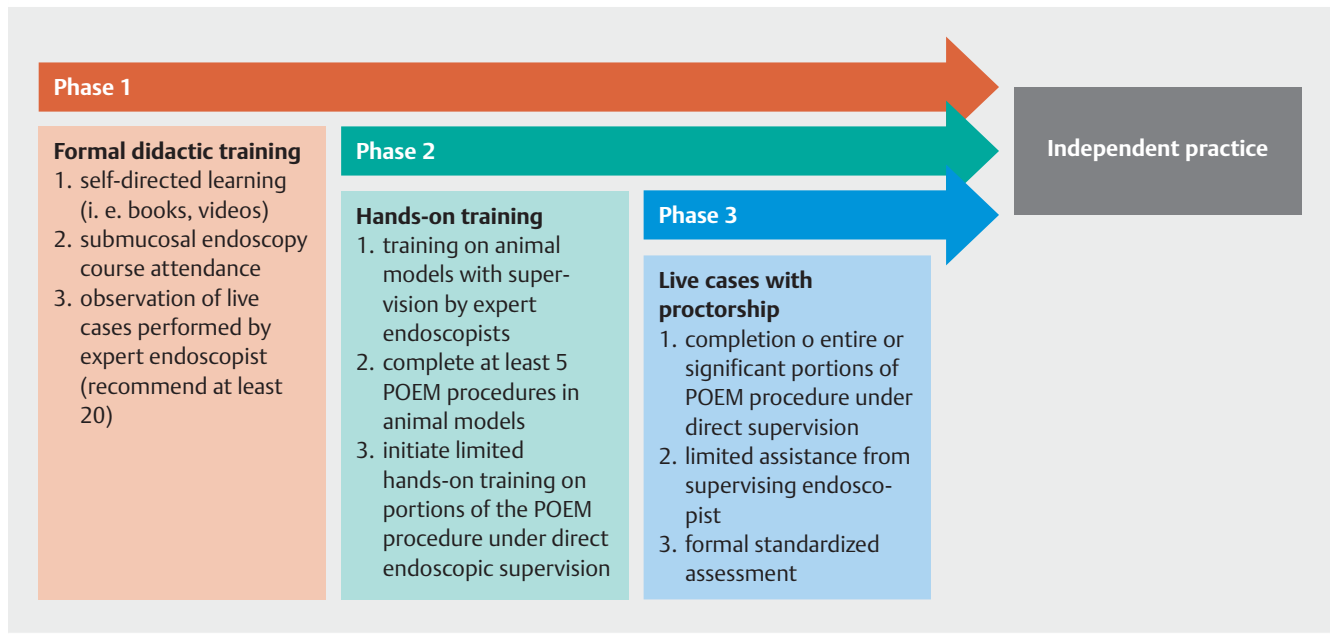
POEM training curriculum

POEM is a complex procedure that requires multiple cognitive and technical skills to achieve competence. According to the ASGE guidelines on novel endoscopic techniques, given its high level of complexity, POEM is considered a "major skill" warranting formal training under the supervision of a preceptor(s) [16]. In recognition of these recommendations, the advanced endoscopy fellowship program at the University of Florida adopted an 18-month duration training model, with the goal of providing comprehensive preceptorship for training in POEM while still meeting the standards for training in endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP) during an advanced endoscopy fellowship [17].

The structure of our POEM training curriculum was based on the recently proposed ASGE core curriculum for POEM training [15], models for training in new technologies in submucosal endoscopy [18–20], the ASGE preservation and incorporation of valuable endoscopic innovations (PIVI) position statement on POEM, the European Society of Gastrointestinal Endoscopy (ESGE) ESD curriculum, and on the Japan Gastroenterological Endoscopy Society (JGES) clinical practice guidelines on training and teaching for POEM [21–23].

Our proposed POEM training curriculum is depicted in ▶ Fig. 1. The training period was divided into three phases. During phase 1, the fellow's training revolved around formalized didactic education. The trainee was provided with resources (i. e. dedicated book with videos on submucosal endoscopy) to gain knowledge regarding the aims, indications and results of the procedure [24]. Further knowledge on the basic strategy, use of tools, and technique was achieved through attendance at ESD/POEM courses and observation of the procedure being performed by two endoscopists (PVD and DY). During phase 2, training in POEM involved hands-on participation on animal models with direct supervision. The trainee was expected to have observed at least 20 cases by experts and completed at least five POEMs in animal models before performing selected portions of POEM in human cases under supervision in the latter portion of phase 2. These thresholds were based on the suggested ESGE training curriculum for submucosal endoscopy and prior studies using animal models for POEM training [22, 25, 26]. In phase 3, POEM cases were partially or completely performed by the trainee under direct supervision [15]. The POEM curriculum was designed so that the fellow would simultaneously obtain comprehensive training in other advanced endoscopic procedures, including ERCP and EUS, during his 18-month fellowship.

