



## POEM: clinical outcomes beyond 5 years

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### Abstract

**Background** The short-term success of peroral endoscopic myotomy (POEM) is well documented but the durability of the operation is questioned. The aim of this study was to evaluate the clinical outcomes of the POEM procedure for esophageal motility disorders in a large cohort in which all patients had at least 5 years of follow-up.

**Methods** All patients from a single center who underwent a POEM between October 2010 and September 2014 were followed for long-term clinical outcomes. Postoperative Eckardt symptom scores of short term and  $\geq 5$  years were collected through phone interview. Clinical success was defined as an Eckardt score  $< 3$ . Overall success was defined as Eckardt score  $< 3$  and freedom from additional interventions.

**Results** Of 138 patients, 100 patients were available for follow-up (mean age 56, 52% male). The indication for operation was achalasia in 94. The mean follow-up duration was 75 months (range: 60–106 months). Dysphagia was improved in 91% of patients. Long-term overall success was achieved in 79% of patients (80% of achalasia patients, 67% of DES patients). Preoperative mean Eckardt score was 6. At 6 months, it was 1, and at 75 months, it was 2 ( $p = 0.204$ ). Five-year freedom from intervention was 96%. Overall, 7 patients had additional treatments: 1 balloon dilation (35 mm), 4 laparoscopic Heller myotomy, and 2 redo POEM at a mean of 51 months post-POEM. Ninety-three percent expressed complete satisfaction with POEM.

**Conclusion** A multitude of studies has shown the early benefits of POEM. Here, we show that nearly 80% of patients report clinical success with no significant decrement in symptom scores between their short- and long-term follow-up. Clearly POEM is an effective option for achalasia with durable long-term treatment efficacy.

**Keywords** POEM · Esophageal myotomy · Endoscopic myotomy · Long-term outcomes · Achalasia · Endoscopic surgery

Peroral endoscopic myotomy (POEM) was developed based on the technique of submucosal endoscopy and endoscopic myotomy [1]. Multiple studies have documented the early POEM experience with excellent clinical results of up to

95% symptom resolution [1–5]. A handful of publications have documented longer-term follow-up showing success rates of 79–92% 2–5 years after the POEM procedure [2, 4–9]. In 2014, we published the results of our first 100 procedures with an 83% success rate [4]. However, despite a mean of 22 months, we like other authors, reported a wide range of follow-up (6–43 months). The question of long-term durability was raised by our group and others who noticed a slight detriment in clinical outcomes when patients were followed longer-term despite initial early success after the POEM [6, 10, 11]. The aim of the current study was to investigate this potentially emerging concern by reporting clinical outcomes in a large cohort of only patients who were at least 5 years out from their POEM procedure.

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## Methods

### Patients

POEM database from a high volume US surgical unit was queried for all patients who underwent POEM between October 2010 and September 2014 such that each patient was at least 5 years out from the procedure. All patients underwent informed and written consent for POEM per an Institutional Review Board approved research protocol. Data was collected from the prospective database and chart review. Patients were then contacted by phone. Those not available for phone interview were excluded. Patients with pre-existing endoscopic esophagitis, age < 18 years, and inability to tolerate general anesthesia were ineligible for the POEM procedure. Endoscopic dilation, botulinum toxin injection, or a history of laparoscopic esophageal myotomy prior to POEM were not considered exclusion criteria. Treatment failures were defined by a long-term Eckardt score > 3 OR reintervention (balloon dilation > 3 cm, laparoscopic esophageal myotomy or revision endoscopic myotomy). All failures were offered full comprehensive testing and further categorized as:

1. Inadequate myotomy- defined as abnormal emptying on contrast study, manometric evidence of persistent outflow obstruction and/or endoscopic findings of persistently tight gastroesophageal junction.
2. GERD objectively confirmed evidence of increased esophageal acid exposure on endoscopy or pH testing in the absence of other evidence of esophageal outflow obstruction (endoscopically, contrast delay, or stasis pattern on pH study)
3. Refractory-persistent symptoms despite adequate, objective myotomy in the absence of GERD

Importantly, this patient cohort is not the same as previously published in our 2014 experience of 100 POEM patients [4]. This current cohort includes 77 of those 100 patients previously published (71 achalasia, 6 DES). The cohort is also not identical to our 2018 study evaluating outcomes of non-achalasia patients, as only 3 of the 29 patients were available for follow-up/did not meet the 5-year criteria [12].

