

Comprehensive analysis of efficacy and safety of peroral endoscopic myotomy performed by a gastroenterologist in the endoscopy unit: a single-center experience

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Background and Aims: The safety and efficacy of peroral endoscopic myotomy (POEM) when performed by gastroenterologists in the endoscopy unit are currently unknown. The aims of this study were to assess (1) the safety and efficacy of POEM in which all procedures were performed by 1 gastroenterologist in the endoscopy unit, and (2) the predictors of adverse events and nonresponse.

Methods: All consecutive patients who underwent POEM at 1 tertiary center were included. Clinical response was defined by a decrease in the Eckardt score to 3 or lower. Adverse events were graded according to the American Society for Gastrointestinal Endoscopy lexicon's severity grading system.

Results: A total of 60 consecutive patients underwent POEM in the endoscopy suite with a mean procedure length of 99 minutes. The mean length of submucosal tunnel was 14 cm and the mean myotomy length was 11 cm. The median length of hospital stay was 1 day. Among 52 patients with a mean follow-up period of 118 days (range 30-750), clinical response was observed in 48 patients (92.3%). There was a significant decrease in Eckardt score after POEM (8 vs 1.19, $P < .0001$). The mean lower esophageal sphincter pressure decreased significantly after POEM (29 mm Hg vs 11 mm Hg, $P < .0001$). A total of 10 adverse events occurred in 10 patients (16.7%): 7 rated as mild, 3 as moderate, and none as severe. Procedure length was the only predictor of adverse events ($P = .01$). pH impedance testing was completed in 25 patients, and 22 (88%) had abnormal acid exposure, but positive symptom correlation was present in only 6 patients. All patients with symptomatic reflux were successfully treated with proton pump inhibitors.

Conclusions: POEM can be effectively and safely performed by experienced gastroenterologists at a tertiary care endoscopy unit. Adverse events are infrequent, and most can be managed intraprocedurally. Post-POEM reflux is frequent but can be successfully managed medically. (*Gastrointest Endosc* 2016;83:117-25.)

Achalasia is an uncommon esophageal motility disorder defined traditionally by manometric criteria in the classic setting of dysphagia. It is an incurable disease characterized by incomplete or absent relaxation of the

lower esophageal sphincter (LES) and aperistalsis of the esophageal body.¹ The symptomatic consequence of this motility disorder is the classic presentation of dysphagia to solids and liquids associated with regurgitation of bland

Abbreviations: BT, botulinum toxin; LES, lower esophageal sphincter; LHM, laparoscopic Heller myotomy; PL, procedure length; OTSC, over-the-scope clip; PD, pneumatic dilation; POEM, peroral endoscopic myotomy; SED, spastic esophageal disorder.

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undigested food or saliva. Substernal chest pain during meals in the setting of dysphagia, weight loss, and even heartburn may be accompanying symptoms. The diagnosis of achalasia is made on the basis of the results of barium esophagography, esophageal manometry, and endoscopy.¹

Traditional endoscopic therapies of achalasia include botulinum toxin (BT) injection and pneumatic dilation (PD), whereas laparoscopic Heller myotomy (LHM) remains the conventional surgical therapy. The use of BT has fallen out of favor due to limited durability and the potential for increased risk of subsequent myotomy. A large portion of patients who undergo PD will relapse, mainly during the first year after treatment.² Perforation is the most important and most serious adverse event of PD, with an overall rate between 2% and 4%. As with PD, the efficacy of LHM decreases with longer follow-up periods. In addition, an antireflux operation is typically recommended with LHM due to a high risk of postoperative reflux. This is associated with increased postoperative dysphagia.²

