



Long-term outcomes of per-oral endoscopic myotomy in patients with achalasia with a minimum follow-up of 2 years: an international multicenter study CME

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Background and Aims: Per-oral endoscopic myotomy (POEM) has shown promising safety and efficacy in short-term studies. However, long-term follow-up data are very limited. The aims of this study were to assess (1) clinical outcome of patients with a minimum post-POEM follow-up of 2 years and (2) factors associated with long-term clinical failure after POEM.

Methods: A retrospective chart review was performed that included all consecutive patients with achalasia who underwent POEM with a minimum follow-up of 2 years at 10 tertiary-care centers. Clinical response was defined by a decrease in Eckardt score to 3 or lower.

Results: A total of 205 patients (45.8% men; mean age, 49 years) were followed for a median of 31 months (interquartile range, 26-38 months). Of these, 81 patients (39.5%) had received previous treatment for achalasia before POEM. Clinical success was achieved in 98% (185/189), 98% (142/144), and 91% (187/205) of patients with follow-up within 6 months, at 12 months, and ≥ 24 months, respectively. Of 185 patients with clinical response at 6 months, 11 (6%) experienced recurrent symptoms at 2 years. History of previous pneumatic dilation was associated with long-term treatment failure (odds ratio, 3.41; 95% confidence interval, 1.25-9.23). Procedure-related adverse events occurred in 8.2% of patients and only 1 patient required surgical intervention. Abnormal esophageal acid exposure and reflux esophagitis were documented in 37.5% and 18% of patients, respectively. However, these rates are simply a reference number among a very selective group of patients.

Conclusions: POEM is safe and provides high initial clinical success and excellent long-term outcomes. Among patients with confirmed clinical response within 6 months, 6% had recurrent symptoms by 2 years. (Gastrointest Endosc 2017;85:927-33.)

Abbreviations: CI, confidence interval; IRP, integrated relaxation pressure; IQR, interquartile range; LES, lower esophageal sphincter; OR, odds ratio; POEM, per-oral endoscopic myotomy.

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See CME section; p. 1086.

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(footnotes continued on last page of article)

BACKGROUND

Achalasia is a rare esophageal motility disorder characterized by loss of enteric neurons resulting in impaired relaxation of the lower esophageal sphincter (LES) and absence of esophageal peristalsis.¹ Current treatment options for achalasia are directed at reduction in esophageal outflow obstruction at the LES, either by botulinum toxin injection, endoscopic pneumatic dilation, or laparoscopic Heller myotomy.

Per-oral endoscopic myotomy (POEM) was developed as a treatment of achalasia based on the technique of submucosal endoscopy and endoscopic myotomy. Numerous cases series have demonstrated that POEM is a safe and highly effective treatment for achalasia in short-term follow-up studies.²⁻⁶ However, data on long-term efficacy are very limited. A recent small retrospective study involving 80 patients from 3 tertiary centers revealed that success rates of POEM declined over time. The initial clinical success rate was 96% but dropped to 79% at 2-year follow-up.⁷ As achalasia is a chronic disease with a risk of recurrence of symptoms after treatment, long-term efficacy, rather than short-term data, is important for decision making surrounding the optimal therapeutic modalities. The aims of the current study were to describe a large, international, multicenter cohort of patients who underwent POEM for treatment of achalasia with a minimum of 2 years of follow-up and assess the factors associated with long-term clinical failure after POEM.

METHODS

This was a retrospective analysis of all consecutive patients with achalasia who underwent POEM between January 2009 and November 2013 with a minimum follow-up of 2 years ($n=238$) at 10 tertiary-care centers (3 in the USA, 4 in Europe, and 3 in Asia). Numbers of patients from the participating centers are shown in [Supplementary Table 1](#), available online at www.giejournal.org. The last date of follow-up was November 30, 2015. Diagnosis of achalasia was made by either conventional or high-resolution esophageal manometry. We excluded patients with diffuse esophageal spasm, jackhammer esophagus or nutcracker esophagus, and those with malignant or premalignant esophageal lesions. Patients who were lost to follow-up were also excluded ($n=33$). This study was approved by the institutional review board for human research at each institution.

Relevant clinical data were extracted including Eckardt scores, previous therapy for achalasia, manometric data (achalasia subtype according to Chicago classification if high-resolution manometry was performed, integrated relaxation pressure [IRP]), endoscopic data (length of myotomy, orientation of myotomy), procedure-related adverse events, post-procedural clinical symptoms, results

of upper endoscopy, and esophageal acid exposure testing/pH testing off proton-pump inhibitor therapy after POEM, when available. Extent of LES myotomy was recorded: full-thickness resection or selective myotomy of the inner circular muscle. If inadvertent splitting of longitudinal muscle fibers occurred during myotomy, despite attempted selective myotomy of the inner circular muscle, the myotomy was considered as full-thickness resection.

POEM operative technique

POEM procedures were performed as previously described.^{8,9} Either anterior or posterior myotomy was performed. In brief, a high-definition gastroscope, fitted with a transparent distal cap attachment, was used. Carbon dioxide insufflation was used throughout the procedures. Antibiotics were administered perioperatively. The LES was endoscopically identified. A submucosal bleb was created in the mid esophagus using saline solution mixed with indigo carmine. A 1.5 to 2 cm longitudinal mucosal incision was made with an endoscopic submucosal dissection knife (triangular tip [Olympus, Tokyo, Japan] or hybrid knife [ERBE, Tübingen, Germany]). An electrogenerator (ERBE, Tübingen, Germany) was used. The submucosal space was dissected and the submucosal tunnel was extended until passing the LES and at least 2 cm into the proximal stomach. Subsequently, myotomy of the muscle bundles was performed starting 2 cm distal to the mucosal entry point and 2 to 3 cm into the gastric cardia. Mucosal entry was then closed using endoscopic clips.

Postoperative care and clinical follow-up

All patients were admitted for hospital observation. An esophagram or CT esophagram was obtained on the following day. If no extra-esophageal leakage was observed, an oral diet was started. All patients have been continually followed by in-person clinic visits and telephone interviews. Follow-up protocols varied among different centers. Overall, patients were called for follow-up at 1 to 6 months, 12 months, and 24 months. Post-POEM upper endoscopy and pH studies were obtained according to each center's follow-up protocol.

Definition

Symptom scores were assessed using the Eckardt score.¹⁰ Clinical response was defined by decrease in Eckardt score to 3 or lower. Initial and late clinical outcomes were determined according to clinical response at 6 months and at least 2 years follow-up, respectively. An abnormal pH study was defined as DeMeester score >14.72 .¹¹ The severity of esophagitis was classified into 4 grades according to the Los Angeles Classification.¹² Duration of follow-up was defined as the time from the POEM procedure to last contact with the patient.

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