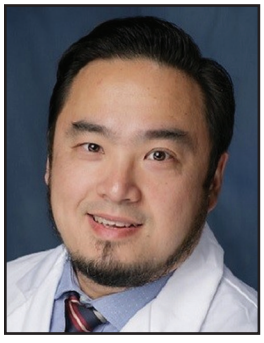
Douglas G. Adler MD, FACG, AGAF, FASGE, Series Editor

Introducing POEM in Your Institution: The Blueprint for Launching a New Program in the Endoscopy Suite



Dennis Yang

Peter V. Draganov

The birth of natural orifice transluminal endoscopic surgery (NOTES) in the early 2000s introduced the revolutionary concept of endoscopy beyond the restrictive walls of the gastrointestinal tract. The initial impetus was subsequently met with skepticism as these novel ideas were crippled by the rudimentary instruments and accessories available on the flexible endoscopic platforms. With advances in technology over recent years, there has been a resurgence of NOTES, as witnessed by the increasing number of interventional endoscopists expanding endoluminal applications outside the confines of the gastrointestinal tract.

Dennis Yang, MD Peter V. Draganov, MD
Division of Gastroenterology and Hepatology, Department of Medicine, University of Florida College of Medicine, Gainesville, FL

Per-oral endoscopic myotomy (POEM) is a prime example of a hybrid technique derived from NOTES and endoscopic submucosal dissection (ESD). Initially introduced as a concept by Pasricha and colleagues in 2007 and translated into clinical application by Inoue et al. in 2008, POEM is an endoscopic therapeutic procedure aimed at treating achalasia and spastic esophageal disorders.[1,2] While POEM was introduced and traditionally performed in the operating room (OR) setting, its well-documented safety and efficacy over the past 8 years has led to its natural acceptance by therapeutic endoscopists worldwide and consequently a growing interest in performing this procedure in the endoscopy suite.[3] This review aims to provide a practical guide of introducing POEM in the endoscopy suite from a gastroenterologist's perspective.

There are tangible and intangible benefits of adopting complex procedures such as POEM in the endoscopy unit. Advantages of the endoscopy unit

over OR include: (1) better ergonomics for endoscopic procedures, (2) readily available endoscopic equipment and accessories and (3) familiarity of the surrounding environment by the endoscopist and the assisting team. We had previously demonstrated that POEM can be safely and efficiently done in the endoscopy suite based on the experience of our first 52 consecutive patients.[4] Since then we have performed an additional 100 cases with excellent clinical response rates to further corroborate our initial results. The POEM program at our institution has become a crucial arm within the spectrum of a comprehensive motility program. That being said, starting a POEM program can be a challenging endeavor and careful planning is essential in order to ensure long-term success and stability. There are several key components that must be addressed prior to launching a POEM program in the endoscopy unit: (1) institutional support, (2) training, and (3) establishing a multi-disciplinary team.[5,6]

Institutional Support

Institutional endorsement on various fronts should be obtained prior to starting a POEM program. The potential advantage of a POEM program should be discussed, with an emphasis on its role in the establishment of a comprehensive motility program at your institution. While the approach may differ at every institution, one should actively seek and contact all stakeholders, which may include the department chair and division chief, the director of the endoscopy unit and other institutional administrators.

Institutional support in terms of protected time to train in an animal laboratory is highly desirable. In our institution, POEM trainees have full access to a well-equipped animal laboratory which facilitates hands-on experience prior to any attempts in humans. This approach permits a realistic exposure to the procedure while removing the high stakes of a clinical setting. Indeed, the international POEM survey on practice patterns demonstrated that most POEM practitioners underwent preclinical training in animal models before human cases.[7]

Institutional support must also be obtained to make infrastructural adjustments in the endoscopy unit to facilitate the introduction of POEM. As noted earlier, POEM has been traditionally performed in the OR, an environment conventionally perceived as more adept at managing complex procedures. For POEM to be safely performed, the endoscopy unit should possess

Figure 1. Mobile endoscopy cart containing all pertinent POEM-related equipment, devices and accessories.

