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Per oral endoscopic myotomy vs. laparoscopic Heller myotomy, does gastric extension length matter?

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Abstract
Objective To report our experience in POEM vs. LHM, with particular focus on myotomy extension.
Background POEM has been adopted worldwide as a treatment for achalasia. While resolution of dysphagia is above 90%, postoperative reflux ranges from 10 to 57%. Myotomy length has been a controversial topic.
Methods Thirty-five cases of POEM were prospectively analyzed and compared retrospectively to the last 35 patients that underwent LHM, from December 2010 to August 2016. Mean follow-up was 10 months (6/32) for POEM and 20 months (6/68) for LHM. All patients with LHM had a myotomy extension ≥3 cm on the gastric side. In POEM cases, extension was defined by direct vision (Hill type II) and never exceeded 2 cm.
Results Follow-up was completed in 100% of patients. Efficacy (ES ≤ 3) was 33/35 (94.2%) for POEM and 32/35 (91.4%) for LHM in a short-term follow-up ($p = 1.000$) and 31/35 (88.6%) and 27/35 (77.1%), respectively, in a long-term follow-up ($p = 1.000$), with average ES drop from 9 to 1.2 ($p = 0.0001$) in POEM vs. 9.2 to 1.3 ($p = 0.0001$) in LHM. Major Postoperative complications occurred in 1 patient (leak) for LHM and 1 patient (massive capnothorax) in POEM. Hospital stay was shorter for POEM than for LHM (1.3 vs. 2.1, respectively) ($p = 0.0001$). Symptomatic reflux cases included 7/35 POEM (20%) vs. 6/35 LHM (17.1%) ($p = 0.4620$). Esophagitis signs in endoscopy appeared in 1/21 POEM (4.7%) vs. 1/22 LHM (4.5%) ($p = 1.000$). Patients requiring PPI included 8/35 POEM (22.8%) vs. 7/35 LHM (20%) ($p = 0.6642$). Further treatment (endoscopic dilation) was performed in 10/35 POEM (28.5%) vs. 8/35 LHM (22.8%).
Conclusions A shorter myotomy on the gastric side in POEM may contribute to an acceptable reflux rate with comparable relief of dysphagia. Although our follow-up for POEM is shorter than for LHM, the trends are promising and warrant future prospective studies to address this topic.

Keywords Achalasia · Endoscopy · Endoscopic myotomy · Laparoscopic heller myotomy · Gastric myotomy extension · POEM

Achalasia is an idiopathic disease of esophageal physiology, characterized by the loss of inhibitory innervation of the lower esophageal sphincter (LES) resulting in inadequate relaxation upon swallowing, higher baseline pressures of the LES and the absence of esophageal peristalsis.

These pathological modifications explain the clinical presentation that includes progressively severe dysphagia for solids and liquids, regurgitation, aspiration, chest pain, weight loss, and eventually an irreversible dilatation of the esophageal body.

Current primary treatment options include laparoscopic surgical myotomy across the LES (Heller myotomy) and endoscopic pneumatic dilation [1]. However, substantial evidence suggests that LHM provides the most durable symptom relief, without the need for repeat interventions, as it is often necessary with endoscopic dilation [2, 3].

Recently, peroral endoscopic myotomy (POEM) has gained wide acceptance worldwide as a minimally invasive

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treatment for achalasia [4]. It joins the concept of natural orifice transluminal endoscopic surgery and expands upon techniques used in endoscopic submucosal dissection in order to achieve the myotomy. POEM shares the advantages of both, endoscopic (no skin incisions, decreased pain, less blood loss, low morbidity) [5], and laparoscopic procedures (durable surgical myotomy and single procedure).

Since the first clinical report by Dr. Haru Inoue and col. in their landmark paper in 2010 [4], several papers have reported perioperative safety and excellent short-term outcomes in terms of symptom resolution. However, the main uncertainty of this procedure remains to be postoperative reflux disease. Most of the centers report excellent resolution of dysphagia, and the postoperative reflux varies substantially ranging from 10 to 57%. Only a few studies had compared POEM with the surgical standard of care LHM, in terms of reflux [6–8].

