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Long-term outcomes following POEM for non-achalasia motility disorders of the esophagus

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Abstract

Background Optimal treatment for symptomatic patients with non-achalasia motility disorders (NAD) such as diffuse esophageal spasm, esophagogastric junction outlet obstruction, and hypercontractile disorder is not well established. POEM has been offered to these patients since it is a less invasive and less morbid procedure but long-term outcomes remain undetermined. The aim of this study was to assess long-term outcomes of POEM for patients with NAD.

Methods Records of 40 consecutive patients undergoing POEM for NAD from May 2011 to January 2016 at a single center were retrospectively reviewed. Preoperative and 6-month postoperative symptom scores, high-resolution manometry, pH testing, and timed barium swallow (TBS) data were collected. Patients were contacted by phone to obtain long-term symptom assessment. Symptoms were assessed using a standardized symptom questionnaire with scores for symptoms graded according to frequency and the Eckardt score.

Results Ten percent had minor complications with no postoperative sequelae. 90% of patients had significant improvement in their mean Eckardt scores (5.02 vs. 1.12, $p<0.001$) at early follow-up. Improvements in chest pain (1.02–0.36, $p=0.001$) and dysphagia (2.20 vs. 0.40, $p=0.001$) were seen. Significant improvements in manometric pressures and esophageal emptying on TBS were observed across groups. 38% (10/26) of patients had a postoperative pH score > 14.72. Long-term (median 48 months) symptom scores were obtained from 29 (72.5%) patients. 82% of patients (24/29) had sustained symptom improvement. A small increase in the dysphagia scores was reported in the long-term follow-up compared to the immediate postoperative period (0.36–0.89, $p=0.046$).

Conclusions Chest pain and dysphagia are effectively palliated with POEM in patients with non-achalasia disorders of the esophagus. Significant improvements are durable in long-term follow-up. Despite earlier reports by our group suggesting possible inferior outcomes from POEM for this difficult group of patients, this study is far more encouraging. POEM should be considered in the treatment of patients with non-achalasia disorders of the esophagus.

Keywords POEM · Esophageal outflow obstruction · Hypercontractile esophagus · Long myotomy · Non-cardiac chest pain · Dysphagia

The per-oral endoscopic myotomy (POEM) procedure is an established and effective treatment for achalasia, including Chicago types 1, 2, and 3. Currently, more than 6000 cases have been performed worldwide with an acceptable morbidity and excellent clinical results. Many patients present with achalasia-like symptoms and various hypercontractile and spastic manometric features but do not precisely meet criteria for any of the classic achalasia subtypes such as diffuse esophageal spasm, esophagogastric junction outlet obstruction, and hypercontractile disorder (formerly nutcracker esophagus). To date, only a few case reports have been published in peer-reviewed literature regarding POEM for such non-achalasia patients [1–6]. We hypothesize that these non-achalasia hypercontractility and spastic disorders

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of the esophagus (NAD) can be successfully treated with POEM. Herein, we report symptomatic and objective follow-up on a single center, sequential cohort of NAD patients treated by POEM.

Methods

Records of 40 consecutive patients undergoing POEM for NAD from May 2011 to January 2015 at a single center were retrospectively reviewed. After obtaining institutional review board approval, all patients presenting with symptoms of dysphagia and chest pain consistent with hypercontractile or spastic esophageal motility disorders had been offered POEM. Exclusion criteria for POEM included evidence of a hiatal hernia on endoscopy or contrast study, endoscopic esophagitis, age of less than 18 years, and inability to tolerate general anesthesia. Previous endoscopic dilation, prior botulinum toxin injection, or a history of laparoscopic esophageal myotomy were not considered exclusion criteria. Patients with defined manometric achalasia (defined as lower esophageal sphincter dysfunction in the setting of 100% failed peristalsis), including type 3 achalasia, were excluded for this study.