Peroral endoscopic myotomy (POEM) is the latest breakthrough as a minimally invasive endoscopic therapy for achalasia.³⁻⁵ It has been widely accepted now as an efficacious therapy, especially in view of the limitations of the current alternative endoscopic and surgical options. Multiple studies from the United States, Asia, and Europe have shown that POEM is an effective and safe procedure for achalasia when performed by experienced operators.^{3,6-17} Nonetheless, POEM requires a demanding skill set that involves both advanced endoscopic skills and knowledge of surgical anatomy and adverse event management.^{6,18} Most published data come from procedures performed by surgeons in operating rooms.¹⁹ The safety and efficacy of POEM when performed by gastroenterologists in the endoscopy unit are currently unknown. The aims of the current study were to (1) study the safety and efficacy of POEM at 1 U.S. center where all procedures were performed by 1 gastroenterologist (M.A.K.) in the endoscopy unit, and (2) assess predictors of adverse events and nonresponse to POEM.

PATIENTS AND METHODS

This retrospective study was approved by the Institutional Review Board for Human Research and complied with Health Insurance Portability and Accountability Act (HIPAA) regulations at Johns Hopkins Hospital. All patients who underwent POEM for the treatment of achalasia or spastic esophageal disorders (SEDs) refractory to medical therapy between May 2011 and September 2014 were included. Diagnosis and disease subtype were based on manometric findings. Relevant clinical data (chest pain, Eckardt score), manometric data (type of achalasia or SED, LES pressure, proximal extent of hypertensive contractions) and endoscopic data (length of submucosal tunnel, length of myotomy, procedure time) were abstracted, and

preprocedural and postprocedural symptoms (eg, Eckardt scores), and manometry data were recorded. Clinical response was defined as improvement of symptoms and a decrease in Eckardt score to ≤ 3 . Results of esophageal acid exposure testing/pH impedance testing after POEM were reported when available. Adverse events were graded according to the American Society for Gastrointestinal Endoscopy lexicon's severity grading system.²⁰ Asymptomatic pneumoperitoneum that did not require drainage was not considered an adverse event because it is expected to occur during myotomy. Procedure length (PL) was calculated as the sum of length of times taken to perform mucosal incision and entry into the submucosal space, submucosal tunneling, endoscopic myotomy, and closure of mucosal entry. The time taken to clean the esophagus of food residue, to perform EndoFLIP (Crospon, Carlsbad, Calif) measurements, and to manage intraprocedural adverse events (other than bleeding) was excluded from PL calculation.

Operative technique

All procedures were performed by 1 interventional endoscopist in the endoscopy unit at Johns Hopkins Hospital with patients under general anesthesia. Initial training in POEM consisted of observing an expert perform 2 live POEM procedures followed by performing 10 POEM experiments in a swine model. POEM procedures were then performed as follows: a high-definition gastroscope (GIF-HQ190; Olympus, Tokyo, Japan), fitted with a straight cap with 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. One bottle of saline solution and a second bottle of saline solution mixed with indigo carmine were directly connected to the water jet channel via a stopcock. Separate foot paddles controlled each bottle.⁷

Carbon dioxide insufflation was used during the entire length of the procedures, and intravenous antibiotics were administered (2 g cefotetan). The lower esophageal sphincter (LES) was identified. A submucosal bleb was created in the mid-esophagus by using saline solution and 0.25% indigo carmine solution. A 1.5- to 2-cm longitudinal mucosal incision was made with a triangular tip knife (KD 640L; Olympus) by using the dry cut mode at 50 W on effect 3 (ERBE, Tübingen, Germany). The endoscope was then maneuvered into the submucosal space, and the triangular tip knife was used to dissect the submucosal fibers by using the spray coagulation mode at 50 W on effect 2 (ERBE). Repeated jet injection of saline solution mixed with indigo carmine was performed to enhance the demarcation between the submucosal layer and muscularis propria whenever the submucosal dissection plane became unclear (Fig. 1).

Care was taken with the orientation of the endoscope to ensure that the mucosal layer was not injured during dissection as the submucosal tunnel was extended, passing the LES and at least 2 cm into the proximal stomach. Subsequently, myotomy of the inner circular muscle bundles

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