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ABSTRACT

Background/aims: Per-oral endoscopic myotomy (POEM) is a new minimally invasive technique to treat achalasia.

Methods: We performed a review of the literature of POEM with a special focus on technical details and the results obtained with this technique in patients with achalasia and other esophageal motility disorders.

Results: Thousands of POEM procedures have been performed worldwide since its introduction in 2008. The procedure is based on the creation of a mucosal entry point in the proximal esophagus to reach the cardia through a submucosal tunnel and then perform a myotomy of the muscular layers of the cardia, esophagogastric junction and distal esophagus, as performed in a Heller myotomy. The clinical remission rate ranges from 82 to 100%. Although no randomized studies exist and available data are from single-center studies, no differences have been found between laparoscopic Heller myotomy (LHM) and POEM in terms of perioperative outcomes, short-term outcomes (12 months) and long-term outcomes (up to three years). Procedure time and length...
of hospital stay were lower for POEM. Post-POEM reflux is a concern, and controversial data have been reported compared to LHM. The technique is safe, with no reported deaths related to the procedure and an adverse event rate comparable to surgery. Potential complications include bleeding, perforation, aspiration and insufflation-related adverse events. Thus, this is a complex technique that needs specific training even in expert hands. The indication for this procedure is widening and other motor hypercontractile esophageal disorders have been treated by POEM with promising results. POEM can be performed in complicated situations such as in pediatric patients, sigmoid achalasia or after failure of previous treatments.

**Conclusions:** POEM is an effective treatment for achalasia and is a promising tool for other motor esophageal disorders. It is a safe procedure but, due to its technical difficulty and possible associated complications, the procedure should be performed in referral centers by trained endoscopists.

**Key words:** Per-oral endoscopic myotomy. Heller myotomy. Achalasia.

**INTRODUCTION**

Achalasia is an esophageal motility disorder characterized by an incomplete or absent lower esophageal sphincter relaxation associated with an abnormal peristalsis in response to swallowing. Classic treatment of achalasia aims to diminish the lower esophageal sphincter pressure, and different approaches have been used, including pharmacological therapy, endoscopic injection of botulinum toxin or pneumatic dilation and surgical myotomy.

Per-oral endoscopic myotomy (POEM) is an innovative, minimally invasive endoscopic treatment for achalasia first described by Inoue et al. (1) in 2008, after the preclinical description by Pasricha et al. in an animal model (2). Since its introduction, thousands of POEM procedures have been performed and indications have been extended to include the three types of achalasia and other spastic esophageal motility disorders.

There is no standard technique adopted by all centers and even the peri-procedural management varies from one center to another. Although good outcomes and excellent efficacy and safety are commonly reported, the rates of clinical success and
adverse events vary among centers. We present the technical aspects of this new technique and review the outcome, safety and results according to published data.

INDICATIONS
The main indication for POEM is achalasia. However, due to its intraluminal route, which allows the length, position and direction of the myotomy to be chosen, its indications are widening. Esophagogastric junction (EGJ) outflow obstruction, diffuse esophageal spasm, jackhammer esophagus, nutcracker esophagus and failed surgical or endoscopic cases have been successfully treated with POEM (3-7). Nonetheless, improvement in chest pain and dysphagia in hypercontractile disorders after POEM seems to be less evident compared to symptom relief in patients suffering from achalasia type I and II.

Table 1 shows some accepted contraindications to POEM according to the responses to an international survey about the procedure (IPOEMS) from experts (8).

PRE-OPERATIVE EVALUATION
Although some centers perform a barium esophagogram in order to study the dynamics of the esophagus such as the site of abnormal contractions, simultaneous contractions and barium accumulation (9), esophageal manometry is the gold standard to determine esophageal motility and it should be always performed to confirm the diagnosis and to define the best therapeutic approach (10). It can also be used to evaluate response to treatment. High-resolution manometry represents an unquestionable advance in esophageal motility assessment, allowing for a better characterization of esophageal disorders (11). The Chicago classification should be used to determine the type of esophageal motor disease (12). Obviously, previous treatments for achalasia and patient comorbidities should be identified in order to select good candidates for this procedure. Preoperative evaluation including ASA assessment by an anesthesiologist is advisable in order to prevent intraoperative adverse events. Some precautions must be taken, for example, achalasia patients are at increased risk of aspiration during intubation due to the presence of esophageal
content. The anesthesiologist should be aware of this condition and airway protection methods should be routinely used.