All patients had comprehensive preoperative subjective and objective evaluations including Symptom scores, high-resolution manometry (HRM), esophagogastroduodenoscopy (EGD), and contrast swallow studies. Preoperative assessment included a standardized validated symptom questionnaire with scores for heartburn, regurgitation, reflux, chest pain, and dysphagia graded according to frequency (grade 0—absent; grade 1—1–2/per month; grade 2—1–2/per week; grade 3—daily; or grade 4—continuous). In addition, the severity of the disorder was staged according to the Eckardt score [7]. Patients who had preoperative symptoms or endoscopic findings consistent with GERD underwent pH testing. Of the 18 patients for whom preoperative pH testing data were available 4 had a pH score > 14.72. PH tracings were specifically reviewed to rule out false-positives due to esophageal stasis. The timed barium swallow was performed for dysphagia and involved upright spot films obtained at 1, 2, and 5 min after ingestion of 100–200 mL of low-density (45% weight in volume) barium sulfate. Patients were seen in clinic 1 month and 1 year after the procedure. Surveillance EGDs were performed at 3 months and at 1 year. Manometry, pH testing, and Timed Barium swallow were also offered at 1 year. All patients were called in August 2017 (Median follow-up 48 months) to obtain long-term follow-up data.

The decision for operation was made based on clinical symptoms in the setting of hypercontractility or spasm seen on HRM pressure topography. Patients were classified according to the Chicago Classification of Esophageal manometric disorders V3 [8]. The authors retrospectively and blindly re-reviewed the HRM topography of all patients for this study (25 previously published patients were initially included [9]. Five of the original group were reclassified as Type III achalasia and excluded by consensus from this study for 20 previous and 20 new patients in the final cohort). Consensus, subjective impressions of the pressure topography by the authors were used for final classification in situations where official Chicago Classification values were unavailable. Distal esophageal spasm (DES) was defined as premature (distal latency of < 4.5 s) or simultaneous waveforms in > 20% of swallows in the absence of any normal peristalsis. Hypercontractile esophagus was defined as a distal contraction integral > 8000 mmHg s cm and/or distal esophageal contraction amplitude of > 200 mmHg that may or may not also involve the lower esophageal sphincter. Isolated Esophagogastric junction outlet obstruction (EGJOO) was defined as elevated integrated relaxation pressure and/or elevated residual pressure.

The procedure was performed as previously described [10]. Length of myotomy was individualized based on intraoperative endoscopic identification of the high-pressure zone as well as comparisons to the preoperative HRM topography and contrast studies. All myotomies were carried 2–3 cm distal across the gastroesophageal junction. Patients had an overnight hospital stay per protocol. Morbidity was defined as requiring additional procedures or prolonged hospital stay. Intraoperative esophageal injuries were scored according to the "Portland Esophagotomy Classification" [9]. These complications were defined as full-thickness entry esophagotomy, mediastinal exposure (longitudinal fiber split), esophageal/gastric mucosotomy, and full-thickness esophageal/gastric perforation (Table 1).

Routine postoperative evaluation (symptom questionnaire, HRM, EGD, timed barium swallow, and standard pH testing) was performed 6 months after surgery. A postoperative Eckardt score of < 3 (Eckardt stage 0) was considered a successful outcome. The difference in the area of the column at 1 min and 5 min quantified an estimate of esophageal emptying. 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 procedures by

Table 1 Intraoperative events according to the Portland Esophagotomy classification

I Full-thickness entry esophagotomy	1 (2.5%)
II Mediastinal exposure	100%
III Inadvertent mucosotomy	5 (12.5%)
IV Full-thickness perforation	0%
Capnoperitoneum requiring decompression	6 (15%)
Postoperative clinical sequelae	0%

using the t-test for continuous variables and the Chi-square test for categorical variables. Chi-square test and logistic regression analysis were used to compare patient and procedural characteristics.