POEM structured assessment tool (POEMAT)

The POEM assessment tool (POEMAT) was designed by both consensus opinion and review of the existing literature by expert endoscopists in POEM (DY, PVD, HA, MAK). The aim of this tool was to include markers of competence for core skills necessary to perform high-quality POEM as outlined by the ASGE core curriculum on POEM, ASGE PIVI on POEM, and the JGES clinical practice guidelines [15, 21, 23].

Fig. 1 Proposed structured POEM training curriculum.

The POEMAT was used by the supervising endoscopist to grade the trainee's performance on all consecutive hands-on POEM procedures after the first 17 cases (phase 3). This threshold was arbitrarily set based on previous studies suggesting that the learning curve plateaus after 13 to 25 procedures [6, 8–10]. The supervising endoscopist (PVD) is considered an expert in POEM, having performed over 300 procedures independently while meeting performance criteria as outlined by both the ASGE and JGES [21, 23].

The POEMAT was designed to include key cognitive and technical steps as outlined by the ASGE core curriculum [15] (**Supplement 2**): identification of important anatomical landmarks during the procedure, creation of a submucosal bleb followed by mucosal incision and submucosal entry, submucosal tunneling, esophagogastric myotomy, mucosal incision closure, prophylactic hemostasis, and management of adverse events (AEs). Indication for POEM, disease severity based on the Eckardt score [21], duration of symptoms and prior interventions were also recorded in each POEMAT. Procedural degree of difficulty and other technical parameters, including procedure time, were also documented. Procedural difficulty was assessed using a POEM difficulty score as previously proposed by Bechara et al [27]. This scoring system consists of five variables: fibrosis, oozing, orientation, distention of tunnel and spastic contractions. Each variable is arbitrarily weighted equally and assigned values ranging from 0 to 2 (the higher numeric score corresponding to increasing difficulty).

A four-point scoring system was developed to grade each skill, based on the format of previously validated endoscopy assessment tools [28–30]: 4 (superior), achieves task without instruction; 3 (advanced), achieves minimal verbal cues; 2 (intermediate), achieves with multiple verbal cues or hands-on assistance; 1 (novice), unable to complete and requires trainer

to take over. In addition, a 10-point overall assessment score (1–3, novice; 4–6, intermediate; 7–9, advanced; 10, superior) was provided by the supervising endoscopist on each case as previously described [28]. Overall, if a trainee was unable to meet the standard for a specific skill (i. e. achieve with minimal verbal cues), the supervising endoscopist would first approach it by providing additional verbal cues and/or minimal hands-on assistance. If these remedial measures failed, then the supervising endoscopist would take over that specific task.

POEM procedure

All POEM procedures performed in this study were part of the routine clinical care provided at our institution. The POEM techniques utilized and the degree of the trainee's hands-on participation in each individual POEM step was at the discretion of the supervising endoscopist. AEs were categorized according to ASGE consensus criteria [31]. Minimal bleeding during submucosal dissection and myotomy with adequate intraprocedural hemostasis are expected during the POEM procedure and were not considered an intraprocedural AE. Full-thickness mucosal injury during POEM was considered an intraprocedural AE even if this was adequately managed endoscopically.

Post-training self-assessment

At the conclusion of his training period, the advanced endoscopy fellow completed a questionnaire (**Supplement 3**) that assessed his level of comfort (using a 5-point Likert scale) with performing different key cognitive and technical POEM skills and his readiness for independent practice.

Performance and competence in POEM during independent practice

Following completion of his 18-month training, the trainee tracked his performance on every POEM completed during the first 12 months of independent practice as faculty at Baylor College of Medicine. Data included patient baseline demographics, indication for the procedure, history of prior interventions, duration of symptoms, baseline Eckardt score, procedure time, and AEs. Technical success was defined as completion of the POEM procedure. Clinical success was defined as an Eckardt score of ≤3 following the procedure.

Study outcomes and definitions

The primary study outcome was to evaluate the adequacy of a structured POEM training curriculum during advanced endoscopy fellowship. Adequate training was determined by formal competence assessment using the POEMAT during hands-on training and by the trainee's performance in independent practice.

For the POEMAT, a grading system was used to assess the individual skills and overall performance. For the individual skills, a rating of ≥3 was considered a success (minimally required numeric score for competence) and a rating <3 was considered a failure. For the overall performance, a rating ≥7 was the minimal score required for competence. The POEM training curriculum was considered adequate if the trainee met the threshold of competence in his overall performance in ≥80% of the hands-on cases performed by the trainee in phase 3.

Competence in the performance of POEM in independent practice was achieved if the trainee met the following threshold criteria as established by the ASGE PIVI on POEM: 80% or greater efficacy (defined as an Eckardt score of ≤3) on follow-up and 6% or lower serious AE rate and 0.1% or lower mortality rate within 30 days after the procedure [21]. Secondary outcomes were to evaluate competence in individual cognitive and technical core skills in POEM based on the POEMAT during phase 3 of training and examine the trainee's perceptions about his readiness for independent practice following fellowship.

Statistical analysis

Results are reported as mean ± standard deviation (SD) or as median with range for quantitative variables and as percentages for categorical variables. When indicated, 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. Statistical significance was based on two-sided design-based tests evaluated at α = 0.05. Statistical analysis was performed with IBM SPSS Statistics, version 21 (IBM Corporation, Armonk, New York, United States).