amenities on par to what is available in the typical OR. Needless to say, full institutional support to obtain all necessary equipment and accessories is imperative. In our endoscopy suite, we store all POEM-related equipment and devices in a dedicated "POEM cart" (Figure 1). On this cart we do maintain inventory of the dedicated POEM devices such as the TT and the Hybrid knifes (Figure 2 and 3) but also devices for hemostasis, perforation closure, chest tube placement kits and peritoneal decompression needles. This approach expedites the movement of items in and out of the endoscopy room, permits quick and easy access to devices intra-procedurally, and also facilitates inventory control. Furthermore, it is our opinion that the endoscopy unit should have permanently stationed general anesthesia equipment as the POEM procedure requires general endotracheal anesthesia. This approach may be conducive for efficient anesthesia preoperative planning and set-up with reduced room turnover time.

Support from institutional administrators must also be sought on issues related to credentialing, scheduling, billing and coding, which again, may differ widely among centers. Prior to starting POEM, it is important to discuss the goals of such a program with

Figure 2. TT knife

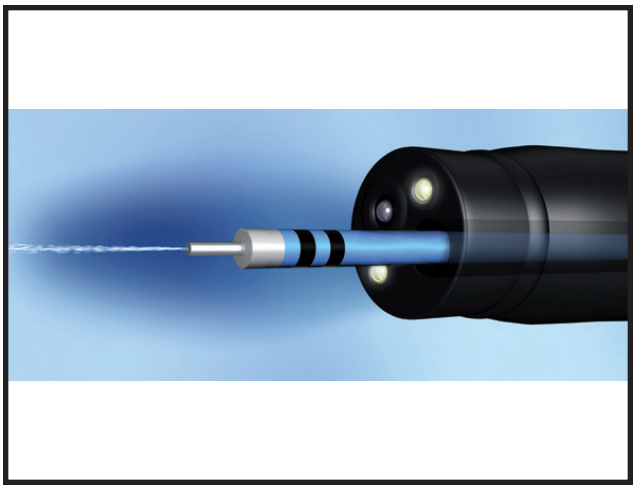


Figure 3. Hybrid knife

the credentialing/privileges committee. In the absence of standardized training guidelines, there should be a conjoint effort between POEM operators and the institution's committee to establish the necessary benchmarks that must be met prior to becoming credentialed for this novel procedure. In addition, we believe that a dedicated preprinted POEM procedure inform consent form should be utilized which describes in detail the procedure and potential complications both of which significantly defer from other endoscopic procedures. With regards to scheduling, based on multiple reports and our own experience, POEM cases can generally be completed within 60-90 minutes. Nonetheless, additional time allotment for set up and room turnover must be factored in order to avoid conflict with the scheduling of other cases in the endoscopy unit. In addition to scheduling, issues related to billing and coding should also be anticipated given the novelty of this endoscopic procedure. There is currently no procedural terminology (CPT) code for POEM. However, many centers apply an unlisted esophageal surgical code (CPT code 43499) billed at the relative value units equivalent of that of a Heller myotomy.[5,7] Discussion with stakeholders with regards to billing and coding should be undertaken prior to scheduling procedures in order to avoid subsequent denials from payers and ensure proper reimbursement.

Training

POEM is a technically complex hybrid procedure that demands advanced endoscopic skills, knowledge of both gastrointestinal (GI) intra and extra luminal anatomy, and a grasp on how to manage complications, including hemorrhage, tension pneumothoraxes, pneumomediastinum, and esophageal perforations. Developing a curriculum and defining a learning curve are complicated by background differences among operators and the relative low incidence of achalasia. Not surprisingly, there is a wide discrepancy in the learning curve plateau reported in the literature, ranging anywhere from 8 to 20 cases.[8-10] Since the principles of POEM are in line with ESD techniques, it appears reasonable that training should follow a similar approach to one previously described for ESD.[11] An in-depth understanding of the POEM principles, technical aspects and equipment will be a good starting point. A detailed discussion of this subject is beyond the scope of this manuscript, but multiple resources are available in the published literature. Two recent excellent reviews by the POEM pioneer Dr. Inoue highlight his experience and evolving technical concepts.[12,13]

