Per oral endoscopic myotomy: Another tool in the toolbox

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ABSTRACT

Objective: Use of per oral endoscopic myotomy is increasing for the treatment of achalasia, with potential for rapid recovery and less invasiveness. We report our experience with per oral endoscopic myotomy to better understand how it fits into a modern paradigm of achalasia management.

Methods: A total of 152 patients with achalasia underwent per oral endoscopic myotomy from April 2014 to March 2018. Type II achalasia was the most prominent subtype in 69 patients (49%), and 33 patients (21.5%) had a prior Heller myotomy. Postoperative Eckardt scores, integrated relaxation pressure, and timed barium esophagram column height and width at 2 months were compared with preoperative measurements.

Results: Per oral endoscopic myotomy was completed in 149 patients (98%). Median operative time was 96 minutes (75 minutes for the last 30 cases), and length of stay was 1 day (interquartile range, 1-2). The most common morbidities were mucosal perforation in 2 patients (1.3%) and bleeding in 3 patients (2.0%), although no nonendoscopic intervention was required. Mortality was zero. Postoperatively, the median Eckardt score decreased from 6 to 0 ($P < .001$), residual lower esophageal sphincter pressure decreased from 22 mm Hg to 6 mm Hg ($P < .001$), and timed barium esophagram column height and width at 5 minutes decreased from 8 and 2.5 cm to 1.5 and 0.8 cm ($P < .001$), respectively. Median time to return to daily activity was 7 days; 49 patients (49.5%) had abnormal acid reflux on 24-hour pH testing postprocedure.

Conclusions: Per oral endoscopic myotomy is a safe and effective intervention that provides clear subjective and objective improvement in patients with achalasia. High postprocedure acid reflux raises concern about future sequelae if used in a nonselective fashion. (J Thorac Cardiovasc Surg 2019;158:945-51)

Algorithm for treatment of achalasia.

Central Message

POEM is a safe and effective tool in the treatment of achalasia. Increased incidence of acid reflux necessitates close long-term follow-up.

Perspective

We believe that POEM has not supplanted Heller myotomy as the gold standard treatment for achalasia because of its increased incidence of acid reflux. However, its low morbidity and quick recovery create a niche for use in certain subsets of patients. POEM takes more than 100 procedures to obtain mastery, whereas a significantly smaller number is likely needed for proficiency.

See Commentaries on pages 952 and 953.

Esophagomyotomy (Heller myotomy) has been the surgical treatment of choice for achalasia for more than a century.¹ The approach has evolved from left thoracotomy to laparotomy, then laparoscopy, and now endoscopy. The

principal role of surgery is to relieve obstruction of the incompletely relaxing lower esophageal sphincter (LES) to better allow esophageal drainage and palliate symptoms. As such, per oral endoscopic myotomy (POEM) was developed by Inoue and colleagues² as an endoscopic alternative to Heller myotomy. Over the past decade, use of POEM has increased, although a paucity of data regarding its safety, efficacy (short- and long-term), and side effects exists. We describe our experience with POEM to add to the growing body of knowledge and determine where this procedure might fit in the modern treatment algorithm of achalasia.

PATIENTS AND METHODS

Patients

From April 1, 2014, to March 31, 2018, 152 patients underwent a POEM procedure for achalasia in the Department of Thoracic and Cardiovascular Surgery at Cleveland Clinic. Patient information is provided in Table 1.

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Abbreviations and Acronyms

HRM	= high-resolution manometry
IQR	= interquartile range
LES	= lower esophageal sphincter
POEM	= per oral endoscopic myotomy
TBE	= timed barium esophagram

The diagnosis of achalasia was made with high-resolution manometry (HRM), timed barium esophagram (TBE), and esophagogastroduodenoscopy. An HRM system (ManoScan, Given Imaging, Los Angeles, Calif) was used to classify the type of achalasia based on the Chicago Classification, version 3.0.³⁻⁷ Only 3 patients did not have HRM data available for analysis: 1 was unable to tolerate probe placement, 1 had a silicone allergy, and 1 previously underwent POEM at an outside hospital before seeking treatment at our institution. All patients underwent TBE to determine esophageal morphology,^{6,8} with spot films taken at 1 and 5 minutes. An endoscopy was performed to rule out pseudo-achalasia and to detect the presence of candida esophagitis. Eckardt scores were recorded routinely at every visit. A prospective database containing patient characteristics, preoperative and postoperative testing results, operative details, and symptom profile was maintained with the approval of our Institutional Review Board.