### Symptom questionnaires

To evaluate postoperative outcomes, a questionnaire was administered over the phone to patients and all were asked the questions for Eckardt scoring (Table 1) [13]. “Clinical success” was defined as a current Eckardt score < 3.

**Table 1** Eckardt symptom scoring and staging. Final score is the sum of the four component scores, ranging from 0 to 12

Symptom	Score			
	0	1	2	3
Dysphagia	None	Occasional	Daily	With every meal
Regurgitation	None	Occasional	Daily	With every meal
Chest pain	None	Occasional	Daily	Several times a day
Weight loss (kg)	0	<5	5–10	> 10

Overall success was defined as Eckardt score < 3 and freedom from reintervention for persistent or recurrent symptoms, in line with prior studies [14].

### High resolution manometry (HRM)

Manometric diagnoses prior to operation were based on Chicago classifications v3.0 for achalasia, DES, and esophageal outflow obstruction. For this paper, authors (CMD, KMR) blindly re-reviewed the preoperative HRM topography of all patients to ensure they fit into the most updated Chicago classification [15]. Type IV achalasia was defined by EGJ outflow obstruction (elevated IRP) and disordered peristalsis not meeting criteria for achalasia but presenting with clinical symptoms suggestive of classic achalasia. Abnormal acid exposure and hiatal hernia were ruled out in these patients prior to POEM. Cross-sectional imaging was obtained selectively (7/19 patients).

### Operative technique

The operations were performed by three surgeons (CMD, LLS, and KMR) as previously described [16]. Length of myotomy was individualized based on intra-operative endoscopic identification of the high-pressure zone, selective intraoperative impedance planimetry, contrast study interpretation, and preoperative HRM topography. All myotomies were carried 2–3 cm distal across the gastroesophageal junction.

### Statistical analysis

Results are reported as mean ± standard deviation and/or range for quantitative variables and absolute and relative frequencies for categorical variables. Outcomes between parameters were compared before and after POEM by using independent or paired t-testing as appropriate for statistical analysis.  $p < 0.05$  was considered to be statistically significant.

## Results

### Patient characteristics

The first 138 cases performed at The Oregon Clinic were followed prospectively for a minimum of 5 years from the date of surgery for recurrence of symptoms or the need for another intervention. Baseline disease consisted of the following: 39 (28%) Type 1; 56 (41%) Type 2; 14 (10%) Type 3, 19 (14%) Type 4; and 10 (7%) DES. Of the 138 individuals, 125 (91%) had a 6-month postoperative evaluation, and 100 (73%) were followed up over the phone at or after 5 years. Thirty-eight individuals were lost to follow-up for a variety of reasons including the following: could not be reached ( $n = 16$ ), died ( $n = 11$ ), and declined ( $n = 11$ ). No patient deaths were related to the POEM procedure. The individuals who were lost to follow-up were not markedly different from those that remained under study (Supplement Table 1). Those who were lost to follow-up were of similar age, gender, and disease state at baseline and at 6 months compared to those who remained under study. Consequently, we present a complete case descriptive analysis of the first 100 individuals who underwent POEM for the purposes of achalasia with Eckardt scores obtained at or after 5 years. All further analyses pertain to these 100 individuals and their long-term follow-up (Table 2).