Results

Patient demographics and preoperative symptom scores

Forty patients with a manometrically confirmed non-achalasia hypercontractility disorder of the esophagus treated with POEM were reviewed (15 hypercontractile esophagus, 11 DES, 14 EGJOO). The mean age was 61 years (± 14 years). There were 19 men and 21 women with a median duration of symptoms of 87 months (± 56 months). Overall, the primary complaint was dysphagia in 30 (75%), chest pain in 7 (17.5%), regurgitation in 2 (5%), and cough in 1 (2.5%). The median Eckardt score before surgery was 5.02 (± 0.27) and was similar in the all groups ($p = 0.17$). Fourteen patients (35%) had previous botox treatment while 17 patients (42.5%) had prior dilations. No patient had prior esophageal myotomy. Mean body mass index was 28.1 (± 6.2 kg/m^2) and mean American Society of Anesthesiology grade was 2.3 (± 0.7).

Preoperative testing

The mean resting and residual pressures at the lower esophageal sphincter were 50.7 mm Hg (± 31.5) and 21.9 mm Hg (± 17.9), respectively. There were no statistical differences between the two groups regarding mean resting pressure (hypercontractile esophagus and DES 55 vs. EGJOO 50; $p = 0.7$) and in the mean residual pressure (hypercontractile esophagus and DES 23 vs. EGJOO 21; $p = 0.97$). Mean preoperative esophageal emptying was 61.9% (± 31.2) at 5 min on timed barium swallow. Early on in our experience, patients who had preoperative symptoms or endoscopic findings consistent with GERD underwent pH testing. In the recent years, preoperative pH testing was obtained for every patient. Of the 18 patients for whom preoperative pH testing data were available 1 had a pH score > 14.72. Given patient's comorbidities and a high operative risk, we elected to treat this patient with POEM.

Operative outcomes

All procedures were completed endoscopically as planned, and there were no conversions to laparoscopy. Median hospital LOS was 1 day (range 1–2 days). The mean number of clips used to close the mucosotomy was 5. Average length of myotomy was 10.1 ± 5.3 cm. Length measurement appeared to correlate with the primary diagnosis with esophagogastric obstruction patients receiving a 7.4 ± 2.4 cm myotomy, hypercontractile esophagus patients receiving a 9.9 ± 5.4 cm myotomy, and DES patients receiving a 13.0 ± 6.2 cm myotomy ($p = 0.034$).

No major morbidity or mortality was observed. Intraoperative events listed in Table 1 did require additional interventions at the time of the index procedure (insertion of a Veress needle for capnoperitoneum or deployment of additional endoluminal clips in the event of an inadvertent mucosotomy). However, these patients did not have a deviation from our standard postoperative protocol. We routinely perform UGI on all our patients on POD 1. Overall morbidity was 10% (4 patients) due to clinically silent radiographic contained intra-tunnel contrast extravasation all of which were recognized on POD 1 and treated endoscopically (placement of additional clips) without further sequelae. These complications were categorized as Clavien–Dindo 3.

Postoperative outcomes

Clinical symptom scores

Mean Eckardt score improved significantly after the procedure from 5.02 to 1.2 ($p = 0.001$). Improvement was sustained at long-term follow-up (median follow-up of 48 months) in 80% of patients as defined by an Eckardt score < 3 (Fig. 1). Dysphagia improved at early postoperative follow-up (2.20 vs. 0.40, $p = 0.001$) (Fig. 2). Although a small increase in the dysphagia score was noted at long-term follow-up (0.49 vs. 0.83, $p = 0.046$), it was still significantly improved from before surgery ($p < 0.001$). Chest pain score also improved significantly in the postoperative period (1.02 vs. 0.37, $p = 0.001$) and at long-term follow-up ($p = 0.345$). Symptom outcomes for non-achalasia dysmotility disorders subgroups can