On the other hand, the myotomy length has been a controversial topic of debate for many years, with most of the academic groups accepting that an extension >3 cm was required to avoid recurrence of dysphagia [9]. The advent of POEM introduces a new paradigm where a shorter myotomy on the gastric side may provide equal relief of dysphagia with less postoperative reflux. We present here our initial experience with POEM, compared to a retrospective database of our last cases of LHM performed at a single tertiary care center in a nonrandomized fashion.

Methods

Seventy patients with manometric diagnosis of achalasia treated in a single tertiary referral center were included in the analysis. Thirty-five were elected to undergo POEM from March 2014 to August 2016, with or without previous treatment (endoscopic pneumatic dilation, LHM). These patients were compared to the last 35 patients of our LHM group that underwent the surgical procedure at the same institution by the same group of surgeons, and were enrolled in a clinical registry from December 2010 to August 2016. Both procedures were performed by the same group of operators.

Mean follow-up was 10 months (6/32) for POEM and 20 months (6/68) for LHM. All POEM cases until the time of data analysis were included, and so this series includes the initial learning curve.

Preoperative evaluation

Both groups were evaluated with a history of symptoms, physical examination, upper endoscopy, and high-resolution manometry (HRM), which were interpreted according to the Chicago Classificaion of esophageal pressure topography [10, 11]. Demographics data and Eckardt symptom score were also recorded (score measures; frequency of dysphagia, regurgitation and chest pain, and amount of weight loss, each on a scale of 0–3 resulting in a total scale of 0–12 with higher scores indicating more severe disease) [12, 13].

POEM operative technique

POEM was performed in a fashion similar to that described by Inoue and colleagues [4]. Performed under general anesthesia with endotracheal intubation, patients were positioned on supine with both arms at the side. An initial upper endoscopy was performed using a single-channel, high-definition flexible gastroscope (Fujinon 4400) with carbon dioxide (CO_2) insufflation; The esophagus and stomach were cleaned up and aspirated of any residual fluid. The endoscope was then fitted with a transparent dissecting cap, and the distance to gastroesophageal junction EGJ was measured. Approximately 10 ml of solution containing methylene blue was injected into the right lateral esophageal wall 14 cm proximal to the EGJ in order to lift the mucosal wall and create an entry into the submucosal space (Fig. 1a). A submucosal tunnel was then created with a combination of blunt dissection and electrocautery using the Hybridknife water jet system (ERBEJET 2 system; ERBE, USA), (Fig. 1b). The end tunnel was extended distal approximately 3 cm from the EGJ.

A selective myotomy of the circular muscle layer was then performed, beginning at around 3 cm below the mucosal opening in 5 h of the esophageal circumference (Fig. 1c). From the begining of the study the extension of the myotomy on the distal side was defined on two morphological findings, spontaneous opening of EGJ with no insufflation, and a visual sign in retroflexion comparable to a type II Hill valve [17]. Once those parameters were achieved, myotomy length was measured. The extension on the gastric side never exceeded 2 cm. Once those parameters were achieved, myotomy was extended one more centimtre on the gastric side for safety margins. The extension on the gastric side never exceeded 2 cm. All parameters that are normally used during endoscopy are influenced by observation bias. In order to limit that to the maximum, we made sure that measuring of myotomy length was performed with the endoscope marks and the edge of the overtube with no pressure on it. We used the Hill valve anatomy which is a clear published landmark, and we used evaluation of spontenous opening of LES without insufflation that could be clearly compared to the pre-myotomy assessment at the beginning of the procedure.