### Outcomes

Long-term symptom scores were obtained at a median (IQR) follow-up interval of 72 months (66–82). Eckardt scores were significantly improved at 6 months postoperatively from preoperative baseline (mean 6 months postoperative  $1.53 \pm 1.82$  vs preoperative  $6.28 \pm 2.3$ ,  $p < 0.001$ ). This improvement was sustained at long-term follow-up (mean  $\geq 5$  years  $1.89 \pm 1.8$  vs 6 months postoperative  $1.53 \pm 1.82$ ,  $p = 0.180$ ) (Fig. 1). There was significant improvement at long-term follow-up in each of the Eckardt score (ES) domains (Table 3). Long-term overall success (ES  $< 3$  and freedom from reintervention) was achieved in 79% of patients and varied based on preoperative manometric diagnosis (Table 4) with classic achalasia subtypes having superior outcomes. Freedom from additional intervention in 96% of patients at 5 years and 90% at 100 months postprocedure (Fig. 2). There were 21 failures over the long term: 14 defined by ES  $> 3$  alone and 7 defined by reintervention. All were offered comprehensive objective evaluations to determine the source of failure and 2 declined (ES 5 and 6). Of the remaining 19 patients underwent objective testing, 4 had inadequate myotomy, 9 had GERD, and 7 were considered refractory (one inadequate myotomy was recategorized after an otherwise successful laparoscopic Heller). In total, there were 7 re-interventions: one 35-mm balloon dilation, 2 redo POEMs, and 4 laparoscopic Heller with partial funduplications. In 2 patients, symptoms were refractory despite additional intervention (one balloon, one LH). There were no statistically identifiable risk factors for failure (Supplement Table 2).

**Table 2** Patient Characteristics

	All patients <i>n</i> = 100	Achalasia <i>n</i> = 94	DES <i>n</i> = 6
Age, mean	57 (20–88)	57 (20–28)	53 (36–80)
Sex	52 male 48 female	49 male 45 female	3 male 3 female
BMI	27.35 (17.2–46)	26.96	28.35
Eckardt score, mean	6.28 (2–12)	6.20 (2–12)	8.0 (6–9)
Mean symptom duration	86.45 months	86.11 months (2–750)	107 months (4–240)
Presenting symptoms			
Dysphagia	83	79	4
Regurgitation	8	8	0
Chest Pain	7	5	2
Cough	2	2	0
Prior endoscopic interventions	23	23	
Dilations	2	2	
Botox	21	21	
Prior Heller Myotomy	6	6	
HRM diagnosis	9 cm (2–23)	29 Achalasia Type I	6 DES
Length of Myotomy		41 Type II	13 cm (6–19)
		5 Type III	
		19 Type IV	
		8 cm (2–23)	