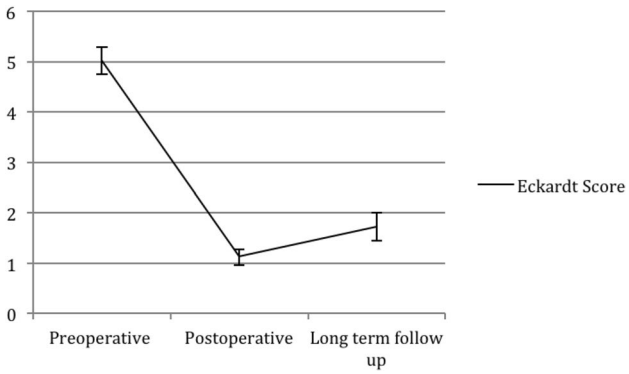

Fig. 1 Eckardt score

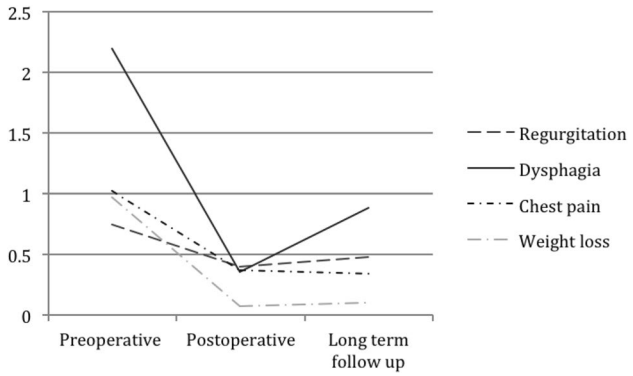

Fig. 2 Eckardt score components

be seen in Figs. 3 and 4. None of the patients who presented with chest pain developed dysphagia after the procedure. Six out of 40 (15%) patients developed new onset heartburn while 5 out of 40 (12.5%) experienced worsening of their previous heartburn symptoms. Heartburn scores did not differ significantly in patients immediately after the procedure (0.52 vs. 0.60, $p=0.74$) but there was a trend towards higher severity of heartburn at 48 months of median follow-up (1.17, $p=0.077$) (Fig. 5). The number of patients taking daily PPI before the procedure was 65%. This decreased to 30% after the procedure ($p=0.001$) On long-term follow-up, however, such number increased again to 55% ($p=0.004$) regardless of objective reflux (Fig. 6). All patients had improvement of chest pain and dysphagia at long-term follow-up except for 1 patient that experienced no change in his symptoms and 1 patient that experienced worsening symptoms in the Hypercontractile esophagus group. Among patients with post-POEM Eckardt scores > 3, two had persistent symptoms despite subsequent myotomy (one laparoscopic Heller and one endoscopic cervical myotomy).

Endoscopy

Thirty-two patients had planned 6-month postoperative esophagogastroduodenoscopies. Upon endoscopic retroflexion, the median Hill grade was 2 (6 grade 1, 16 grade 2, 6 grade 3, 4 grade 4) compared to a preoperative median Hill grade of 1 (38 grade 1, 2 grade 2). Seven patients had visible erosive esophagitis: 4 patients LA grade A (2 with Hill grade I and 2 with Hill grade II) and 3 patients LA grade B (2 with Hill grade II and one with IV). pH testing was available for 26 patients, 38% (10/26) of those had a pH score > 14.7 on follow-up. Esophagitis correlated with objective pH testing in 3 patients.

Timed barium swallow (TBS)

Postoperative 6 months of timed barium swallow was available in 24/40 of the patients. The median esophageal emptying at 5 min significantly improved from 61.9% (±31.2) preoperatively to 93.6% (±14.6), $p=0.002$. Two patients (one with DES and one with EGJOO) failed to completely empty their esophagus at 5 min although overall emptying was improved to 80%. These are among the same patients who had persistently elevated Eckardt scores and went on to repeat myotomy. Objective testing and postoperative outcomes are summarized in Tables 2 and 3.