POEM TECHNIQUE
Many centers perform an esophagostroduodenoscopy (EGD) one to three days before the procedure in order to remove any residual material from the esophagus. However, fasting for at least 24 hours should be recommended before the procedure. POEM is performed under general anesthesia with airway intubation. There is no evidence in support of using either the left lateral or supine position; however, some experts recommend the supine position as it results in a more neutral position for the endoscope, thus minimizing the tension in the mucosal flap, and diminishes the angulations in the sigmoid esophagus (13). Broad-spectrum intravenous antibiotics are given before the procedure.

A forward-viewing endoscope with CO₂ insufflation is used. A transparent plastic cap is attached to the tip of the endoscope. Before beginning the procedure, the gastroesophageal junction (GEJ) must be identified and its distance to the incisors should be determined. The anatomical landmarks such as the upper and lower esophageal sphincters, spine, trachea, left main bronchus and the aortic arch help to orient the operator during the procedure. Subsequently, the procedure is carried out as follows.

Mucosotomy
The site of submucosal entry is chosen between 10 and 15 cm proximal to the GEJ. Two different approaches have been proposed: the right-anterior orientation (11-2 o'clock) method, which is the most commonly used procedure (used by Inoue in his first 500 hundred cases) (1,14), and the posterolateral orientation (5 o’clock) approach (8). There is no evidence to define the best approach, although some practitioners think that the posterior method is more effective to reduce dysphagia and the anterior path may reduce reflux after POEM. Injection of approximately 10 cc of saline solution stained with indigo carmine is used to create a bleb in the mucosa (Fig. 1A). Subsequently, a 2 cm longitudinal incision of the mucosa (mucosotomy) is performed
with a cutting current to expose the submucosal space (13) with the following parameters: dry cut mode 50 W, effect 3 (9) or with the following parameters if the ERBE300D is used: endocut 1, effect 1, duration 1, interval 3 (13).

**Submucosal tunneling**

A technique similar to endoscopic submucosal dissection is used to create a submucosal tunnel from the esophagus to 2-3 cm beyond the EGJ (Fig. 1B). Different devices and techniques have been described. The T-Type Hybrid Knife (ERBE, Tübingen, Germany) showed (16) a shorter procedure time, a lower bleeding rate and less frequent use of coagulation forceps to control bleeding compared to the most preferred Triangle-Tip Knife (Olympus Medical Systems, Tokyo, Japan) in a head to head prospective study. Other new devices such as the water-jet assisted triangle-tip knife have been developed to reduce procedure time (17). Experts recommend maintaining the dissection in proximity to the muscular layer to avoid injury of the mucosa and keeping the circular muscle bundles perpendicular to the endoscope to ensure progression in the desired direction (13). Some indicators to confirm that the GEJ has been reached have been described. These include the narrowing of the submucosal space as well as the presence of an increased vascularity with “spindle” shaped veins and the visualization of a blue hue on intraluminal inspection of the mucosa of the gastric cardia. The previous endoscopic measurements can be used and other anatomical changes should be checked, such as the presence of aberrant longitudinal muscle bundles at the GEJ, the presence of large perforating vessels in the cardia and palisading vessels at the distal end of the esophagus. For this step, soft coagulation mode 40-60 W, effect 1-2 is recommended (9,13,15).