Results

Trainee background in submucosal endoscopy

On the survey questionnaire, the trainee reported no prior training in submucosal endoscopy at the start of his advanced endoscopy fellowship. He did not undergo formal training on cognitive aspects (i.e. indications/contraindications, benefits, risks, limitations of the procedure, components of pre-endoscopic evaluation and post-procedural care) on POEM. The trainee did not observe any live procedures by experts or participate in any hands-on training on animal models or human cases prior to this study.

POEM procedure characteristics

The trainee observed 22 POEM procedures (phase 1) and underwent hands-on training with an additional 35 POEM cases (17 in phase 2 and 18 in phase 3) during his advanced endoscopy fellowship from July 2018 to December 2019. The baseline characteristics of all hands-on POEM cases performed by the trainee are shown in ▶Table 1. The most common indication for POEM was achalasia type II (19; 54.2%) and the mean baseline Eckardt score of these patients was 7.1 (interquartile range: 5.5–9). Many patients had some type of intervention prior to POEM (16; 45.7%): 10 patients had botulinum toxin injection (28.6%), one patient had pneumatic balloon dilation (2.9%), whereas no patients had prior surgical myotomy or POEM. All patients were admitted overnight for observation as part of our institution's protocol on POEM [32, 33]. There were no intraprocedural or delayed AEs encountered.

POEM training curriculum
Phase 1: Didactics and observation of cases

During phase 1, training revolved around gaining knowledge regarding the aims, indications, basic strategies, devices and accessories as recommended by the ASGE core curriculum for POEM. This was achieved through self-directed learning using various resources, including dedicated books on submucosal endoscopy [24] and ASGE technological reviews (with video) on POEM [34] (▶Fig. 2). As part of his structured POEM training curriculum, the fellow attended three dedicated courses on submucosal endoscopy during his advanced endoscopy fellowship: the ASGE-JGES Masters Course in ESD/POEM (https://learn.asge.org), an industry-sponsored course (Olympus America) on submucosal endoscopy, and the innovations in ESD/POEM workshop held by the University of Florida (https://cme.ufl.edu/advanced-endoscopy-conference-and-workshop). As opposed to introductory (level-1) courses, these three courses are regarded as level-2 courses, characterized by in-depth didactic lectures and intensive hands-on training over the period of several days [35]. In addition to these courses, the trainee observed a total of 22 POEM cases performed by two endoscopists at the University of Florida (PVD and DY) during phase I of his training (▶Fig. 2).

Phase 2: Training on animal models and limited hands-on human cases

Phase 2 of his structured POEM training curriculum focused on intensive hands-on experience. During this period, the trainee performed a total of 7 POEMs, all on live animal models. Five of these were performed with expert faculty at the live endoscopy courses. Two POEM procedures were performed on live animal models at a dedicated hands-on laboratory designed as

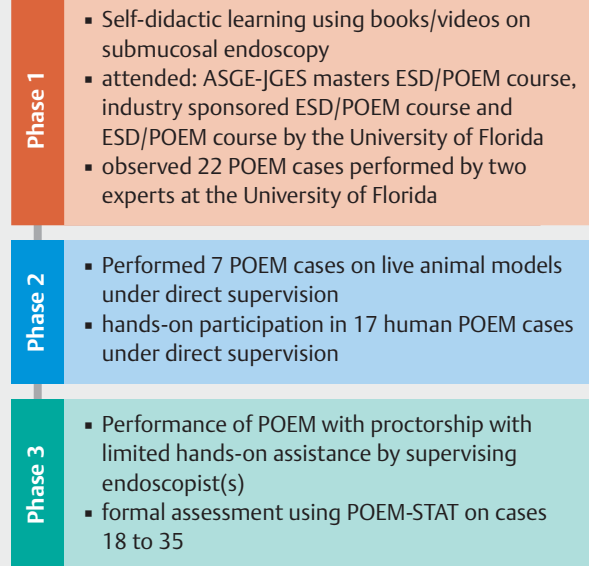▶**Table 1** Characteristics of POEM procedures with trainee hands-on participation (N = 36).

Indication for POEM; n (%)	
Achalasia	
▪ Type I	3 (8.6 %)
▪ Type II	19 (54.2 %)
▪ Type III	7 (20 %)
Jackhammer esophagus	3 (8.6 %)
Esophagogastric outlet obstruction	3 (8.6 %)
Mean baseline Eckardt score (range)	7.1 (5.5–9)
Interventions prior to POEM; n (%)	
▪ None	16 (45.7 %)
▪ Balloon dilation < 30 mm	11 (31.4 %)
▪ Botulinum toxin injection	10 (28.6 %)
▪ Pneumatic balloon dilation	1 (2.9 %)
▪ Surgical myotomy	0
▪ POEM	0
Post-POEM adverse events; n (%)	0

POEM, per-oral endoscopic myotomy.