Discussion

Non-achalasia hypercontractility and spastic disorders of the esophagus are a frequent cause of non-cardiac chest pain and dysphagia. They are associated with significant healthcare costs and compromised quality of life. Therapeutic options are limited [11–13]. Most clinicians start with anti-spasmotic drugs such as calcium channel blockers, nitrates, or tricyclic antidepressants [14], however, studies have showed

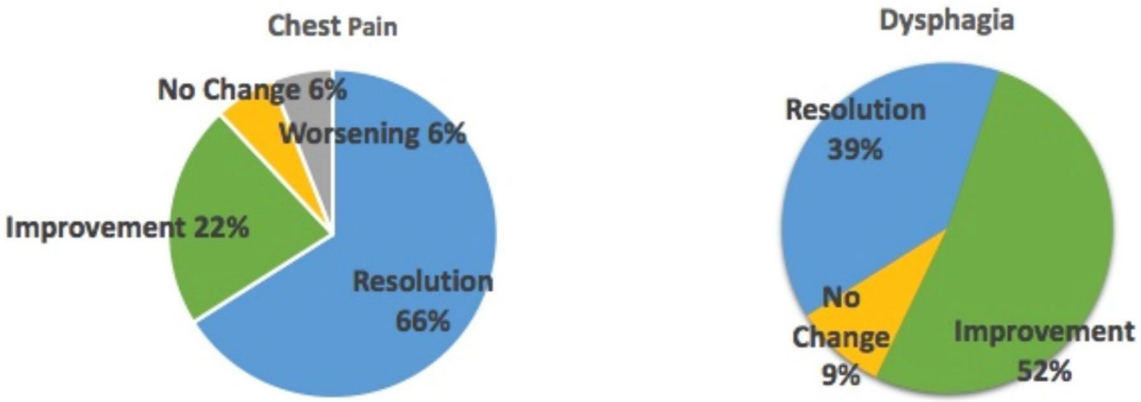

Fig. 3 Dysphagia and chest pain long-term improvement rate across all patients