Patient Selection

Once the diagnosis of achalasia was established and the type of achalasia defined, patients were assessed for fitness for surgery. Our algorithm for patient selection is described in Figure 1. Patients deemed to be poor surgical candidates were offered pneumatic dilatation or endoscopic Botox injection to the LES. For all surgically fit patients, both a traditional minimally invasive Heller myotomy and a POEM procedure were discussed. For those who underwent POEM, lack of long-term data was also presented.

Patients with type II achalasia aged less than 70 years and whose esophagus was not severely dilated (<5 cm) or sigmoidal were offered minimally invasive Heller myotomy with a 180-degree anterior fundoplication. Heller myotomy without fundoplication was offered to patients with end-stage, sink-trap esophagus who had not undergone prior surgical intervention. Patients with type II achalasia aged more than 70 years were offered Heller myotomy with fundoplication or POEM.

POEM was offered to patients with type III achalasia, morbid obesity, type I achalasia, type II achalasia with dilated esophagus (>5 cm), or prior upper midline laparotomy, and to those who had undergone a prior Heller myotomy. POEM was also performed for patients who opted to undergo it despite our recommendations based on the discussed benefits and limitations.

For purposes of this study, any patient with a hiatal hernia or history of mediastinal radiation or Barrett ablation was excluded from undergoing POEM. They instead underwent a minimally invasive Heller myotomy. Last, patients whose poor esophageal emptying was refractory to myotomy or dilatation were offered an esophagectomy. Early in our experience, the split between POEM and Heller myotomy was 40:60, respectively. However, this quickly evened out to 50:50 within 1 year of performing our first POEM procedure.

Per Oral Endoscopic Myotomy Technique

All POEM procedures were performed under general anesthesia with CO₂ insufflation in an operating room, using standard steps as described by Grimes and Inoue.⁹ We used our previously published 2-person technique in every case.¹⁰ During this procedure, the second person

provides additional forward tension and torque to allow a faster operation. The steps were as follows:

1. A 2-cm mucosotomy and creation of a submucosal tunnel starting approximately 10 to 12 cm proximal to the LES, extending distally 2 to 5 cm into the gastric side. The submucosal tunnel was created in the anterior esophageal wall except in patients having a prior Heller myotomy; for them, the submucosal tunnel was created 180 degrees opposite from the prior myotomy.
2. Myotomy of the circular muscle fibers starting 3 to 4 cm distally from the mucosotomy and extending 2 to 4 cm into the gastric wall.
3. Closure of the mucosotomy with endoscopic clips.

We believe the key to a successful POEM procedure is ensuring adequate extension of the myotomy into the gastric side. Given that the distance from the mucosotomy to the LES measured within the lumen of the esophagus can be different from the distance measured extraluminally, due to esophageal dilatation or accidental spiraling of the tunnel, we recommend extending the tunnel 4 to 5 cm from the measured LES to compensate for this phenomenon and prevent incomplete myotomy.

Postoperative Follow-up

On postoperative day 1, patients underwent a water-soluble contrast swallow radiograph to exclude transmural perforations. If the swallow study was unremarkable, patients were started on clear liquid diet, placed on twice daily proton pump inhibitors for 2 months, and advised to advance to a soft diet in 1 week, then to a regular diet at 4 weeks.

Patients who had undergone a successful POEM were asked to return in 8 to 12 weeks for their first testing, which included a repeat HRM, a 24-hour pH study off medications, and TBE (Table 2). If the 24-hour pH study showed abnormal results, then patients were maintained on proton pump inhibitors. Subsequently, they were asked to return for yearly follow-up with TBE and clinical assessment with Eckardt scores.

Statistical Analysis

Data are summarized by simple descriptive statistics. Categorical data are summarized using frequencies and percentages, and continuous variables are summarized with 25th, 50th (median), and 75th percentiles. For continuous variables, comparisons were made using the paired Wilcoxon rank-sum (nonparametric) test.

