

ORIGINAL ARTICLE

Optimal simulation and tissue platforms for acquiring surgical endoscopy skills to perform per oral endoscopic myotomy (POEM)

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Abstract

Background: Per oral endoscopic myotomy (POEM) represents a natural orifice transluminal endoscopic surgery (NOTES) approach to the treatment of achalasia and some esophageal motility disorders. Promising preliminary results necessitate the development of a training system for this procedure. No dedicated measure of competency or standard training has been established. Training that optimizes the use of simulation and tissue platforms to learn the surgical endoscopic skills needed to perform the POEM procedure is required for its development. **Methods:** Our team consists of an interventional endoscopist and an advanced minimally invasive surgeon, experienced with NOTES procedures, as part of a Combined Endoscopy Center at a major medical facility. The task force focused on establishing POEM training platforms at a fully accredited American College of Surgeons simulation center, vivarium, and bioskills center. After a thorough assessment, an optimal curriculum was established using inanimate and animate platforms. **Results:** Our recommended curriculum is as follows. Fundamentals of Endoscopic Surgery (FES) certification establishes a foundation in flexible esophagoscopy. The recommended training platforms include: (1) simulation (inanimate) for FES and instrument familiarization, (2) a porcine ex vivo Erlangen model for endoscopic submucosal dissection followed by submucosal endoscopy with mucosal flap, including blunt balloon dissection, (3) porcine non-survival: submucosal myotomy and mucosal flap closure followed by necropsy, (4) porcine survival: complete procedure followed by necropsy, (5) simulation (inanimate) and video format for management of intra-operative adverse events, including bleeding, hemodynamic capnothorax, and full-thickness incision. **Conclusion:** POEM requires specific knowledge and technical skills spanning gastroenterology and surgery. We provide training that optimizes the use of simulation and tissue platforms for trainee acquisition of the advanced surgical endoscopy skills necessary to perform POEM.

Keywords: achalasia; per oral endoscopic myotomy; POEM; surgical endoscopy; natural orifice transluminal endoscopic surgery; NOTES

Introduction

Achalasia is an esophageal motility disorder characterized by an immune-mediated failure of inhibitory neurons, resulting in inadequate relaxation of the lower esophageal sphincter (LES) and disorganized esophageal peristalsis. This disorder classically presents with progressive dysphagia to solids and liquids, odynophagia, and regurgitation with a rare incidence of 1 in 100,000 persons per year.^{1,2} There is no known curative treatment and, therefore, therapeutic options focus on symptom relief. Multiple therapeutic

modalities are available to treat symptomatic achalasia, including pharmaceuticals, endoscopic interventions, and surgery.^{3,4} Historically, the more invasive the technique, the more effective the therapy, with surgical distal esophageal myotomy or Heller myotomy serving as the definitive treatment. With the development of natural orifice transluminal endoscopic surgery (NOTES), a hybrid procedure between endoscopy and surgery has been developed.

Per oral endoscopic myotomy (POEM) represents a NOTES approach to the treatment of achalasia and other esophageal

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motility disorders.⁵ This novel procedure involves myotomy of the distal esophageal muscle fibers into the proximal stomach performed endoscopically through a submucosal tunnel. The feasibility of this technique was initially described by Pasricha *et al.*⁶ in a swine model in 2007, and then Inoue *et al.*⁷ reported the first successful procedure in a human patient. Currently, over 4000 POEM procedures have been performed worldwide.⁸ Studies with 2-year or longer follow-up of patients have reported a durability of symptomatic relief ranging between 79% and 92%.⁹⁻¹¹ The long-term durability is reportedly 83%, and evidence suggests that when POEM results are compared with current standard-of-care interventions for achalasia, there is an equivalent treatment efficacy and durability.^{12,13} Despite the likelihood that a fifth of patients experience symptoms of gastroesophageal reflux disease after POEM,¹⁴ increasingly POEM is considered a standard treatment for certain esophageal motility disorders, and specialized centers are steadily emerging worldwide.¹⁵

As a NOTES procedure, POEM represents a new paradigm for both interventional endoscopists and minimally invasive surgeons. Even with the growing enthusiasm for the procedure, there are no current guidelines that determine the training required to gain competency. Simulator and bioskills training models should be developed and validated before starting this novel procedure on humans. We offer training that can be incorporated into a residency or fellowship program by expanding on the endoscopy graduation requirements of the American Board of Surgery¹⁶ through the use of simulation technology as well as animal and cadaver platforms to learn the surgical endoscopy skills needed to perform the POEM procedure.