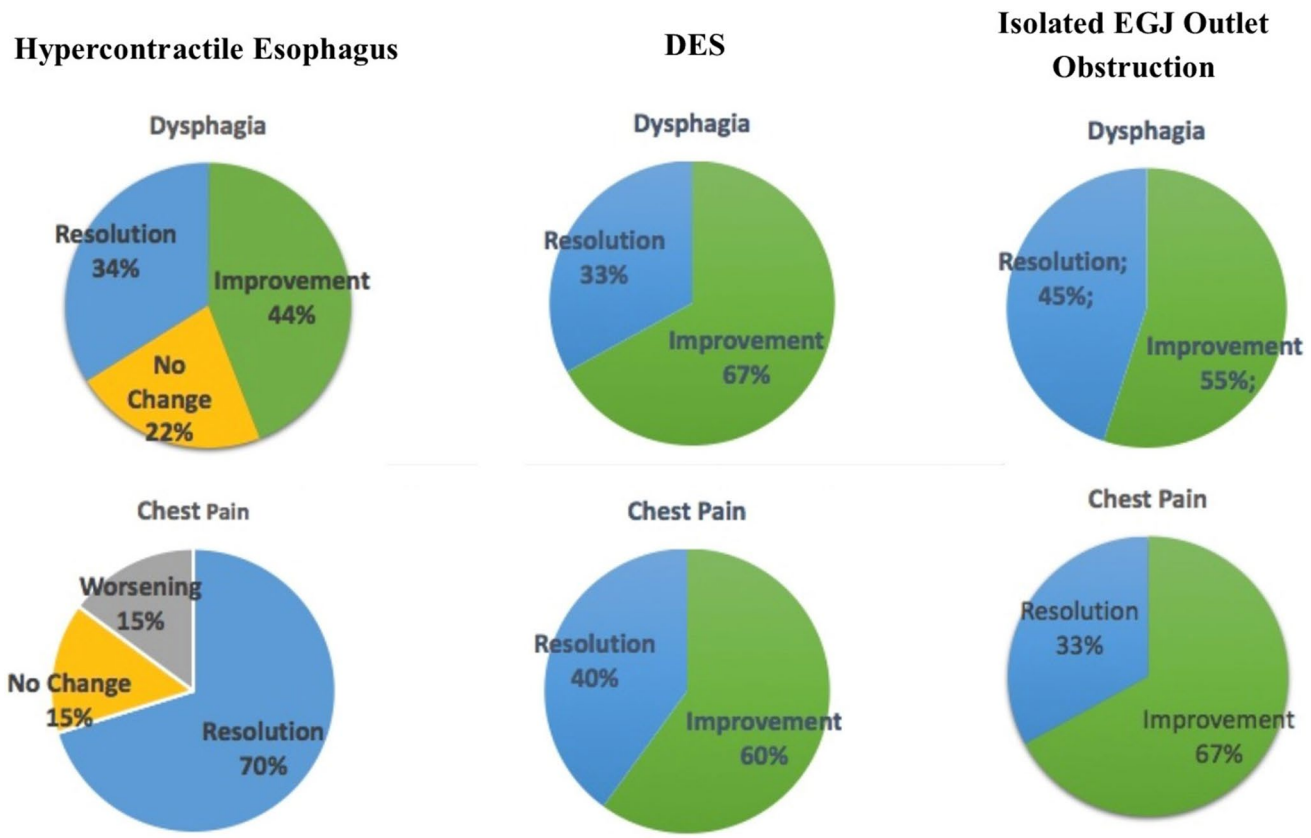

Fig. 4 Dysphagia and chest pain long-term improvement rate of each Non-Achalasia disorder subtype

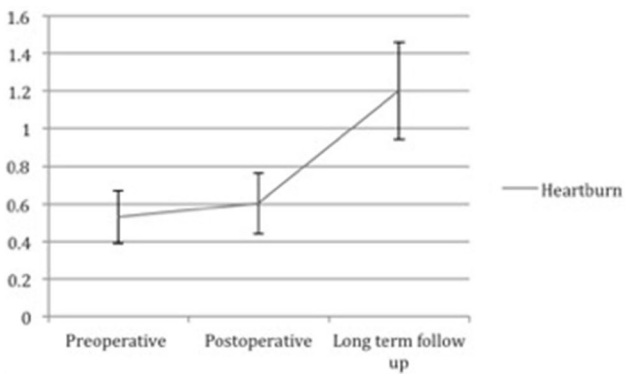

Fig. 5 Heartburn

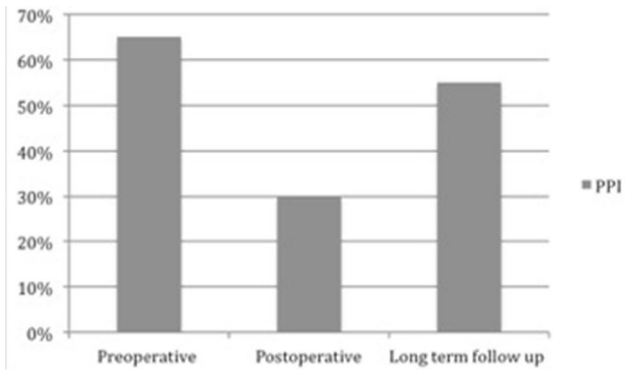

Fig. 6 PPIs usage

that medical treatment have up to 74% failure rates [15]. Traditional surgical treatments ranging from limited distal to long thoracic myotomy are controversial due to unpredictable outcomes and associated morbidity [16]. Thus, for decades, the ideal treatment of non-achalasia motility disorders has been controversial.