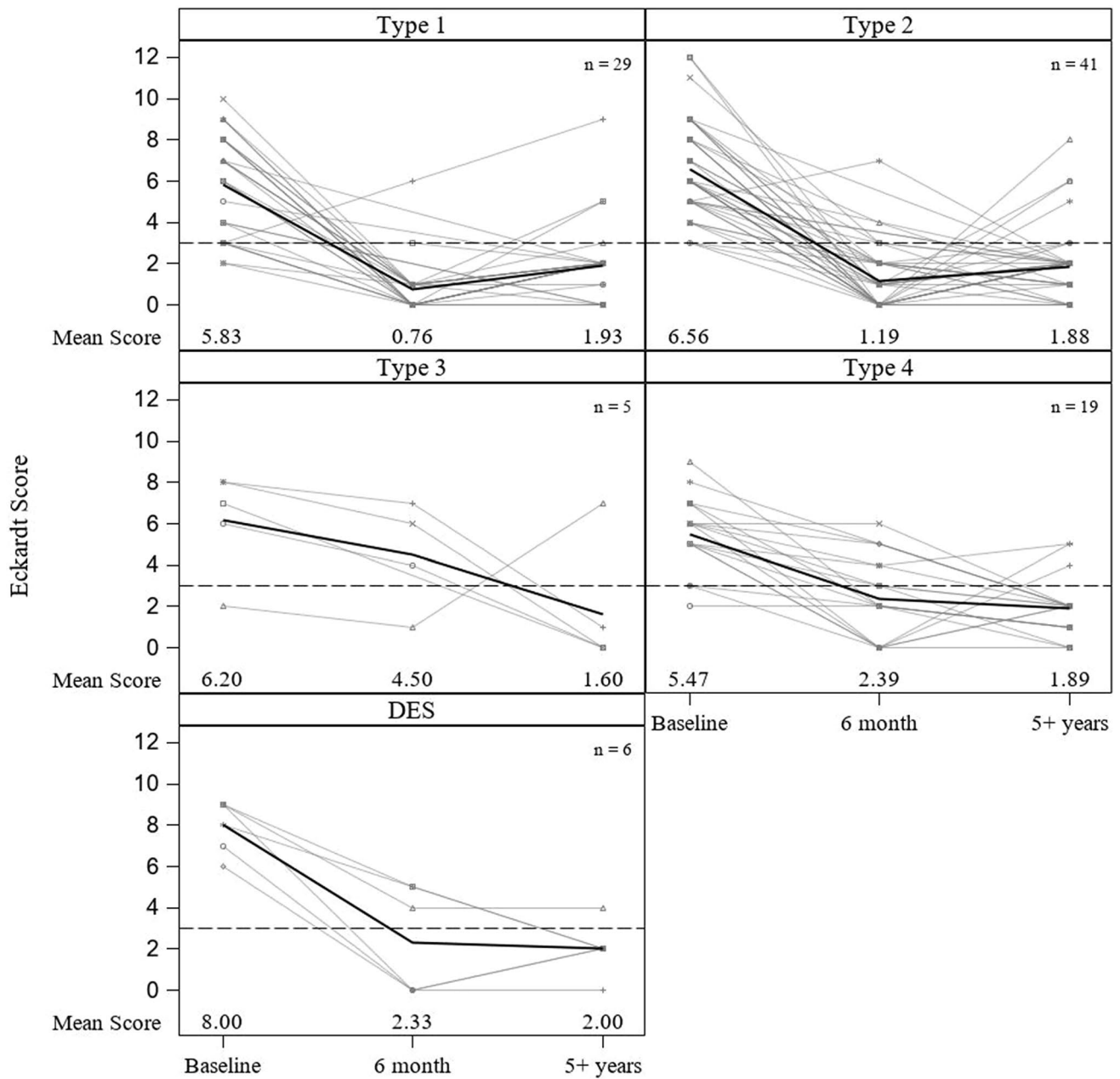


Fig. 1 Eckardt score domain trends in the full patient cohort, classified by disease type

Table 3 Eckardt scores by domain for entire patient cohort

	Preop baseline	≥ 5 years postop
Eckardt score (range 0–12)	6.28 ± 2.3	1.89 ± 1.8*
Dysphagia (range 0–3)	2.65 ± 0.79	0.90 ± 0.95*
Regurgitation (range 0–3)	1.22 ± 1.24	0.48 ± 0.62*
Chest pain (range 0–3)	1.14 ± 1.28	0.4 ± 0.85*
Weight loss (range 0–3)	1.26 ± 1.34	0.15 ± 0.63*