Methods

Our medical center is one of the largest training facilities in the Department of Defense with a robust graduate medical education program, including general surgery residency and gastroenterology fellowship. The campus has a fully accredited American College of Surgeons simulation center that is a Fundamentals of Endoscopic Surgery (FES) test center, a bioskills training center as well as an active vivarium.

We established a task force from our Combined Endoscopy Center (CEC) to develop optimal POEM training led by an expert interventional gastrointestinal endoscopist (RDL) and an advanced minimally invasive surgeon (GGW) experienced with NOTES and surgical endoscopy. Our CEC facility offers a unique environment where general surgeons and gastroenterologists share the clinical space and perform diagnostic and therapeutic endoscopy side by side. This

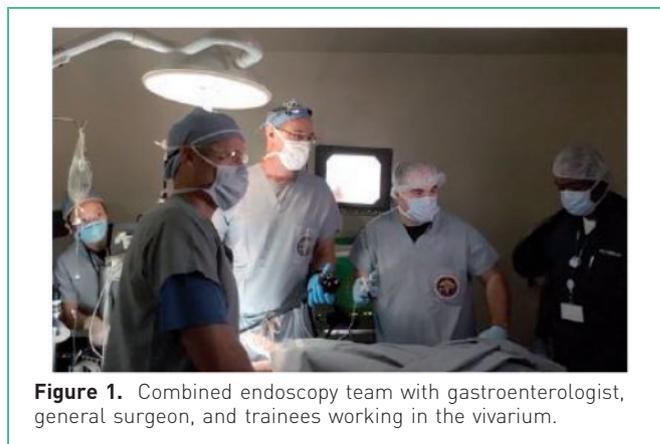


Figure 1. Combined endoscopy team with gastroenterologist, general surgeon, and trainees working in the vivarium.

partnership allows for the cross fertilization of endoscopic and surgical techniques and provides a preferred environment to further interventional endoscopy and improve patient care (Fig. 1).

POEM procedure

All procedures were performed under the supervision of RDL and GGW in a swine non-survival model (80–100 kg) under endotracheal general anesthesia in accordance with a protocol approved by the Institutional Animal Care and Use Committee. The animal was placed in the supine position and an upper gastrointestinal endoscopy was performed using a high-resolution upper endoscope (GIF-H180, Olympus) with carbon dioxide (CO₂) insufflation. After initial endoscopic surveillance, a conical-shaped, dissection cap was mounted onto the endoscope to provide a submucosal view. Our stepwise approach was performed according to Inoue's original technique⁷ and outlined as follows.

Step 1. Creation of a submucosal window

Approximately 7–10 cm proximal to the gastroesophageal junction (GEJ) was identified as the site for mucosotomy. Methylene blue solution was injected submucosally to elevate the mucosa followed by an approximate 1.5 cm longitudinal incision using needle-knife cautery.

Step 2. Creation of a submucosal tunnel

The endoscope was advanced through the mucosal entry, and a tunnel in the submucosal layer was formed. A combination of blunt dissection with the cap and attentive electrocautery with a triangle-shaped tip needle-knife (TT-knife, Olympus) and dry cut mode (ERBE Electromedizen, Tübingen, Germany) was applied. Carbon dioxide insufflation and methylene blue solution infusion facilitated the dissection. Larger submucosal vessels were coagulated with hot biopsy forceps before dissection. The submucosal tunnel was extended below the LES along the lesser curvature onto

the gastric cardia. A retroflexed view in the esophageal lumen was used to ensure an adequate extension onto the stomach, approximately 2 cm beyond the GEJ.

Step 3. Performance of myotomy of the circular muscle layer

Myotomy of the inner circular muscle layer was performed with the scope reinserted into the submucosal tunnel starting approximately 4 cm above the LES. This myotomy was extended 2–3 cm onto the gastric cardia. A complete myotomy was created of both the longitudinal and circular layers at the level of the GEJ with LES and gastric portion. A special triangle-tip knife was utilized for submucosal dissection with monopolar coagulation. Radial tension from both the CO₂ insufflation and the dissecting cap further delineated the circular muscle fibers for division.

Step 4. Closure of submucosal window

The mucosal entry incision was closed by standard endoscopic hemoclips (E-Z clip, HX610-050L, Olympus) after the endoscope was withdrawn from the submucosal tunnel

Objectives

Our task force was charged with determining the optimal learning platform for the required technical skills in each step of the POEM procedure. To achieve this mission, we did the following: (1) identified the skills required, (2) determined the training platforms available, (3) reviewed current literature, (4) studied expert case observations, (5) attended NOTES hands-on animal laboratories, and (6) performed a series of simulation, cadaver, and animal training sessions with trainees. Based on this experience and professional expert opinion, we determined the optimal inanimate and/or animate platform for each step of performing a POEM procedure.