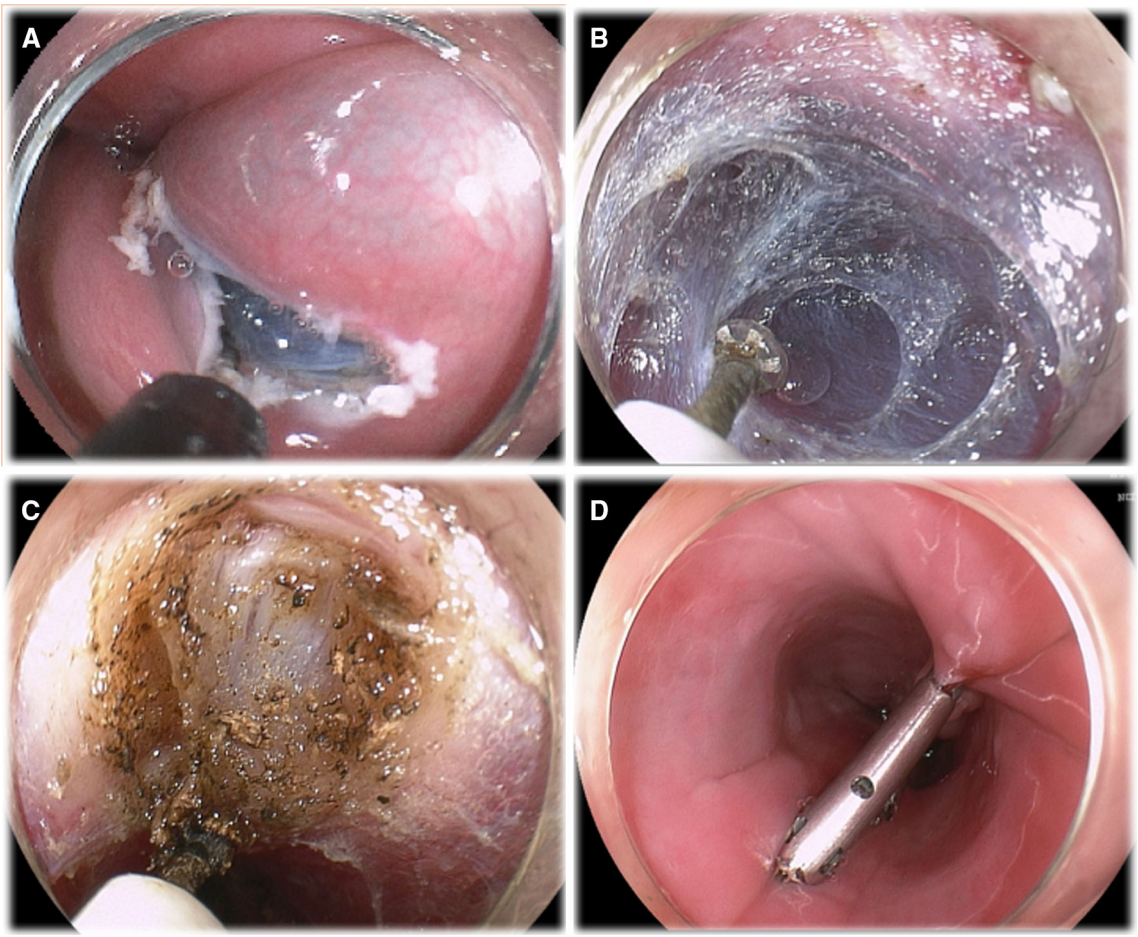

Fig. 1 POEM procedure: **a** Mucosal incision. **b** Tunnel creation. **c** Myotomy. **d** Mucosal clousure

Although observation bias cannot be fully discarded, we believe it was limited when combining these options. Mucosal entry was closed with endoscopic clips (Resolution clip, Boston Scietific), (Fig. 1d).

Postoperatively patients were extubated, kept hospitalized on the night of surgery, and received antiemetics and pain medication as needed. On the morning of postoperative day one, they were started on liquids, and discharged. A full liquid diet was maintained for 1 week and then gradually progressed to include soft and solid meals.