**Myotomy**

Most endoscopists perform a selective dissection of the circular muscle alone, in a proximal to distal direction, starting at 2-3 cm above the mucosal entry. However, some centers use a distal to proximal direction and dissect both circular and longitudinal muscle layers, especially at the level of the lower esophageal sphincter (8,15) (Fig. 1C). One retrospective study found no differences in efficacy, GERD or adverse events, although the procedural time was shorter in the full thickness
myotomy group (18). To avoid massive bleeding from the intramuscular vessels, spray coagulation current is recommended (40-60 W, effect 1-2). With regard to the Heller myotomy, the dissection in POEM is continued to 2-3 cm within the cardia for a total length of 8-10 cm, including the esophageal myotomy, lower esophageal sphincter and cardia myotomy. To ensure an adequate length of the myotomy, identification of the anatomical landmarks of the GEJ inside the tunnel is useful. The easy passage of the endoscope into the lumen without difficulty at the level of the lower esophageal sphincter (LES) is consistent with a good myotomy, and the integrity of the mucosa must be verified at the same time. However, Grimes et al. have recently proposed the use of a second ultra-slim endoscope to observe the transillumination at the end of the tunnel in the cardia from the stomach (19,20).

**Closure of the mucosal entry**

To avoid a potential leakage of luminal content into the tunnel and mediastinum, the entry is closed with hemostatic clips (Fig. 1D). Alternative methods of closure include endoscopic sutures (Overstitch, Apollo, Austin, TX), over-the-scope clips (Ovesco, Tübingen, Germany) or fully covered metal stents. Some authors use a prophylactic antibiotic solution which is sprayed into the tunnel before closing the mucosa. The clips must be deployed symmetrically and the first clip must be deployed beyond the distal margin of the incision in order to create a symmetrical fold that will allow an easier closure which requires less clips (13), which diminishes the risk of pocket formation and tunnel infection (21).

Patients are hospitalized after the procedure. Twenty-four hours of fasting is recommended before starting a clear water intake on day 1 provided that the esophagogram with gastrografin (Bracco Diagnostics Inc., Princeton, NJ) and/or EGD confirm the absence of leaks and ischemic or hemorrhagic complications. On day 2, a soft diet can be started and maintained for some days and then a regular diet can be safely introduced. During hospitalization, intravenous antibiotics are administrated and then oral medication given (if the patient is discharged) until completion of a ten-day treatment. The postoperative hospitalization length after POEM is $3.6 \pm 0.38$ days.
ADVERSE EVENTS IN POEM

Table 2 summarizes adverse events (AE) related to POEM, their frequencies and management. CO₂ insufflation is mandatory. Ventilation with positive pressure helps to avoid complications related to gas insufflation such as a pneumothorax, pneumomediastinum, pneumoperitoneum, subcutaneous emphysema, etc. Even if these measures are taken, the escape of gas into the mediastinum, thorax and abdomen is common, and CO₂ flow should be set as low as possible and the operator should avoid excessive insufflation especially while in the tunnel.

Bleeding during the creation of the tunnel is frequent and can usually be managed with endoscopic treatment. Pulsed irrigation, gentle suction and tamponade might help to recover visibility, and the bleeding vessel can be selectively coagulated with coagulation forceps (13) or with the tip of the knife. Bleeding is more frequent at the GEJ and cardia.

Mucosal perforation during tunneling must be avoided and perforations should be immediately closed with clips to prevent leakage of esophageal contents into the tunnel. If a full-thickness myotomy is present at the level of the mucosal entry, the use of over-the-scope-clips has been proposed to ensure a complete and safer closure (22).

Postoperative adverse events include mediastinitis caused by esophageal leakage. This is an uncommon but major complication of POEM and it often requires surgical drainage. Delayed hemorrhage incidence is low (16,23,24) and can be managed conservatively in most cases by observation and transfusion. Some authors advocate the use of Blakemore-Sengstaken tubes for EGD management (25) or tamponade (25,26) but others are concerned about the risk of continuous bleeding into the mediastinum or peritoneum when a complete myotomy has been performed, as there is no barrier to prevent this internal hemorrhage (13). Finally, no procedure-related deaths have been reported to date.