Our aims for this project were two-fold:

- (1) To develop the foundational endoscopic skills and pique the interest in trainees for the future pursuit of advanced endoscopic training including POEM techniques at the fellowship level;
- (2) To advance the mastery of technology and techniques at our institution for the future treatment of achalasia and other esophageal motility disorders in humans.

Results

After following the method described above, our task force determined the optimal platform for acquiring the required

skills for each step of the POEM procedure, and our suggested training curriculum is outlined below.

Recommended training curriculum

Initial exposure and competency is gained during standard concentrated clinical rotations in flexible gastrointestinal endoscopy and training on GI Mentor II with gastroenterologists and general surgeons as instructors. To ensure a proper foundation of knowledge, skills, and abilities, each trainee is required to pass the FES written and manual skills examination. During follow-on rotations, trainees will gain clinical exposure to advanced endoscopic techniques such as endoscopic mucosal resection, endoscopic submucosal dissection, and submucosal tunneling endoscopic resection.

Complimentary non-clinical training includes a series of hands-on simulation labs and training sessions in porcine ex vivo and in vivo models. Tasks are practiced repeatedly in a low-stress environment without risk to patient. These sessions will emphasize the importance of achieving the skill before advancing to the next station.

These various training platforms include (Table 1):

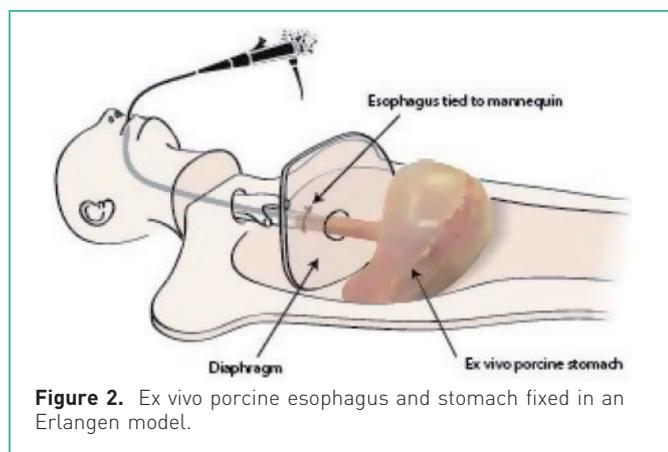
- (1) Simulation (inanimate) for FES and instrument familiarization
- (2) Porcine ex vivo (Fig. 2) organ model with esophagus and stomach as one unit for endoscopic submucosal dissection followed by submucosal endoscopy with mucosal flap including blunt balloon dissection
- (3) Porcine non-survival/survival: submucosal myotomy and mucosal flap closure followed by necropsy.

The steps of the POEM technique in a swine model are shown in Fig. 3.

After completion of the task, all ex vivo and in vivo specimens undergo gross examination to determine the adequacy of dissection and possible complications. Simulation (inanimate) and video format are used to teach management of intra-operative adverse events, including bleeding,

Table 1. Summary of the steps of the POEM procedure and recommended training platform.

Steps of the POEM procedure	Training platform
Flexible endoscopy/FES	Clinical rotation, simulation
1. Submucosal window	Ex vivo, non-survival/survival
2. Submucosal tunneling	Ex vivo, non-survival/survival
3. Myotomy	In vivo porcine
4. Submucosal window closure	Ex vivo, non-survival/survival