\*Indicates  $p < 0.001$

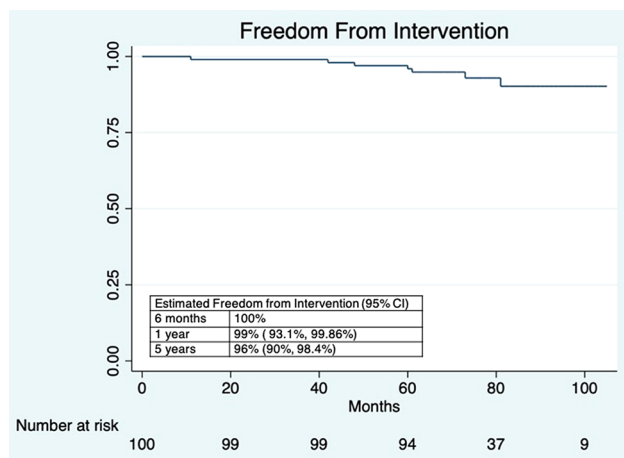
### Dysphagia

Ninety-one percent of patients with preoperative dysphagia ( $n = 90$ ) reported improved or resolved symptoms at long-term follow-up. At 6 months postoperatively, improvement in dysphagia was seen in 81 patients (90%) (preop mean  $2.65 \pm 0.79$  vs  $0.73 \pm 0.97$ ,  $p < 0.001$ ) and sustained at long-term follow-up (6 month mean  $0.73 \pm 0.97$  vs long-term  $0.90 \pm 0.95$ ,  $p = 0.2459$ ). New onset dysphagia was reported in 2 patients (1 at 6 months postoperatively, 1 at long-term follow-up).

**Table 4** Comparison of mean preoperative and long-term Eckardt scores for patients in each diagnosis subtype

Diagnosis	Patients	Mean Eckardt score			Clinical success (%)	Reintervention for persistent or recurrent symptoms	Overall Success (%)
		Preop	6 mo postop	≥ 5 years postop			
Achalasia	94	6.2	1.4*	1.8*	84	6	80
Type 1	29	5.8	0.8*	1.9*	87	1	87
Type 2	41	6.6	1.2*	1.9*	81	2	78
Type 3	5	6.2	4.5*	1.6*	80	0	80
Type 4	19	5.5	2.4*	1.9*	84	3	68
DES	6	8.0	2.3*	2.0*	83	1	67

\*Indicates  $p < 0.001$  as compared to preoperative value. Clinical success defined as Eckardt score  $< 3$ . Overall success defined as freedom from additional intervention and Eckardt score  $< 3$

**Fig. 2** Freedom from intervention of entire patient cohort

## Regurgitation

Ninety-two percent of patients with preoperative regurgitation ( $n = 50$ ) reported improved or resolved symptoms at long-term follow-up. At 6 months postoperatively, improvement in regurgitation was seen in 47 patients (94%) (preop mean  $1.22 \pm 1.24$  vs  $0.3 \pm 0.69$ ,  $p < 0.001$ ) and sustained at long-term follow-up (6 month mean  $0.30 \pm 0.69$  vs long-term  $0.48 \pm 0.62$ ,  $p = 0.07$ ). New onset regurgitation developed in 20/50 patients (5 at 6 months postoperatively, 15 at long-term follow-up).

## Chest pain

Ninety-one percent of patients with preoperative chest pain ( $n = 45$ ) reported improved or resolved symptoms at long-term follow-up. At 6 months postoperatively, improvement in chest pain was seen in 43 patients (96%) (preop mean  $1.14 \pm 1.28$  vs  $0.22 \pm 0.63$ ,  $p < 0.001$ ) and sustained at long-term follow-up (6 month mean  $0.22 \pm 0.63$  vs long-term  $0.4 \pm 0.85$ ,  $p = 0.1044$ ). The mean 6-month postoperative

symptom scores were significantly different between the achalasia and DES patients ( $p = 0.03$ ). New onset chest pain was reported in 7/55 patients (2 at 6 months postoperatively, 5 at long-term follow-up).

## Weight loss

Forty patients reported substantial weight loss preoperatively (score  $< 2$ ). Weight loss score was significantly improved at 6 months postoperatively (mean preop  $1.26 \pm 1.34$  vs  $0.29 \pm 0.84$ ,  $p < 0.001$ ) and improvement was sustained at long-term follow-up (6 month mean  $0.29 \pm 0.84$  vs long-term  $0.15 \pm 0.63$ ,  $p = 0.216$ ). Only 3 patients reported weight loss at long-term follow-up (all achalasia).