LHM operative technique

LHM combined with Dor fundoplication was performed in a standard fashion as previously described [14, 15]. Briefly, the phrenoesophageal ligament was divided, and the diaphragmatic crura was opened. The anterior mediastinal esophagus was dissected, and the short gastric vessels were divided to mobilize the fundus. The anterior gastric fat pad and anterior vagus nerve were dissected free from the stomach and esophagus, and a full-thickness myotomy was performed to at least 5 cm proximal and 3–4 cm distal to the EGJ (Fig. 2a), which was recognized by typical anatomical findings, as the periesophageal fat, changes of the muscle fibers, and the His angle. Finally, a Dor fundoplication was completed (Fig. 2b). There are no published prospective randomized trials that conclude if it is better a partial posterior versus anterior fundoplication in association to a Heller myotomy in patients with achalasia. Some groups feel that a posterior fundoplication is a better procedure as it keeps the edges of the myotomy separated, and it may be a more effective antireflux operation. Dor fundoplication does not have the need for posterior dissection, and it adds the advantage of covering the exposed mucosa.

Postoperatively, patients received antiemetics and pain medication as needed. They were allowed clear liquids on the morning of postoperative day one, as in the POEM group. Patients were typically discharged either that afternoon or the next morning according to their recovery.

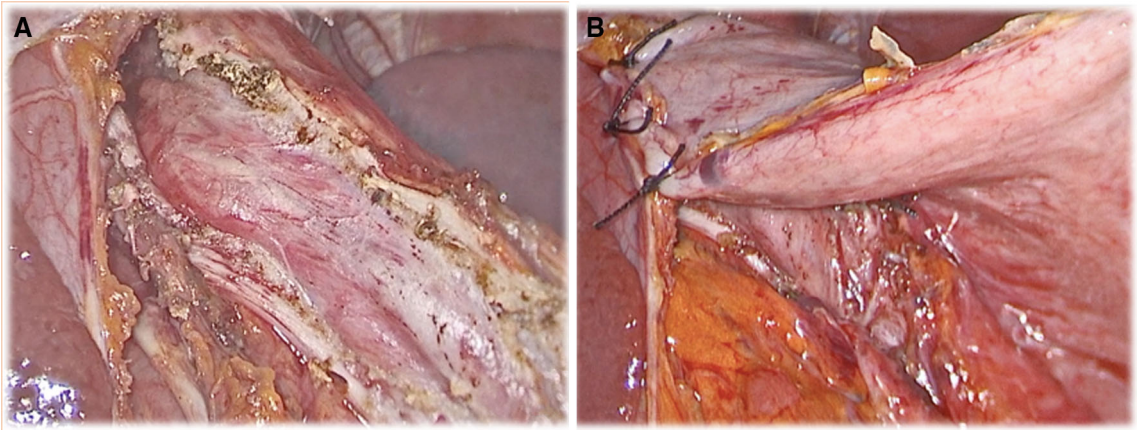

Fig. 2 Laparoscopic Heller myotomy: **a** Heller myotomy. **b** Dor funduplication

Perioperative data collection

Perioperative data collected included follow-up, clinical success measured by Eckardt score ($\leq$3 at the time of their last follow-up), symptomatic recurrence and further treatment, myotomy length, intraoperative and postoperative complications, as well as hospital length of stay.

Presence of symptomatic reflux measured by GERD-HRQL score. This questionnaire was developed and validated to measure changes of typical GERD symptoms such as in response to surgical or medical treatment. Heartburn Score is calculated by summing the individual scores to six questions. Worst heartburn symptoms =30. No heartburn symptoms =0. Scores of $\leq$12 indicate heartburn elimination [16]. Signs of esophagitis (measured by routine esophagogastroduodenoscopy at 6 months) and need for PPI intake.

Results

POEM and LHM were completed in 100%. Follow-up was completed in 70/70, 100%. Mean follow-up was 10 months (6/32) for POEM and 20 months (6/68) for LHM. The procedure was clinically successful in 33/35 patients (94.2%) for POEM and in 32/35 (91.4%) patients for LHM, in a short-term follow-up ($p = 1.000$). In a midterm follow-up (more than 6 months), success rates dropped to 31/35 (88.6%) for POEM, and 27/35 (77.1%) for LHM ($p = 1.000$). Among POEM patients, the ES dropped from 9 to 1.2 ($p = 0.0001$) and 9.2 to 1.3 ($p = 0.0001$) for LHM group. There was no mortality in any of the groups. Intraoperative full-thickness injury to the esophagus occurred in two cases in each group. In both groups, the injuries were diagnosed and treated during the procedure. One of the LHM perforations had a leak, well-controlled conservability, and without clinical sequela, none of them required reintervention. Postoperative complications occurred in one patient in POEM with massive capnothorax that was managed with conservative measures, and one patient for LHM that presented with a delayed leak due to mucosal thermal damage requiring reoperation (Table 1). Average hospital stay was significantly shorter for POEM than for LHM (1.3 vs. 2.1, respectively) ($p = 0.0001$).