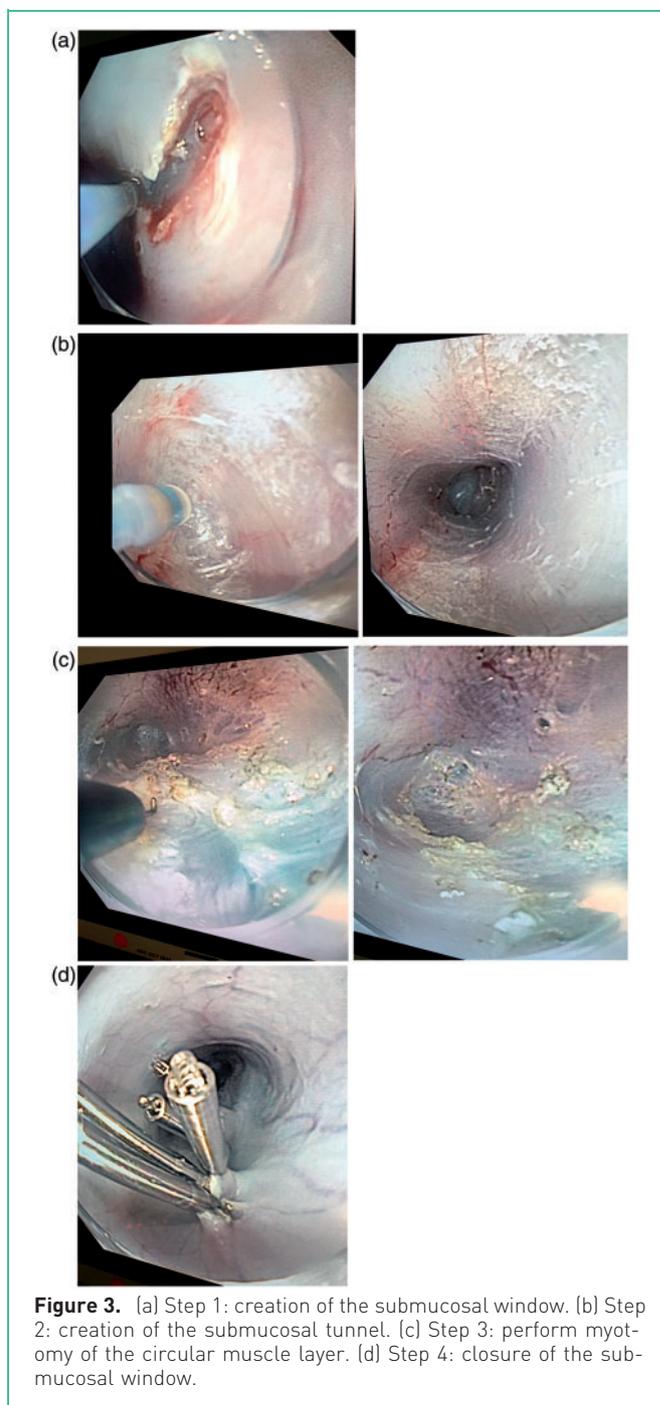
hemodynamic capnothorax, and full-thickness incision. These techniques in live porcine training sessions further refine the management of these procedural complications. These sessions serve to develop and refine delicate and advanced endoscopic techniques for eventual treatment of human disease.

Quality assurance

Appropriate measures of performance proficiency and improvement include: (1) length of procedure in minutes (LOP) divided by the length of myotomy (LOM) in centimeters or LOP/LOM and (2) number of clips placed. Complications that could lead to poor outcome include incidence of inadvertent mucosotomies, full-thickness perforation of the esophagus, and serosal perforation of the stomach.

Discussion

POEM is a technically challenging procedure that requires both advanced endoscopic skills and intimate knowledge of the esophagus layers as well as surrounding structures in the mediastinum. Before surgeons or interventional gastroenterologists start clinical cases, they typically undergo training on animal models, however this practice is not required. The rapid growth of this procedure calls for an established training program to efficiently optimize the quality of therapy. Surgeons who are proficient in advanced laparoscopic surgery will need to obtain the necessary flexible endoscopy skills. Similarly, advanced interventional endoscopists proficient in flexible endoscopy will need to be comfortable with the intramural anatomy of the LES or handling complications that have been reported with POEM, such as disorientation when entering the mediastinum, tension pneumothoraxes, or mediastinal hemorrhages. Case observations and, if progressing to human therapeutic treatment, proctoring of the initial cases by an expert offers an



additional hurdle to be overcome in establishing a successful program.

The learning curve has been evaluated and associated parameters reported in the literature. Kurian *et al.*¹⁷ found that the learning curve plateau was reached after 20 cases with a decreased LOP associated with improvement of skills as well as a decreased number of mucosal injuries as a marker of

improvement. Similarly, Martinek *et al.*¹⁸ found the learning curve plateau was reached after 18 clinical cases, and that increased experience was associated with a significant decrease in LOP and time needed for 1 cm of myotomy (LOP/LOM) and with a decrease in the mean number of clips required to close the mucosal incision. The most comprehensive analysis of the learning curve was published by Patel *et al.*¹⁹ They found a plateau was reached after 40 cases and mastery after 60 cases. Interestingly, procedure time was significantly decreased during each case number associated with increased experience.