## Early POEM failures

Seven patients were early treatment failures. Four were categorized as inadequate myotomy due to persistent dysphagia and objective evidence of inadequate myotomy (barium tablet study, HRM, and/or endoscopy) and were offered revision surgery. One laparoscopic Heller myotomy and two redo POEM were successful (postop ES 2) and one laparoscopic Heller was refractory despite normal postoperative testing (ES 4). Three had complex and confounding factors and were categorized as refractory: one had end-stage achalasia with sigmoid esophagus and prior laparoscopic Heller who declined esophagectomy, one had concurrent oropharyngeal dysfunction and persistent dysphagia on symptom questionnaire, and one had DES and chronic pain disorder with persistent chest pain on questionnaire.

## Late POEM Failures

Twelve patients were considered late treatment failures. Three had normal comprehensive testing at the time of failure despite persistent complaints and are categorized as refractory. Two of these had ES of 3 and normal objective evaluations for recurrent dysphagia. They both are satisfied

with occasional empiric 20 mm balloon dilations. One had persistent chest pain and dysphagia (ES 5) and was offered a 35 mm balloon dilation which was ineffective. Testing confirmed adequate myotomy and objective GERD in 9 late failures. Eight of these patients also had persistent dysphagia (ES 3–8) and one had chest pain (ES 5). One had developed scleroderma and was treated with PPI. The rest were offered fundoplication (transoral or laparoscopic) or PPI. All managed successfully with PPI except two who had developed a concurrent hiatal hernias and elected repair.

## Discussion

This study reports the clinical outcomes of POEM in a large cohort in which all patients have follow-up of at least 5 years. The primary finding is that POEM provides excellent long-term relief of symptoms for patients with achalasia. Ninety percent of patients reported improvement in dysphagia, with either complete or nearly complete resolution, for more than 5 years after the POEM procedure. Furthermore, 93% of patients were free from further therapeutic interventions after their index procedure. When both Eckardt score and freedom from intervention were considered together, long-term success was nearly 80%. Importantly, these results are comparable to the 82–100% dysphagia relief rates reported with other achalasia treatments [17, 18] including the European Achalasia Trial comparing pneumatic dilation to laparoscopic Heller myotomy at 5 years [19] as well as a recently presented abstract documenting the long-term laparoscopic Heller experience at Massachusetts General Hospital [20]. Not surprisingly, dysphagia relief was better in achalasia patients compared to those with DES. Although the study is not powered for robust analysis to identify predictors of failure, it appears that achalasia (subtypes I–III) have the highest likelihood of success whereas individuals with Type IV achalasia or DES and prior intervention were more likely to fail. This suggests that POEM, like laparoscopic Heller and pneumatic dilation, is most successful in patients with classic achalasia subtypes.

While a majority of patients in this study had classically defined achalasia, nearly 20% were classified as type IV achalasia. The term “type IV achalasia” was coined by the authors of the Chicago Classification in an effort to distinguish a clinical entity that most resembles achalasia from other causes of manometrically identified esophago-gastric outlet obstruction (EGJOO) defined by an elevated integrated relaxation pressure (IRP) (personal communication, Peter Kahrilas 2019). Type IV achalasia is akin to the historical “hypertensive, non-relaxing lower esophageal sphincter.” When carefully selected, these patients have been shown to respond favorably to laparoscopic Heller myotomy [21, 22]. Today, these patients are given the diagnosis of

EGJOO on the high-resolution manometry report. However, by itself, manometric EGJOO is not pathognomonic for any diagnosis and should not, in isolation, be used to justify any operation. Rather EGJOO is a manometric finding that is associated with a multitude of alternative causes such as GERD, obesity, hiatal hernia, and external compression among other things.

In this study, type IV achalasia was defined by EGJ outflow obstruction (elevated IRP) and disordered peristalsis not meeting criteria for achalasia but presenting with clinical symptoms suggestive of classic achalasia. GERD and hiatal hernia were ruled out. However, the overall success rate for POEM in type IV achalasia was less than that of the classic subtypes suggesting there is room for improvement. It may be that these data reflect a less stringent evaluation than we currently subscribe. For example, EUS was not used as liberally during the study period from 2010 to 2014 as is currently recommended. Yet no mass or other structurally based lesion was found in the submucosal space during POEM calling into question the utility of EUS in these patients. Still, it is important to emphasize that type IV achalasia is a diagnosis made by exclusion only after careful, detailed, and meticulous evaluation. While we have always subscribed to this concept, our vigilance has increased over the years with experience and expected that with increased discernment in patient selection, the outcomes in this group will be the same as classic achalasia. This is an evolving field of study to more clearly delineate precise surgical criteria for this subgroup.