Phase 1
- Self-didactic learning using books/videos on submucosal endoscopy
- attended: ASGE-JGES masters ESD/POEM course, industry sponsored ESD/POEM course and ESD/POEM course by the University of Florida
- observed 22 POEM cases performed by two experts at the University of Florida

Phase 2
- Performed 7 POEM cases on live animal models under direct supervision
- hands-on participation in 17 human POEM cases under direct supervision

Phase 3
- Performance of POEM with proctorship with limited hands-on assistance by supervising endoscopist(s)
- formal assessment using POEM-STAT on cases 18 to 35

▶**Fig. 2** Trainee completion of the proposed structured POEM training curriculum during the dedicated advanced endoscopy fellowship.

part of our curriculum, with the goal of providing in-depth demonstration of the technique and dedicated 1:1 supervision (PVD and DY). In addition to hands-on training on animal models during phase 2, the fellow also participated in 17 hands-on human POEM cases (▶**Fig. 2**). During these cases, the trainee performed portions of the different components of the POEM procedure (i. e. mucosal incision and entry, submucosal tunneling, myotomy, and mucosal closure).

Phase 3: Competence assessment in POEM using the assessment tool (POEMAT)

The POEMAT was used to grade each POEM procedure performed by the fellow in phase 3 of his training (case 18 to 35) (▶**Fig. 2**). Data on the trainee's competence assessment for various individual cognitive and technical endpoints are summarized in ▶**Table 2**. From a procedural standpoint, only four of 18 cases had a POEM procedural difficulty above 1. Three cases received a difficulty score of 1 due to: mild to moderate submucosal fibrosis (case #25), moderate oozing (case #26), and spastic contractions during tunneling (case #35), respectively. Unlike most of the other cases, case #21 was graded as very challenging (score of 5) due to a sigmoid esophagus, severe fibrosis, difficult orientation during tunneling, and poor distention in spite of continuous insufflation.

In general, competence (score ≥ 3) was attained in 94.4 % of the cases (17/18) for all cognitive core skills for POEM. From a technical standpoint, the proportion of cases in which the trainee crossed the threshold for competence varied based on the individual task: 100 % (18/18) for submucosal bleb formation,

77.7 % (14/18) for mucosal incision/submucosal entry, 85.7 % (12/14) for submucosal tunneling, 100 % (7/7) for myotomy and 72.7 % (8/11) for mucosal incision closure. The trainee achieved competence in 100 % of the cases in which prophylactic hemostasis (13/13) or management of bleeding (6/6) were performed. The trainee achieved competence in their overall performance score in 83.3 % (15/18) of the cases during phase 3.

Training in other advanced endoscopic procedures during fellowship

In addition to POEM, the trainee also completed his training in other advanced endoscopic procedures. This included hands-on training in 428 ERCP and 320 EUS procedures. The trainee was able to successfully complete all consecutive ERCPs and EUS over the last 6 months of his fellowship without hands-on assistance and with minimal supervision.

Trainee self-assessment on training in POEM

The trainee completed a post-POEM training self-assessment questionnaire (**Supplement 3**). Overall, the trainee either strongly agreed or tended to agree on feeling comfortable with recognizing the indications and contraindications for POEM and in performing all the individual cognitive and technical core skills related POEM. The trainee tended to agree about feeling comfortable in performing POEM in independent practice upon completion of the POEM training curriculum.

▶ **Table 2** Competence assessment in POEM using the structured assessment tool (POEMAT).

POEM evaluation based on POEMAT

| | Cognitive core skills | | | Technical core skills | | | | | | Management of adverse events | | | POEM difficulty Score[1] | |
Case number	Identifying landmarks[2]	Recognition esophageal wall layers[3]	Identification GEJ/cardia[4]	Submucosal bleb[5]	Mucosal incision and submucosal entry[6]	Submucosal tunneling[7]	Endoscopic myotomy[8]	Mucosal closure[9]	Prophylactic hemostasis[10]	Bleeding[11]	Perforation[12]	Pneumoperitoneum[13]		Overall Score
18	4	3	3	4	3	3	–	3	4	–	–	–	0	8
19	3	4	3	4	4	4	–	2	4	4	–	–	0	7
20	4	4	4	4	4	–	4	2	–	3	–	–	0	7
21	4	4	4	3	2	4	–	–	4	–	–	–	0	8
22	4	3	4	4	3	3	–	–	4	–	–	–	5	6
23	4	4	4	4	2	3	–	3	4	4	–	–	0	7
24	2	3	2	4	1	3	–	3	4	–	–	–	0	6
25	3	4	4	4	4	4	–	–	–	–	–	–	1	9
26	4	4	3	4	3	4	3	–	4	4	–	–	1	8
27	4	4	4	4	4	4	–	–	4	–	–	–	0	8
28	4	4	4	4	2	4	4	3	–	4	–	–	0	8
29	4	4	4	4	4	4	–	–	4	4	–	–	0	9
30	4	4	4	3	4	–	4	3	4	–	–	–	0	9
31	4	4	4	3	3	–	4	2	–	–	–	–	0	9
32	4	2	3	4	3	2	–	3	4	–	–	–	0	6
33	4	4	3	4	4	4	4	4	4	–	–	–	0	9
34	4	4	4	4	3	–	4	4	–	–	–	–	0	8
35	4	4	4	3	3	2	–	–	4	–	–	–	1	7
Proportion of cases in which competence threshold was reached.	94.4 %	94.4 %	94.4 %	100 %	77.7 %	85.7 %	100 %	72.7 %	100 %	100 %			--	83.3 %

▶ Table 2 (Continuation)

The threshold for competence was defined as a rating score ≥3 on a 4-point grading system for individual cognitive and technical skills and ≥7 on a 10-point scoring system for overall assessment.