Before embarking on advanced endoscopic procedures, a foundation of knowledge, skill, and abilities in flexible endoscopy is essential. The FES program includes an assessment section that has considerable published evidence of validity to support use in determining competency in flexible gastrointestinal endoscopy.²⁰⁻²² Beginning in 2018, the American Board of Surgery, as part of the Board's Flexible Endoscopy Curriculum, will require all candidates to have acquired certification in FES written and manual skills examinations.¹⁶ In general, the simulation lab is a non-clinical learning environment that provides a low-stress environment to practice tasks repetitively without risk to patients. This setting allows trainees to achieve a pre-determined learning benchmark or skill without a time limit, before progressing to more advanced tasks.

This concept, termed simulation-based mastery learning (SBML), has been applied across a wide range of health care education settings and demonstrates reliable translation of training effectiveness into the clinical arena. Several studies have been reported that reveal outcomes relevant to surgical education by improved performance by the operator, decreased errors committed intraoperatively and reduced operative time with laparoscopic cholecystectomy,²³⁻²⁵ improved cecal intubation rates for colonoscopy,²⁶ and decreased complications occurring postoperatively from laparoscopic inguinal hernia repair.²⁷ A recent meta-analysis of 82 studies applying SBML concepts showed a large effect on advancement of surgical skills compared with both standard clinical as well as non-mastery simulation-based instruction.²⁸ An SBML-based curriculum will provide a safe on-ramp for the trainee or non-expert to develop the necessary competency to pursue advanced gastrointestinal endoscopic procedures.

Currently, there are no guidelines that define how a practitioner should become competent in all the requirements of a POEM procedure.⁵ POEM requires specific knowledge, judgement, and technical skills that encompass both surgery and gastroenterology training and is rarely acquired by solo practitioners. The POEM literature describes practitioners'

competency as ranging from "experienced" to preclinical training with *ex vivo* and *in vivo* porcine models or human cadavers to clinical experience that includes NOTES cholecystectomy procedures using flexible endoscope.²⁹ As mastery of these endoscopic techniques demands a high degree of endoscopic technical acumen, we have established POEM training that can be incorporated into the general surgery residency program and utilizes our CEC, vivarium, and American College of Surgeons Accredited Education Institutes Simulation Center with an FES program. We build the endoscopic skills foundation for POEM at the resident and fellow training level and allow for the mastery of this technique for the future treatment of patients through collaboration between gastroenterology and general surgery. Specifically, management of complications will remain the domain of general surgery. Thus, it is important for surgeons to remain on the cutting edge of skills development and techniques as well as to remain experts in the field. Preclinical simulation-based training enhances knowledge, skills, patient safety practices, and confidence levels in providing safer patient care, and this should therefore be used as a strategy to facilitate clinical learning to improve patient outcomes. As this technique gains clinical validity, there will be more demand for delivery to appropriate patients and, therefore, necessary training with an established curriculum.

Based on our experience and understanding of the literature, we offer a suggested training curriculum for efficiency and skills retention that would require future validation to include an initial flexible endoscopy/FES clinical rotation followed by: (1) submucosal window *ex vivo* (minimum): efficiency 20 procedures with biannual refresher; (2) submucosal tunneling *ex vivo* (minimum): efficiency 20 procedures with quarterly refresher; (3) myotomy *in vivo* porcine (minimum): efficiency 20 procedures with quarterly refresher; (4) submucosal window closure *ex vivo* (minimum): efficiency 20 procedures with biannual refresher.

A major limitation of this article is the lack of scientific assessment and validation of our training curriculum. However, the intent of this project was to chronicle successful efforts to develop a training program and on-ramp for trainees and staff to develop the knowledge and skills required to develop a POEM program. We have the unique opportunity to have the components necessary to develop and recommend suitable platforms for preclinical training. Our goal is to entice current residents and fellows to pursue competency in this burgeoning field and provide a platform upon which other programs can build. Pursuing endoscopic surgery skills that combine advanced

interventional endoscopy, including endoscopic mucosal resection, endoscopic submucosal dissection, submucosal tunneling endoscopic resection, and NOTES will greatly benefit patients with achalasia and an expanding range of disorders.

Conclusion

POEM requires specific knowledge, judgement, and technical skills that encompass both surgery and gastroenterology training and are rarely acquired by solo practitioners. As this technique gains clinical validity, there will be more demand for delivery to appropriate patients and, therefore, necessary training. We provide training that optimizes the use of simulation and porcine platforms for trainee acquisition of the advanced surgical endoscopy skills necessary to perform POEM.

Conflict of interest

None declared.

Disclaimer

The views expressed herein are our own and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the US Government.

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