While a majority of patients do not develop objective gastroesophageal reflux (GER) after POEM, the rate of reflux after surgery remains a concern. We specifically do not report GERD rates in this present study because the data were collected by phone interview. During this data review, it was disheartening to see how so many patients had ignored our requests for objective follow-up over the years and nearly 1/2 were taking PPIs without a clear indication. All achalasia therapies create the potential for increased esophageal acid exposure due to disruption of the reflux barrier by inducing a dysfunctional lower sphincter. Laparoscopic Heller myotomy has the advantage of being able to add a concurrent fundoplication to mitigate reflux while pneumatic dilation and POEM do not. However, the data are conflicting regarding if any of the available therapies (pneumatic dilation, laparoscopic Heller, or POEM) offer any significant advantages over the others in terms of objective reflux. Postintervention GER rates have been well documented to vary between 20 and 40% [14, 23–27]. The issue of GER is further complicated by the fact that symptoms alone are an inaccurate metric to assess for objective reflux defined as evidence of increased esophageal acid exposure either by endoscopic esophagitis or determined with pH testing. We have previously shown that only 50% of patients with



symptoms of GER post-POEM meet objective criteria for the diagnosis [4]. Conversely, only about half of patients with objective acid reflux are symptomatic. This discordance between reflux symptoms and objective findings has been demonstrated in multiple studies over decades [4, 24, 28]. Similarly, PPI is not an accurate surrogate measure of objective reflux. However, this diagnostic dilemma poses a major challenge in the long-term care of these patients—without objective testing a significant number of patients have untreated reflux which may lead to complications such as peptic stricture or Barrett’s esophagus while a different set of patients may take unnecessary risks of taking medications without proper indication.

What can be concluded from the current, as well as previously published studies, is that POEM is an effective therapy for the palliation of dysphagia caused by manometric esophageal disorders and that the potential reflux after POEM needs to be monitored with objective testing. The fact that symptoms alone are insufficient to diagnose patients at risk for complications mandates close follow-up. Our current practice includes objective surveillance at one year and every 5 years for life. We recognize that the lack of objective outcomes in the present study represents a weakness of the report. Although we stress the importance of long-term surveillance with our patients, some were lost to follow-up, which may have introduced unintended selection bias to the findings. We are actively and continually working to obtain long-term objective data on this cohort and suggest clear follow-up recommendations are presented prior to any operative intervention to address this issue. However, as dysphagia relief is the primary objective of POEM, we felt it was important to report these long-term subjective outcomes presently.

This study has some additional limitations. We and others have published that there is a learning curve associated with POEM [6, 29]. These patients represent our initial experience with the procedure and it is possible that outcomes over time have changed to impact the generalizability of the data. Certainly, inclusion criteria and follow-up protocols have become more defined over time. Additionally, although we were able to contact > 70% of the patients who had their operation over the study time frame, some were lost to follow-up. This may have introduced unintended selection bias to the findings although we did not identify major differences between the study cohort and those lost to follow-up. Also, we found that two patients had to be reminded that they did in fact have a surgical procedure so there could be some recall bias when asked about additional therapies especially if they were done elsewhere.

In conclusion, the main outcome of the study is that POEM provides excellent palliation of symptom that endures despite a slight decay from early success rate. Although a concern, the potential for GER does not outweigh the

advantages of POEM as patients invariably experience adequate treatment from adjunctive antacid medications alone. Our findings are consistent with the assertion that POEM is an effective and durable therapeutic option for patients seeking definitive intervention for achalasia and other esophageal motility disorders.

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## Compliance with ethical standards

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