POEM, per-oral endoscopic myotomy.

1 Procedure difficulty was assessed based on the "FOODS" score as previously described (Bechara R et al. Dig Endosc 2019; 31: 148–155).
2 Able to identify the lesser and greater curvature of the stomach, gastroesophageal junction, anterior vs posterior orientation of the esophagus
3 Identifies and differentiates the mucosa, submucosa, circular and longitudinal esophageal muscle layers
4 Identifies the GEJ (gastroesophageal junction) and cardia during submucosal tunneling by recognizing narrowing of the submucosal space, presence of palisade vessels
5 Effectively injects into the submucosal space to lift the mucosa and obtaining a submucosal cushion
6 Effectively creates a 1.5–2 cm mucosal incision and trims the submucosa at the edges to facilitate insertion of the endoscope without "overstretching" the entry site or causing bleeding.
7 Effective submucosal tunneling (dissects in the plane near the muscular propria and away from the mucosa – able to maintain orientation in the tunnel)
8 Can selectively perform either circular or full-thickness myotomy (circular and longitudinal muscles)
9 Effectively approximates the mucosal incision borders using either clips and/or sutures
10 Identifies and prophylactically ablates visible vessels
11 Effectively achieves intraprocedural hemostasis
12 Identifies when mucosal injury has occurred and is able to approximate the defect using clips/sutures/stenting as indicated
13 Recognizes need for abdominal decompression (decrease in tidal volume and/or increase in peak/plateau pressures) and capable of using Veress needle/angiocatheter for abdominal decompression

Competence in performing POEM during independent practice

From March 2020 to March 2021, the trainee independently completed 16 POEM procedures as faculty at Baylor College of Medicine. Patient and procedural characteristics are summarized in ▶ Table 3. Patient mean age was 43 years (IQR:27.7–54.5) with a mean baseline Eckardt score of 7.2 (IQR:5.5–8.8). Most patients had achalasia type II (13/16; 81.3%) based on pre-procedural high-resolution manometry. Prior interventions included non-pneumatic balloon dilation and botulinum toxin injections in five (31.3%) and four patients (25%), respectively. One patient had a previous Heller's myotomy. In all, technical success, defined as successful completion of POEM as intended, was achieved in all cases (16/16; 100%). The mean lengths of the esophageal and gastric myotomies were 9.2 cm (IQR: 8–10) and 2.3 cm (IQR: 2–3), respectively. Mean total procedure time was 79.8 minutes (IQR: 67–94 min). There were no im-

▶ Table 3 Patient and POEM characteristics performed by trainee during independent practice (n = 16).

Mean age; (interquartile range)	43 (27.7–54.5)
Indication for POEM; n (%)	
Achalasia	
▪ Type I	0
▪ Type II	13 (81.3%)
▪ Type III	0
Spastic esophageal dysmotility	1 (6.2%)
Esophagogastric outlet obstruction	2 (12.5%)
Mean baseline Eckardt score (interquartile range)	7.2 (5.5–8.8)
Interventions prior to POEM; n (%)	
▪ None	
▪ Balloon dilation <30 mm	5 (31.3%)
▪ Botulinum toxin injection	4 (25%)
▪ Pneumatic balloon dilation	0
▪ Surgical myotomy	1(6.3%)
▪ POEM	0
POEM technical success; n (%)	16 (100%)
Mean length of POEM myotomy, cm (interquartile range)	
▪ Esophageal	9.2 (8–10)
▪ Gastric	2.3 (2–3)
Total procedure time; mean (interquartile range) minutes	79.8 (67–94)
Adverse events; n (%)	0
Mean post-POEM Eckardt score (interquartile range)	0.2 (0–0.25)
POEM, per-oral endoscopic myotomy.	

mediate or delayed post-procedural AEs. Clinical success (Eckardt score <3), was achieved in all patients (16/16; 100%) at a median follow-up of 20 weeks (range 8–48 weeks), with a significant decrease in their mean Eckardt score (0.3; IQR: 0–0.25) (P < 0.0001) when compared to baseline.

Discussion

The ASGE recently introduced a core curriculum highlighting core concepts and skills required for the performance of POEM [16]. However, many of these recommendations are based on expert opinion and data on hands-on training for POEM, particularly within the context of an advanced endoscopy fellowship (AEF), is limited. In this pilot study, we applied a structured POEM training curriculum during a dedicated AEF and prospectively evaluated a trainee's performance using an assessment tool (POEMAT). Results from this study demonstrated that a trainee with no prior experience in submucosal endoscopy was able to achieve competence on key cognitive and technical aspects of POEM while still meeting the recommended standards in ERCP and EUS training. Importantly, by the end of the study, the trainee was able to demonstrate competence in performance of POEM during the initial phase of independent practice without requiring additional post-fellowship dedicated training in POEM.