Symptomatic reflux cases included 7/35 POEM (20%) vs. 6/35 LHM (17.1%) ($p = 0.4620$). Postoperative upper endoscopy was performed on 21 POEM and 22 LHM, esophagitis signs appeared in 1/21 POEM (4.7%) vs. 1/22 LHM (4.5%.) ($p = 1.000$), and there were no cases of esophagitis in preoperative endoscopies.

Patients requiring PPI included 8/35 POEM (22.8%) vs. 7/35 LHM (20%) ($p = 0.6642$). Symptomatic recurrence and further treatment (endoscopic dilatation) occurred in 10/35 POEM (28.6%) vs. 8/35 LHM (22.8%). In both groups, symptoms were successfully salvaged.

Gastroesophageal reflux disease

Gerd symptoms were usually evaluated in every single visit, and a GERD-HRQL was performed. In POEM group, seven patients were GERD symptomatic (GERD-HRQL $>$ 12), and only one of them had endoscopic signs of esophagitis (Grade A according to Los Angeles Classification). No reflux patient required additional antireflux procedure.

PPI were started immediately postoperatively and discontinued after 30 days. GERD symptomatic patients with GERD-HRQL $>$12 or esophagitis were treated on daily medication. Mild and occasional symptoms were treated with medication on demand. Nevertheless, only two of them had heavy symptoms requiring daily medications. Symptoms substantially improved and were well controlled in all cases. In LHM group, six cases complained of reflux, three of them needed daily PPI medication, and only one

Table 1 Patients outcomes

	Poem	Heller
Demographic data		
Sex (m–N)	15/35	20/35
Age (Av)	50	45
Results		
Follow-up patients	35/35 (100%)	35/35 (100%)
ES-Pre/Post op	9/1.2	9.2/1.3
HS (Average days)	1,3	2,1
Reflux symtpoms	7/35 (20%)	6/35 (17.1%)
PPI (*n*)	8/35 (22.8%)	7/35 (20%)
Esophagitis (*n*)	1/21 (4.7%)	1/22 (4.5%)
Major postoperative complications (*n*)	1/35 (2.8%) (Massive capnothorax)	1/35 (2.8%) (Leak)
Follow-up months mean (range)	10 (6–32)	20 (6–68)
Further treatment	10 (28.5%)	8 (22.8%)

case had grade A esophagitis. Esophagitis completely healed in all the patients.

Discussion

This study adds to the existing evidence that POEM is a feasible and safe procedure for creating an endoscopic myotomy in patients with achalasia, combining the obvious benefits of a minimally invasive endoscopic therapy with the efficacy of a surgical myotomy [17]. We confirm the good outcomes in both procedures, with a similar clinical success and long-term dysphagia relief. The safety profile of a new therapeutic procedure is imperative. Complications associated with POEM have been reported, with most of the adverse events (pneumoperitoneum, pneumomediastinum, and cervical emphysema) always self-limited. In general these events do not modify the postoperative course and some of them might be not considered as complications.