RESULTS

Perioperative Details

POEM was successfully completed in 149 of 152 patients. Of the 3 patients whose procedure was unsuccessful, 2 had a fusion of planes in the setting of end-stage renal disease that required dialysis, and 1 had excessive subcutaneous emphysema without hemodynamic instability. Median operative time was 96 minutes (interquartile range [IQR], 77-114). For the first 30 cases, median operative time was 120 minutes (IQR, 98.5-148.8), but 75 minutes (IQR, 64.5-85.5) for the last 30 cases (Table 3). Operative time plateaued after 100 cases (Figure 2). Median lengths of the esophageal and gastric myotomies were 5 cm (IQR, 4-6) and 4 cm (IQR, 3-4), respectively. Median length of stay was 1 day (IQR, 1-2).

Perioperative Complications

No serious complications were encountered intraoperatively. The most common minor complication was

TABLE 1. Patient demographics and baseline characteristics (total n = 152)

Variable	N*	No. (%) or median [25th-75th IQR]
Age (y)	152	57.8 [48.8-73.2]
Male	152	81 (53.3)
Race	152	
White		103 (67.8)
Black		15 (9.9)
Other		11 (7.2)
Unknown		23 (15.1)
Body mass index (kg/m ²)	152	27.9 [24.2-34.0]
ASA classification	152	
I		8 (5.3)
II		46 (30.3)
III		63 (41.4)
IV		35 (23.0)
HRM	149	
Unable to pass probe		13 (9.6)
Resting LES pressure (mm Hg)		39.3 [22.0-56.8]
Integrated relaxation pressure (mm Hg)		23.6 [14.7-32.7]
Achalasia type	142	
I		41 (28.9)
II		69 (48.6)
III		25 (17.6)
Other (variant)		7 (4.9)
TBE	148	
Column height at 5 min (cm)		8.5 [4.3-12.0]
Column width at 5 cm (cm)		2.5 [1.5-4.0]
Eckardt score	146	
Dysphagia		
0		6 (4.1)
1		16 (11.0)
2		36 (24.7)
3		88 (60.3)
Chest pain		
0		43 (29.5)
1		47 (32.2)
2		35 (24.0)
3		21 (14.4)
Regurgitation		
0		24 (16.4)
1		36 (24.7)
2		42 (28.8)
3		44 (30.1)
Weight loss		
0		57 (39.0)
1		21 (14.4)
2		24 (16.4)
3		44 (30.1)
Total score (0-12)†		7 [5-9]
Stage of symptoms		
0 (0-1)		2 (1.4)
1 (2-3)		20 (13.7)

(Continued)

TABLE 1. Continued

Variable	N*	No. (%) or median [25th-75th IQR]
2 (4-6)		42 (28.8)
3 (>6)		82 (56.2)

IQR, Interquartile range; *ASA*, American Society of Anesthesiologists; *HRM*, high-resolution manometry; *LES*, lower esophageal sphincter; *TBE*, timed barium esophagram. *Patients with data available. †Sum of the 4 component scores, ranging from 0 to 12.

capno-peritoneum requiring needle decompression, which occurred in 37 patients (25%). No radiographic evidence of postoperative leaks was found in this series. Several patients had pooling by the clips, which was not of ultimate consequence. Three patients had delayed bleeding complications 2 weeks after surgery; 2 were related to a gastroesophageal junction ulcer, and 1 was related to a mediastinal hematoma after an episode of retching. One patient had an empyema without gross evidence of transmural esophageal perforation and required only pigtail drainage and antibiotics. The etiology could have been due to occult leak or pleural space contamination during the procedure.

Postoperative Palliation

Palliation of symptoms was excellent at 2 months postoperatively (Table 4, Figure 3, A and B). The median Eckardt score was 6 (IQR, 5-8) preoperatively and decreased significantly to 0 (IQR, 0-1) postoperatively ($P < .001$). Likewise, there was a dramatic improvement in esophageal emptying. Median TBE height decreased from 8 cm (IQR, 4.5-12) preoperatively to 1.5 cm (IQR, 0-6) postoperatively ($P < .001$), and median TBE width decreased from 2.5 cm (IQR, 1.5-3.7) to 0.9 cm (IQR, 0-2) ($P < .001$). Integrated relaxation pressure or residual LES pressure decreased from a median of 22 mm Hg (IQR, 15.1-32.6) to 6 mm Hg (IQR, 1.8-8.6) ($P < .001$). Median time to return to regular activity was 7 days (IQR, 5-7).