In Japan and other East Asian countries, training in submucosal endoscopy, including POEM and ESD, follows a traditional master-apprentice model [19, 35]. While this master-apprentice model has been very successful in Asia, it is not directly translatable to training during a standard AEF. For one, unlike our Asian counterparts who spend years training in a specific technique, most advanced endoscopy trainees in the United States also expect to be fully trained in ERCP and EUS at the completion of their fellowship. In recognition of these challenges, we developed an AEF with a dedicated POEM training curriculum based on the format suggested by GI societies recommendations [15, 23]. The structured POEM training curriculum introduced in this study adapted the stepwise approach to skill acquisition as followed in the master-apprentice model, yet we introduced other complementary pathways that facilitated comprehensive training in a practical and effective manner. Dedicated endoscopy courses have been a source for additional endoscopic education [18, 19, 35]. As part of the POEM training curriculum in this study, the trainee participated in 3 comprehensive courses in submucosal endoscopy during the initial phases of his training. These courses supplemented his self-study with formalized didactic education, observation of live cases by experts and supervised hands-on training in animal models. Given the training time constraints and relatively limited volume of cases that may be encountered during an AEF, these courses are a crucial resource for additional in-depth training. Indeed, a prior study by our group demonstrated that attendance of a dedicated ESD training course notably increased the adoption of the technique by the participants in their practice [14]. More data are needed to formally evaluate the effectiveness of these type of endoscopic courses during fellowship training.

Most of the current data on learning curves for POEM have used procedure time as a measure of performance [6–10]. However, procedure time is not the ideal surrogate for competence, as this can vary significantly with various patient and procedural factors. With the increasing focus on outcomes-based endoscopic training, there has been an ongoing emphasis to develop instruments designed to evaluate procedure-specific core skills and quality metrics [36]. In this study, we developed and used a pilot assessment tool to analyze a trainee's performance for relevant individual cognitive and technical aspects of POEM during his last phase of hands-on training. The content of this tool is in line with the core concepts and skills required for POEM training as outlined by the ASGE [16]. Our results demonstrated that the threshold for competence in various cognitive skills were uniformly attained throughout phase 3 of training. On the contrary, from a technical standpoint, mucosal incision followed by submucosal entry and mucosal incision closure were the most challenging steps, as competence threshold for these core skills was achieved in 77.7% and 72.7% of the cases, respectively. Our data are consistent with those recently published in a pilot study identifying submucosal entry as a technically difficult step during POEM training [12]. Overall, use of the POEMAT allowed us to objectively evaluate the trainee based on individual competence benchmarks defined a priori and provided an opportunity to target potential core skills requiring further attention during training. This, in turn, may have permitted the trainee to hone those specific skills and account for their adequate performance during independent practice. Irrespectively, larger studies with more trainees are needed to validate the assessment tool and to help establish competence thresholds based on representative learning curves.

The trainee in this study had no prior experience with submucosal endoscopy, which should be highlighted when comparing our data with previous studies on training for POEM. For instance, a recent study by Liu et al. suggested that 100 POEM cases are needed to decrease the risk of technical failure, AEs and clinical failure based on cumulative sum analysis [11]. Yet, all of the endoscopists involved in this study had already successfully completed more than 200 ESDs prior to their first POEM. It is highly unlikely that most trainees in the West, including expert interventional endoscopists, would have amassed such a high volume of cases in submucosal endoscopy prior to initiating their training in POEM. Hence, we believe that our pilot data may provide a more approachable strategy for structured training in POEM in the West. Indeed, at the completion of this pilot study, the trainee indicated feeling comfortable with all cognitive and technical aspects of POEM. More importantly, the trainee demonstrated competence in performing POEM cases independently. The trainee achieved 100% technical and clinical success in all POEM cases performed at the onset of independent practice with no reported AEs, thereby meeting the performance threshold criteria as recommended by the ASGE. Hence, these preliminary findings suggest that the POEM training curriculum was both feasible and adequate in providing comprehensive training within the context of an AEF

and supports its viability as a potential training pathway in the United States.