The use of POEM to treat both achalasia and non-achalasia hypercontractility disorders of the esophagus is increasingly discussed among esophageal specialists. There is good evidence supporting the efficacy and safety of POEM for treating achalasia with multiple publications worldwide [1–6]. However, there are only a few reports detailing outcomes for the treatment of non-achalasia esophageal motility disorders such as diffuse esophageal spasm, esophagogastric junction outlet obstruction, and hypercontractile esophageal disorder due to the relative rarity of these disorders. In 2014, Inoue et al. reported a case study of two patients with diffuse esophageal spasm who were successfully treated with

Table 2 Demographics and intraoperative details

Patient's population (Patient $n=40$)	
Age (± SD)	61.5 (± 14.0)
Diagnoses	Hypercontractile esophagus (37.5%), DES 27.5%, EGJOO (35%)
Presenting symptoms	Dysphagia 88%, chest pain (55%), regurgitation (40%)
ASA (± SD)	2.3 (± 0.7)
Length of procedure	121.9 min (± 52.8)
Gender	21F/19M
N. patients pretreated with botox	14/40 (35%)
N. patients pretreated with dilations	17/40 (42.5%)
Number of clips used	5.2 (± 1.6)
Length of stay	83% of patients discharged on POD 1 (Range 1–2 days)

Table 3 Objective outcomes

Outcome	Preoperative	Post-op	*p*
Timed barium swallow clearing (5 min)	61.9% (± 31.2)	93.6% (± 14.6)	0.002
Median Hill EGD grade	1 (range 1–2)	2 (range 2–4)	0.001
Resting LES pressure	50.7 (± 31.5)	21.9 (± 17.9)	0.001
Residual LES pressure	25.8 (± 18.4)	13.8 (±14.5)	0.392
% Positive pH test score > 14.7		10/26 (38%)	

POEM as evidenced by normalization of preoperative Eckardt score [1]. There have been additional anecdotal mentions of POEM for the treatment of non-achalasia motility disorders as occasional cases within larger achalasia experiences. One multi-institutional study, focused on POEM for spastic esophageal disorders, has been published [2]; however, in that series, type 3 Achalasia patients constituted 74% of the patient population and only 19 patients had NAD. One recent meta-analysis has looked at success rates of POEM for spastic esophageal disorders of the esophagus [17]. This meta-analysis included 8 observational studies and 179 patients, 65% of which were diagnosed with type 3 Achalasia. In that series, the clinical success rate defined by an Eckardt ≤ 3 was 87%. Interestingly success rates for patients with hypercontractile esophagus were found to be lower, which is similar to our findings. Our series of 40 patients represents an in-depth analysis of isolated non-achalasia motility disorders treated with POEM and represents to our knowledge the largest single center observational study in the literature to date.

When examined as a group, we found a significant improvement in subjective outcomes for chest pain, dysphagia, and Eckardt scores. Most patients complaining of chest pain before POEM had at least partial improvement, with 66% reporting complete resolution. Similarly, dysphagia symptoms were greatly improved or resolved for most patients (91%).

In addition to symptomatic relief with POEM, objective improvement was demonstrated as well. On manometry, LES resting pressures significantly fell and LES residual pressures decreased with normalization in 70% of patients. Furthermore, esophageal emptying improves considerably on 5-min timed barium swallow. When the subgroups are examined, diffuse esophageal spasm, esophagogastric junction outlet obstruction, and hypercontractile esophagus all have notable symptomatic improvement after POEM, with only the hypercontractile esophagus group having any failures to respond (22% dysphagia, 28% chest pain). Objective changes in LES measurements correlated with improved symptom scores supporting the concept that esophageal outflow obstruction is the etiology of chest pain and dysphagia in patients with isolated LES dysfunction.