Remarkable benefits like absence of skin incisions, high efficacy, and low complication rates reinforce the concept that POEM is a less-invasive procedure than LMH, with similar intraoperative and perioperative complication rates. Additionally, we have found, with a 2 cm myotomy length over the gastric side, very similar reflux symptoms rate. It is important to note that the endoscopic surveillance ruled out severe esophagitis, with only one case of "grade A" esophagitis. Iatrogenic GERD incidence represents a major concern of the procedure. However, the incidence of symptomatic GERD after POEM varies between 10 and 57% [6–8, 18]. To date, only four series have presented substantial data on the evaluation of GERD in their patients using all three methods (systematic symptom assessment, endoscopic evaluation, and outpatient pH study) [19, 20] These studies found that 27–59% of patients had endoscopic reflux symptoms (mainly mild esophagitis class A or B of Los Angeles), 29–38% had abnormally high acid exposure in the pH studies, and 15–23% had frequent reflux symptoms. These patients have been treated effectively with PPI. It should be noted that the fundoplication of Dor or Toupet performed in conjunction with a laparoscopic Heller myotomy in patients with achalasia have modest efficacy. High-quality studies of laparoscopy centers have shown that 18–42% of patients present abnormal exposure to the acid in the postoperative period, similar to that observed in the post-POEM study [21, 22].

It is not clear why the rate of GERD after POEM is not substantially greater than after a Heller myotomy combined with fundoplication. The published incidence of symptomatic GERD after LHM without any antireflux procedure is substantially higher than symptomatic GERD after POEM. This indicates at least some benefits of preserving some antireflux mechanisms. There is no hiatal dissection during POEM compared to extensive dissection of the hiatus during a standard myotomy. This extensive dissection disrupts important ligaments of the esophagus, which are thought to contribute to the maintenance of the angle of His. The latter is the main barrier after myotomy eliminates the LES. This mechanism is not altered during POEM. Moreover, esophageal clearance, considered the third antirreflux mechanism, is improved after myotomy, and this benefits reflux prevention [23].

In this series, we have shown an acceptable low rate that compares to that of LHM. The majority of patients did not consider reflux as a significant adverse event, and a standard PPI dose was usually enough to control GERD symptoms. The ability of identifying a complete myotomy

with other signs than length while performing POEM, as compared to LHM, seem to allow preservation of natural antireflux mechanisms that together with a selective myotomy of the circular muscle layer may contribute to the reported findings.

We hypothesize that POEM allows for shorter myotomy on the gastric side due to the many indications that the operator has to call a complete myotomy compared to LHM. Some of these parameters include endoscopic assessment of LES relaxation and endoscopic passage pre- and post-myotomy that is natural in POEM and very rare in LHM. Hill type evaluation allows for clear vision of LES opening. The LES area during POEM is easier to recognize during the procedure, and it is usually easy to recognize once the restricting fibers have been cut.

Recently, a study using Endoflip technology has measured LES compliance during different stages of myotomy in POEM [14, 24, 25]. They have found the main impact to compliance is through the cardial portion and the first centimtre of the gastric side, with no changes after 2 cm on the gastric portion. This finding is consistent with our observation and may explain a more limited reflux rate compared to that of groups that resembled the same gastric length that in LHM.

Although recurrence rates in our series were similar to our LHM in the long term, there was a trend to lower recurrence in the POEM group. We believe this finding is biased by the difference in follow-up terms, and therefore, it is too early for conclusions on this matter.

A potential limitation of this study was the lack of postoperative pH monitoring to assess the GERD in asymptomatic patients. However, previous studies assessing pathological Ph Monitoring in asymptomatic patients have shown no significant difference between POEM and LHM [26, 27]. Longer term follow-up may show different recurrence rates that can affect these conclusions. However, the strength of this comparison study warrants the need for future long-term controlled studies.

Conclusions

This study confirms the safety and the efficacy of POEM (with a 2 cm myotomy over the gastric side) with comparable results to LHM (with a classic myotomy) and a shorter hospital stay. Reflux rates that remain to be a concern in POEM appear to be similar to LHM in our series and can be well controlled with PPI. Longer term follow-up and Ph Monitoring are required to yield stronger conclusions about myotomy extension that can be a relevant technical tip to improve outcomes. It is likely that LES compliance studies will provide further light to this issue.

Compliance with ethical standards

Disclosures Mauricio Ramirez, Cecilia Zubieta, Franco Ciotola, Alfredo Amenabar, Adolfo Badaloni, Fabio Nachman, and Alejandro Nieponice have no conflict of interest or financial ties to disclose.

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