We acknowledge the limitations of this study. First, this pilot study was conducted at a single site with only one trainee, limiting the overall generalizability of these results. Nonetheless, given the limited data on POEM training among advanced endoscopy fellows, these initial data provide an important framework and a potential blueprint for how to achieve these training parameters as outlined by the gastroenterology societies' core curricula on POEM. We recognize that this study involved an 18-month training period, which is longer than most AEFs across the nation. However, the reality is that comprehensive training in complex advanced endoscopic procedures beyond ERCP and EUS within the constraints of a standard 12-month AEF may be challenging if not impossible. Hence, as outlined in the ASGE core curriculum for POEM, most trainees may need to learn the performance of POEM through a dedicated AEF or in special Third Space Endoscopy programs [15]. Furthermore, it should be noted that the study site is a high-volume POEM center (approximately 75–100 cases per year), and therefore, may not be representative of all advanced endoscopy programs in the country. Irrespective of that, institutions planning on providing POEM training should follow the recommended criteria as outlined by the ASGE and JGES clinical practice guidelines [23]. POEM training, alike other endoscopic procedures, should be offered at centers in which adequate hands-on training is available; albeit the minimum volume threshold remains to be determined. Second, while the trainee was involved in 57 POEM cases (22 observation and 35 hands-on) during his fellowship, the relatively low number precluded learning curve analysis and limited competence assessment when evaluating certain POEM-related endpoints (i.e. management of perforation, pneumomediastinum). Furthermore, although phase 3 consisted of hands-on training, the degree of trainee involvement in each specific step during the procedure varied at the discretion of the supervising endoscopist. Nonetheless, this is an expected finding during endoscopic education, with increasing trainee participation as he/she gains more experience. We also recognize that the structure of the proposed POEM training curriculum in this pilot study was mainly based on expert opinion as there are no available data on training in POEM during an AEF. Hence, the duration of training, the type and number of submucosal endoscopy courses, and the volume of cases observed or with hands-on participation during the training phases were all arbitrarily established. The effectiveness of this training pathway as compared to other strategies remains to be determined. Furthermore, we acknowledge that the subjective opinion of the supervising endoscopist was regarded as the criterion standard for several endpoints of the POEMAT. This is an inherent limitation of any study assessing endoscopic training using this methodology [28–30]. Furthermore, the cut-offs of acceptable and non-acceptable score parameters using the POEMAT were loosely based on previously validated endoscopic assessment tools but have yet to be validated for POEM training. In addition, there was no cross-validation performed among the two evaluators. Hence, while the pilot study employed a structured data collection tool as part of

the POEM training curriculum, future studies are needed to validate, define scoring parameters, and establish the utility of these training instruments. Lastly, it is unclear if and how differences in the type and volume of other advanced endoscopic procedures (i.e. ERCP, EUS, advanced endoscopic resection techniques) performed by the trainee during his fellowship may have influenced his endoscopic acquisition skills during POEM training. Nonetheless, the impact of these factors was to some extent mitigated by using the structured assessment tool with well-established predefined procedural endpoints.

Conclusions

In summary, results from this pilot study support the feasibility of adopting the ASGE core curriculum for POEM within the context of a dedicated AEF program. Using a structured assessment tool, we demonstrated that a trainee with no prior experience in submucosal endoscopy was able to meet competence thresholds for various cognitive and technical aspects of POEM. Upon completion of the fellowship, the trainee was able to perform POEM procedures during independent practice without requiring additional post-fellowship training, supporting the efficacy of the proposed POEM training pathway and providing a potential blueprint for future studies on training in POEM.

Competing interests

References

[1] Yang D, Draganov PV. Expanding role of third space endoscopy in the management of esophageal diseases. Curr Treat Options Gastroenterol 2018; 16: 41–57

[2] Jawaid S, Draganov PV, Yang D. Esophageal POEM: the new standard of care. Transl Gastroenterol Hepatol 2020; 5: 47

[3] Khashab MA, Benias PC, Swanstrom LL. Endoscopic myotomy for foregut motility disorders. Gastroenterology 2018; 154: 1901–1910

[4] Werner YB, Hakanson B, Martinek J et al. Endoscopic or surgical myotomy in patients with idiopathic achalasia. N Engl J Med 2019; 5: 381: 2219–2229

[5] Ponds FA, Fockens P, Lei A et al. Effect of peroral endoscopic myotomy vs pneumatic dilation on symptom severity and treatment outcomes among treatment-naïve patients with achalasia: a randomized clinical trial. JAMA 2019; 322: 134–144

[6] Kurian AA, Dunst CM, Sharata A et al. Peroral endoscopic esophageal myotomy: defining the learning curve. Gastrointest Endosc 2013; 77: 719–725

[7] Teitelbaum EN, Soper NJ, Arafat FO et al. Analysis of a learning curve and predictors of intraoperative difficulty for peroral esophageal myotomy (POEM). J Gastrointest Surg 2014; 18: 92–98

[8] Patel KS, Calxte R, Modayil RJ et al. The light at the end of the tunnel: a single-operator learning curve analysis for per oral endoscopic myotomy. Gastrointest Endosc 2015; 81: 1181–1187

[9] El Zein M, Kumbhari V, Ngamruengphong S et al. Learning curve for peroral endoscopic myotomy. Endosc Int Open 2016; 4: E577–E582

[10] Houning L, Zhao N, Zheng Z et al. Analysis of the learning curve for peroral endoscopic myotomy for esophageal achalasia: single-center, two-operator experience. Dig Endosc 2017; 29: 299–306

[11] Liu Z, Zhang X, Zhang W et al. Comprehensive evaluation of the learning curve for peroral endoscopic myotomy. Clin Gastroenterol Hepatol 2018; 16: 1420–1426