OUTCOMES AND EFFICACY OF POEM

Global outcomes

POEM has shown its efficacy in both symptom relief and improvement of esophageal motility. Clinical remission after POEM ranges from 82 to 100% (27,28). Table 3 shows
the results from the largest POEM studies. There are two meta-analysis (with more than 1,000 patients each) that demonstrate the short-term (one year) efficacy of POEM with both a reduction in the Eckardt score and LES pressure (29,30). Another meta-analysis evaluating 16 prospective and retrospective studies conducted between 2010 and 2013 with a total number of 551 patients suffering from achalasia found a technical and clinical success in 97% (95% CI: 94-98%) and 93% (95% CI: 90-95%) of cases respectively, after a median follow-up of six months (range 3-12). Major adverse events requiring surgical or medical intervention occurred in 14% of cases and only one patient needed post-POEM surgery (31).

Finally, a more recent meta-analysis by Akintoye et al. (32) evaluated the results from 36 studies which included 2,373 patients. An Eckardt score of 3 or less was achieved in 98% of cases (95% CI: 97-100%), and symptoms relief was maintained at 1.6 and 12 months after treatment. They also found a significant decrease in the lower esophageal sphincter pressure and integrated relaxation pressure from 33 ± 1.7 and 30 ± 1.4 mmHg to 14 ± 1.2 and 13 ± 1.6 mmHg respectively within six months of the procedure (p < 0.05). Perioperative adverse events were frequent; these included mucosal injury (4.8%), esophageal perforation (0.2%), bleeding requiring intervention (0.2%), subcutaneous emphysema (7.5%), pneumothorax (1.2%), pleural effusion (1.2%), pneumomediastinum (1.1%) and pneumoperitoneum (6.8%).

**Long-term follow-up**

One cohort of 500 patients with at least three years of follow-up showed that the overall success was maintained over time (88.5%) in this study (14).

**POEM versus laparoscopic Heller myotomy**

There are only a few studies comparing POEM with historical laparoscopic Heller myotomy (LHM) controls (33-36). The results for both procedures were similar with regard to complications and clinical success rates; however, operative times, blood loss, postoperative pain, hospital stay and return to normal activity tended to be better after POEM. A meta-analysis by Marano et al. (37) investigated the efficacy and safety of POEM compared with LHM in 486 patients (196 in the POEM group and 290
in the LHM group). Outcomes were comparable with no significant differences in both groups with regard to clinical improvement, operative time, post-operative pain scores, analgesic requirements and complications. The length of hospital stay was significantly shorter for POEM. Remarkably, the quality of most of the studies included in this meta-analysis was poor due to the fact that the patients were not randomized, the patients included were treatment naive or non-responders, and the follow-up was less than a year in all the cases.

Type III achalasia might be especially challenging due to its spastic nature and low incidence. Kumbhari et al. (38) compared the outcomes after POEM and LHM in patients with type III achalasia in a retrospective multicenter study. They found that the clinical response was more frequent in the POEM cohort (98% vs 80.8%; p = 0.01), with a shorter procedure time for POEM even if the myotomy length was longer. The author hypothesizes that a longer myotomy with POEM may result in improved clinical outcome in this type of achalasia where spastic contractions are found.

The current treatment for other hypercontractile esophageal motility disorders is challenging due to the inefficacy of pharmacological and endoscopic treatment, with failure rates above 70% (39). The potential need of a thoracoscopic approach to perform an extended surgical myotomy and its suboptimal success rates (69-86%) make it important to find new treatments for these entities. POEM has many potential benefits, such as the possibility to choose the length or the orientation of the myotomy in order to treat these disorders (40-42). Indeed, several case-reports and small series have been performed where POEM has shown good results in treating DES, jackhammer esophagus and nutcracker esophagus (4-6,43-45). In contrast, Sharata et al. found that complete dysphagia relief was better in achalasia patients than in other hypercontractile disorders (46/47 patients; 97% vs 17/24 patients; 70%) (7).