Postoperative Gastroesophageal Reflux Disease

Twenty-four-hour pH testing was performed in 99 (65%) of the 152 patients undergoing POEM. Abnormal acid reflux was identified in 49 patients (49.5%). The median DeMeester score was 14.9 (IQR, 2.4-48.3). Of the patients who had an abnormal pH study, the median DeMeester score was 47.6 (IQR, 26.9-67.8), and 34 (36%) reported symptoms of gastroesophageal reflux disease. However, with medications, all but 1 had effective symptom control. The patient with poor control of gastroesophageal reflux disease after POEM underwent a laparoscopic 180-degree partial anterior fundoplication, with complete resolution of symptoms.

DISCUSSION

Principal Findings

POEM is a safe alternative to traditional Heller myotomy, with no major perioperative complications when performed

FIGURE 1. Algorithm for treatment of achalasia. *POEM*, Per oral endoscopic myotomy.

in experienced centers. The learning curve reaches its plateau at approximately 100 cases. Short-term palliation of symptoms and improvement in esophageal drainage are both excellent. There is a more rapid return to activities of daily living relative to minimally invasive Heller myotomy. Postoperative abnormal esophageal acid exposure is high, at approximately 50%.

Findings in Context

POEM for the treatment of achalasia is no longer an experimental procedure. A recent meta-analysis by

Schlottmann and colleagues¹¹ describes 2000 POEM procedures reported in 21 articles worldwide. In experienced centers, this appears to be a relatively safe procedure with minimal morbidity and mortality.¹² POEM's effectiveness in palliating dysphagia at 2 years compares favorably to laparoscopic Heller myotomy, at 93.5% and 90.4%, respectively.¹¹ We also noted excellent palliation of symptoms, with a median postoperative Eckardt score of 0. The goals of a myotomy for achalasia are to both decrease symptoms and improve esophageal emptying, but there is lack of concordance between symptoms and esophageal emptying.^{6,13,14} As such, objective measurement of esophageal drainage is also an important component of postoperative evaluation. The novel aspect of our study is that in addition to our subjective evaluation with Eckardt scoring, we demonstrate objective improvement in esophageal drainage via preoperative and postoperative TBE.

We noted 1 major complication—empyema—in our series, but with minimal minor complications. In published series,

TABLE 2. Completeness of follow-up (total n = 152)

Mode of follow-up	No. (%)
Clinic visit	128 (84.2)
HRM	108 (71.1)
Postoperative Eckardt score	123 (80.9)
TBE	120 (78.9)
pH probe	99 (65.1)

HRM, High-resolution manometry; TBE, timed barium esophagram.

TABLE 3. Operative characteristics (total n = 152)

Characteristic	No. (%) or median [25th–75th IQR]
Operative time (min)	96.0 [77-114]
First 30 cases	120.0 [98.5-148.8]
Last 30 cases	75.0 [64.5-85.5]
Submucosal tunnel length (cm)	14.0 [12.0-15.0]
Myotomy length (cm)	
Esophageal	5 [4-6]
Gastric	4 [3-4]
Total	9 [8-10]
Veress needle decompression (%)	34 (23.4)
No. of endoscopic clips	6 [5-8]
Proximal mucosotomy distance from GE junction (cm)	10 [8-11]
Mucosotomy site	
Anterior (%)	122 (78.1)
Other (%)	33 (21.9)
Length of stay (d)	1 [1-2]

IQR, Interquartile range; GE, gastroesophageal.

occurrence of major complications, such as surgical conversion, mediastinitis, empyema, bleeding requiring blood transfusion, and mucosal injury requiring intervention, was 0.5% to 3.3%.¹² At least 1 death within 30 days of surgery has been reported.¹⁵ With occurrence of complications being similar to that of laparoscopic Heller myotomy,^{16,17} it is reasonable to expect that this is a safe procedure in experienced centers. We did note that of the 3 patients with noticeable bleeding complications after surgery, 2 had resumed smoking. We believe that smoking in the perioperative period may be a risk factor for ulcer formation and bleeding. Last, we noted that the 2 patients who had fused planes preventing a successful POEM also had end-stage renal disease requiring dialysis. We suspect that nephrogenic sclerosis may have played a role, making it a possible risk factor for a technical failure of POEM.