[12] Schlachterman A, Aziz A, Alajlan B et al. Per-oral endoscopic myotomy (POEM) training and skills evaluation tool: a pilot study. Endosc Int Open 2020; 8: E1826–E1831

[13] Mittal C, Wagh MS. Training pathways and competency assessment in peroral endoscopic myotomy (POEM). Tech Gastrointest Endosc 2017; 19: 17–174

[14] Schlachterman A, Yang D, Goddard A et al. Perspectives on endoscopic submucosal dissection training in the United States: a survey analysis. Endosc Int Open 2018; 6: E399–E409

[15] Dacha S, Aihara H, Anand GS et al. Core curriculum for peroral endoscopic myotomy (POEM). Gastrointest Endosc 2021; 93: 539–543

[16] Faulx AL, Lightdale JR. ASGE Standards of Practice Committee. et al. Guidelines for privileging, credentialing, and proctoring to perform GI endoscopy. Gastrointest Endosc 2017; 85: 273–281

[17] Wani S, Han S, Simon V et al. Setting minimum standards for training in EUS and ERCP: results from a prospective multicenter study evaluating learning curves and competence among advanced endoscopy trainees. Gastrointest Endosc 2019; 89: 1160–1168

[18] Yang D, Wagh MS, Draganov PV. The status of training in new technologies in advanced endoscopy: from defining competence to credentialing and privileging. Gastrointest Endosc 2020: doi:10.1016/j.gie.2020.05.047

[19] Kotzev AI, Yang D, Draganov PV. How to master endoscopic submucosal dissection in the USA. Dig Endosc 2019; 31: 94–100

[20] Draganov PV, Coman RM, Gotoda T. Training for complex endoscopic procedures: how to incorporate endoscopic submucosal dissection skills in the West? Expert Rev Gastroenterol Hepatol 2014; 8: 119–121

[21] Chandrasekhara V, Desilets D, Falk GW et al. The American Society for Gastrointestinal Endoscopy PIVI (preservation and incorporation of valuable endoscopic innovations) on peroral endoscopic myotomy. Gastrointest Endosc 2015; 81: 1087–1100

[22] Pimentel-Nunes P, Pioche M, Albeniz E et al. Curriculum for endoscopic submucosal dissection training in Europe: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement. Endoscopy 2019; 51: 980–992

[23] Inoue H, Shiwaku H, Iwakiri K et al. Clinical practice guidelines for peroral endoscopic myotomy. Dig Endosc 2018; 30: 563–579

[24] Advanced Techniques for Endoscopic Resection in the GI Tract, 1st Edition. Draganov PV, Gotoda T, Yang D. Slack Inc; 2019

[25] Penazola-Ramirez A, Suarez-Correa J, Baez-Blanco J et al. In vivo experience with peroral endoscopic myotomy: an essential activity for developing the technique in humans. Rev Gastroenterol Mex 2018; 83: 86–90

[26] Bang BW, Choic YC, Kim HG et al. Peroral endoscopic myotomy for treating achalasia in an animal model: a feasibility study. Clin Endosc 2013; 46: 54–58

[27] Bechara R, Woo M, Hookey L et al. Peroral endoscopic myotomy (POEM) for complex achalasia and the POEM difficulty score. Dig Endosc 2019; 31: 148–155

[28] Wani S, Keswani RN, Petersen B et al. Training in EUS and ERCP: standardizing methods to assess competence. Gastrointest Endosc 2018; 87: 1371–1382

[29] Wani S, Keswani R, Hall M et al. A prospective multicenter study evaluating learning curves and competence in endoscopic ultrasound and endoscopic retrograde cholangiopancreatography among advanced endoscopy trainees: the Rapid Assessment of Trainee Endoscopy Skills Study. Clin Gastroenterol Hepatol 2017; 15: 1758–1767

[30] Wani S, Keswani RN, Han S et al. Competence in endoscopic ultrasound and endoscopic retrograde cholangiopancreatography, from training through independent practice. Gastroenterology 2018; 155: 1483–1494

[31] Cotton PB, Eisen GM, Aabakken L et al. A lexicon for endoscopic adverse events: report of an ASGE Workshop. Gastrointest Endosc 2010; 71: 446–454

[32] Yang D, Pannu D, Zhang Q et al. Evaluation of anesthesia management, feasibility and efficacy of peroral endoscopic myotomy (POEM) for achalasia performed in the endoscopy unit. Endosc Int Open 2015; 3: E289–E295

[33] Pannu D, Yang D, Abbitt PL et al. Prospective evaluation of CT esophagram findings after peroral endoscopic myotomy. Gastrointest Endosc 2016; 84: 408–415

[34] Pannala R, Abud Dayyeh BK, Aslanian HR et al. Per-oral endoscopic myotomy (with video). Gastrointest Endosc 2016; 83: 1051–1060

[35] McCarty TR, Aihara H. Current state of education and training for endoscopic submucosal dissection: Translating strategy and success to the USA. Dig Endosc 2019: doi:10.1111/den/13591

[36] Wani S, Keswani RN, Petersen B et al. Training in EUS and ERCP: standardizing methods to assess competence. Gastrointest Endosc 2018; 87: 1371–1382