One potential advantage of POEM is the ease with which a long myotomy can be achieved compared to traditional transthoracic approaches. Long thoracic myotomy for esophageal spasm has been reported to have a success rate ranging between 70 to 82% [18, 19]. Our study included 40 patients who had myotomies tailored to their manometric diagnosis including 50% with myotomy more than 8 cm. POEM was also safe as a treatment for non-achalasia disorders. Our data show that myotomy length is directly correlated with procedure time (data not shown). In our experience, POEMs for DES proved to be some among the most difficult because of the thickness of the esophageal muscle. However, compared to POEMs for Achalasia the lack of marked hypertrophy of the LES generally makes the procedure less challenging. All complications were minor and treated conservatively with no further sequelae. We had no conversions to laparoscopy, no procedure related mortalities, and no occurrences of

mediastinitis. There was one full-thickness esophagotomy that was recognized and repaired with clips at the time of the initial operation. Overall, we found objective and subjective success rates equal to or better than those seen in similar studies and with a substantially lower patient morbidity [15, 20, 21]. Two patients underwent repeat myotomy. The first patient was diagnosed with EGJOO and had only transient and partial symptomatic improvement after POEM and a persistently elevated EGJ relaxation pressure on repeat high-resolution manometry. She likely had an incomplete initial myotomy and was treated with laparoscopic Heller and despite an initial symptomatic improvement she then developed recurrent dysphagia. The second patient was diagnosed with DES and had an excellent initial symptomatic response after POEM. Years later, she developed recurrent chest pain and new cervical dysphagia. On repeat manometry, she had low EGJ pressures, but had a hypertensive upper esophageal sphincter and a spastic segment in the proximal esophagus. A repeat endoscopic myotomy was performed, dividing the cricopharyngeal muscle with extension through the upper esophagus, which resulted in transient resolution of dysphagia which, however, recurred 2 years later. Careful patient selection plays a very important role when considering POEM for spastic esophageal disorders. Despite that we were not able to identify any preoperative findings which could predict treatment failures.

Concerns have been raised over the generation of abnormal reflux inherent with destruction of the LES in POEM. However, recent studies suggest that these concerns regarding post-POEM reflux may be exaggerated. Inoue et al. described a series of 70 patients who underwent POEM for achalasia and NADs. Endoscopically visible post-POEM GERD was found in 32.9%. Yet only 11.4% of patients were symptomatic, and all were well controlled with PPIs [22]. Similarly, we recently published results on 100 consecutive POEM patients, with objective findings of post-POEM GERD (as evidenced by abnormal routine postoperative pH testing) in 38.2% of patients. Only 50% of these were symptomatic, and all symptomatic patients were controlled with PPI use [9]. Furthermore, 4-year follow-up suggests that the endoscopic and symptomatic features of GERD actually decrease with time [22]. Presently, the fear of the development of GERD does not seem to be prohibitory for POEM given the effectiveness of antisecretory medications. Nevertheless, we believe that postoperative studies, especially pH testing and endoscopy, should be mandatory as symptoms alone are completely unreliable in this patient population and uncontrolled reflux may cause late failure due to refractory stricture. Our current protocol follows patients closely with objective testing at 3 months, 12 months, and every 5 years thereafter. Acid reducing medications are recommended after surgery until we can assure there is no abnormal acid reflux.

In conclusion, we show that POEM is both a safe and effective treatment of non-achalasia hypercontractility disorders of the esophagus providing complete eradication of dysphagia and chest pain in a majority of patients. Our earlier data showed slightly worse outcomes for POEMs in patient with spastic esophageal disorders, however, better patient selection and improved technique resulted in better outcomes over time. POEM's unique ability to provide full access to the entire length of the esophagus, low morbidity, and minimal impact on the patient's return to normal activity sets it apart from traditional esophageal myotomy. We therefore believe that POEM should be the preferred approach for hypercontractile and spastic motility disorders of the esophagus associated with symptoms of chest pain and dysphagia that are refractory to medical therapy.

Compliance with ethical standards

Disclosures Kevin Reavis is a consultant for Boston Scientific, Endogastric Solutions and Stryker. He perceived advisory honoraria from Ethicon, Gore and Apollo. Steven Demeester and Christy M. Dunst are consultants for Bard. Lee Swanstrom is on the Scientific Advisory board of Olympus, Boston Scientific and Apollo. Filippo Filicori, Ahmed Sharata, Walaa F. Abdelmoaty, Ahmed M. Zihni have no conflict of interest or financial ties to disclose.

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