The obvious difference between POEM and Heller myotomy is the ability to perform a fundoplication. Thus, one would expect an increased incidence of acid reflux, which our study and others have found to be true.¹¹ This incidence of acid reflux is nearly identical to that in a series published by Richards and colleagues,¹⁸ wherein 2 of 22 patients (9.1%) who had undergone a Heller myotomy with partial fundoplication had abnormal acid reflux, compared with 10 of 21 patients (47.6%) who did not receive a fundoplication.

Until long-term data become available, durable efficacy can be debated. However, there are subsets of patients who clearly benefit from POEM compared with Heller myotomy in regard to operative morbidity. The first group

FIGURE 2. Operative times over number of consecutive POEM cases from 2014 to 2018. Solid blue line represents learning curve for mastery of the POEM technique.

comprises patients who have had a prior myotomy with a fundoplication, in whom a reoperation can be challenging. The need to take down their existing fundoplication and associated adhesions results in a higher risk of perforation. A second group that benefits includes patients with multiple prior abdominal operations, for whom a minimally invasive approach carries a higher risk of injury or open conversion. Last, a potential group that may benefit from POEM is patients with type III achalasia and a defined area of spasticity. These patients require a longer myotomy on the esophageal side, which may not be performed as easily from the abdomen. Therefore, for type III achalasia, we perform a longer esophageal myotomy. However, the optimal length for these patients is unknown.

Study Strengths and Limitations

This is a single-institution study in which POEM procedures were performed by the same team of experienced endoscopists (S.R., M.R.S., and S.C.M.). Patients are well characterized and well followed.

TABLE 4. Comparison of preoperative and postoperative per oral endoscopic myotomy tests

Test	N	Before POEM median [25th–75th IQR]	After POEM median [25th–75th IQR]	P value
Residual LES pressure (mm Hg)	91	22 [15.1–32.6]	5.9 [1.8–8.6]	<.001
Eckardt score	108	6 [5–8]	0 [0–1]	<.001
TBE (cm)				
Column height at 5 min	105	8 [4.5–12]	1.5 [0–6]	<.001
Column width at 5 min	101	2.5 [1.5–3.7]	0.8 [0–2]	<.001

POEM, Per oral endoscopic myotomy; IQR, interquartile range; LES, lower esophageal sphincter; TBE, timed barium esophagram.

A weakness of the study is that these procedures were performed on a group of patients who were generally different from patients offered a minimally invasive Heller myotomy. As such, direct comparison with a Heller myotomy control group was not possible. Additionally, not all patients returned to the Cleveland Clinic for short-term follow-up. However, approximately 85% of patients did have symptom and objective follow-up data. Medium- and long-term follow-ups are currently not available, prohibiting any assessment of the long-term effectiveness of this technique.

making it ideal for frail patients. The high prevalence of abnormal acid exposure, presumably due to the lack of a fundoplication, raises concerns about future sequelae, such as esophagitis and stricture. Continued follow-up is needed to determine if this procedure offers long-term palliation equivalent to that of minimally invasive Heller myotomy. POEM certainly should be considered a tool in the toolbox of achalasia surgery, but not the only option. For now, a minimally invasive Heller myotomy should still be discussed with patients who would benefit from an anti-reflux procedure.

CONCLUSIONS

POEM is an effective therapy in achalasia surgery. It is even less invasive than current minimally invasive options,

Conflict of Interest Statement

S.R. is a consultant for Smiths-Medical. All other authors have nothing to disclose with regard to commercial support.

FIGURE 3. Eckardt score and integrated relaxation pressure before and after POEM for individual patients. A, Eckardt score. B, Integrated relaxation pressure. IRP, Integrated relaxation pressure; POEM, per oral endoscopic myotomy.

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