**Post-POEM gastroesophageal reflux**

The rate of reflux after POEM ranges from 5.7% to more than 50% depending on the series (46-49). Objective reflux confirmed on endoscopy or pH study is estimated to be between 20-46%; these rates are similar rates to LHM (33,50,51). The meta-analysis of
Akintoye et al. (32) showed rates of symptomatic reflux, esophagitis on endoscopy and abnormal acid exposure during 24h of pH monitoring of 8.5% (CI 95%: 4.9-13%), 13% (CI 95%: 5-23%) and 47% (CI 95%: 21-74%), respectively. Two meta-analyses found no statistically significant differences between reflux rates after LHM and POEM (29,31). However, there is a concern about POEM and GERD due to the absence of an anti-reflux associated procedure in POEM compared with the systematic fundoplication during LHM. It is thought that many asymptomatic patients after POEM may have abnormal acid exposure. Familiari et al. (52) and Jones et al. (53) described the absence of a correlation between GERD symptoms and acid exposure after POEM. In the former study, acid exposure was elevated in 50% of patients, 20% had esophagitis (including 5.8% of grade C or D esophagitis) whereas only 18% complained about GERD symptoms.

There is no evidence-based recommendation with regard to handling this situation after POEM, but experts use two strategies. These are routine proton pump inhibitor (PPI) use after treatment or endoscopic follow-up in order to rule out the development of significant esophagitis before starting PPI therapy (54).

**Special situations and future perspectives**

POEM has been successfully used in patients with sigmoid-type 2 achalasia where the lumen of the tortuous esophagus turns upwards, a situation that was initially considered to be a contraindication for POEM (55-57). However, more technical difficulties may appear and some authors recommend posterior or bilateral POEM to increase the rates of success, although further experience and evidence is needed (56). Failure after surgical myotomy is another difficult clinical situation that may be solved with POEM. Although uncommon, recurrence after surgery due to incomplete myotomy, scarring, fibrosis, tight fundoplication or progression of disease is a challenging scenario if a redo Heller myotomy is attempted. In contrast, POEM has shown good results in this situation where the myotomy is performed at the opposite axis to the previous myotomy in order to avoid scars and fibrosis. No complications were reported and the rates of success reached 90% (3,58).
In the case of a failed POEM, re-performing the procedure in the opposite direction is recommended. However, it is important to note that LHM is an option, as POEM does not involve adjacent tissues surrounding the esophagus (59).

Pediatric achalasia patients have also been treated with POEM in some centers with a minimum age of three years (60,61). There are several series in pediatric patients that show similar results and safety to that in adult patients (62,63).

As a result of the acceptance of POEM in the treatment of achalasia, a similar tunneling approach has recently been proposed as an alternative to surgical pyloroplasty to treat dysfunctions of the pylorus and impaired gastric emptying. Peroral pylorotomy (POP) would be less invasive than surgery and would have a more durable effect than other endoscopic treatments such as pyloric dilation, botulinium toxin injection or stent placement. Technically, POP is based on the same principles of POEM with the creation of a submucosal tunnel followed by the division of the pyloric sphincter muscles. Since the first two case reports describing the technique in patients with refractory gastroparesia, other prospective series and case reports have been published showing promising results (64-68).

CONCLUSIONS

POEM is an effective and safe treatment for achalasia. There are several technical issues that need to be clarified, including the optimal length and location of the myotomy. The management of periprocedural aspects or complications such as post-POEM reflux should be standardized. More evidence is required to establish the role of POEM in the management of achalasia, especially in relation to LHM.

REFERENCES


### Table 1. Per-oral endoscopic myotomy contraindications

<table>
<thead>
<tr>
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<tr>
<td>Sever pulmonary disease</td>
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<td>Mucosal resection</td>
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<tr>
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<td>Delayed mucosal barrier failure</td>
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<td>Abnormal 24h pH study</td>
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IP: Intra-procedure adverse event; D: Delayed adverse event.
Table 3. Principal studies: per-oral endoscopic myotomy

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<tr>
<th>Author</th>
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<th>N</th>
<th>Procedure time (min)</th>
<th>Myotomy length (cm)</th>
<th>Technical success (%)</th>
<th>Clinical success (%)</th>
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<th>Follow-up (months)</th>
<th>Complications (n)</th>
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<td>50</td>
<td>90</td>
<td>14</td>
<td>100</td>
<td>91.3/91/88.5</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

ES: Eckardt score; GERD: Gastroesophageal reflux.
Fig. 1. Different steps during peroral endoscopic myotomy (POEM). A. Submucosal injection. B. Submucosal tunneling in the esophagus. C. Myotomy. D. Closure of the submucosal entry with clips.