In summary, initial exposure can be achieved by attending training courses and observing POEM performed by an expert operator. The trainee should be familiar with all the necessary equipment for POEM and also that required for the management of potential adverse events (i.e. hemostasis equipment, suturing devices, enteral stents). Hands-on training should start with explanted models which may be more cost-effective and allow assessment of the gross specimen following the procedure. Once trainees are comfortable with POEM on the explanted model, progressing to a live animal represents the next natural step. The porcine model is ideal given its long esophagus and anatomical resemblance to that of a human. Following preclinical hands-on training, we strongly recommend that trainees be proctored by an experienced operator, who can provide step-by-step supervision and guidance

through the initial cases. There are currently no standardized credentialing requisites for POEM and these are urgently needed as we continue to see the increasing adoption of this technique by interventional endoscopists worldwide.

The POEM Multidisciplinary Team

Establishing a multidisciplinary team is perhaps the most important element when initiating a POEM program. Before the introduction of POEM, a multidisciplinary team approach should be adopted to address various technical and clinical aspects of patient management from pre-procedure evaluation to post-procedural discharge:

1. Motility gastroenterologists play an invaluable role in the nonoperative evaluation of patients and should be involved in the multidisciplinary discussions of potential POEM candidates. Their investment in the POEM program not only aids with the identification and recruitment of patients, but it also facilitates longitudinal patient care and assessment of clinical outcomes post-POEM.

2. Participation of the surgical team is also an indispensable component when initiating the POEM program. The surgical team members should become familiar with the endoscopic aspects of the procedure. In turn, the POEM operator can benefit from the surgeons' perspective and knowledge of extraluminal anatomy. Surgical team members should be readily available to assist in case of a complex procedure or in the management of adverse events. A contingency plan should be well-outlined prior to initiating cases. Prearrangement of surgical back-up before POEM cases may need to be determined based on their accessibility at each respective institution.

3. Before a POEM program is initiated in the endoscopy unit, it is highly advisable to establish a well-defined anesthesia plan for these patients. Overall, the predetermined anesthesia protocol should include details regarding patient position, type of anesthesia, degree of paralysis, ventilation mode as well as clinical and technical parameters that should be monitored throughout the procedure (i.e. peak airway pressure, tidal volumes, end-tidal carbon dioxide, train-of-4 twitches, oxygen saturation). A standardized anesthesia protocol and clear communication among team members is key; particularly in those endoscopy units where coverage is performed by various different rotating anesthesia providers. Specifics regarding anesthesia management are further detailed in our experience with starting a POEM program in the endoscopy suite.[4]

4. The POEM nurses and technicians should be an integral part of the team. We strongly recommend that the POEM team practice together with explanted or live animal models in order to become familiar with the equipment, steps of the procedure, and management of adverse events. This approach will permit hands-on training and allow the POEM team identify and fine-tune areas for improvement. More importantly, it is an ideal scenario that will foster cohesiveness among team members prior to embarking on human cases.

5. Surveillance imaging post-POEM procedure is routinely performed in all patients to assess for adverse events (i.e. esophageal mucosal injury, leak, perforation). At our institution, we developed a novel computed tomography (CT) esophagram protocol in conjunction with our radiology department. In a prospective study of 84 patients, we demonstrated that numerous and dramatic post-procedural radiographic findings are captured with the CT esophagram; although most of these do not require any intervention.[14] Therefore, radiologists should be educated on the POEM procedure and the spectrum of post-procedure radiographic findings that can be encountered. Their awareness of these imaging findings will facilitate its clinical interpretation and prompt intervention when indicated. Imaging surveillance should be tailored according to local resources, expertise, and feasibility.

In summary, POEM has evolved into a recognized minimally invasive endoscopic approach for the

management of achalasia and certain esophageal spastic disorders. POEM can be safely performed by experienced interventional endoscopists in a well-equipped endoscopic suite. Nonetheless, starting a POEM program can be a challenging task. Institutional support, proper training, and developing a multidisciplinary team are the essential building blocks to ensure the successful initiation and establishment of a POEM program. ■

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