Impact of prior interventions on outcomes during per oral endoscopic myotomy

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Abstract

Background Per oral endoscopic myotomy (POEM) is performed by accessing the submucosal space of the esophagus. This space may be impacted by prior interventions such as submucosal injections, dilations or previous myotomies. These interventions could make POEM more difficult and may deter surgeons during their initial experience. We sought to determine the impact of prior interventions on our early experience.

Methods Prospective, single-center study of consecutive patients undergoing POEM. Patients were grouped according to their anticipated complexity: Group A: no prior interventions ($N = 19$); Group B: prior interventions such as submucosal injections and/or dilations ($N = 11$) and Group C: sigmoidal esophagus, prior esophageal surgery, balloon dilation >30 mm ($N = 8$). We compared operative times, inadvertent mucosotomy rates, complications and short-term outcomes between groups.

Results A total of 38 patients underwent POEM for achalasia subtypes: I ($N = 9$), II ($N = 19$) and III ($N = 7$). Three had other dysmotility disorders. Patients between the groups were similar. Operative times were similar between Group A and Group B but significantly longer for Group C (133 vs. 132 vs. 210 min, $p = 0.001$). Mucosotomy rates were highest in Group A (6/19) with 1 each in Group B/C ($p = 0.46$). One patient in Group A required an esophageal stent. Eckardt scores improved in all groups (6–1; 8–2; 6–0.5, $p = 0.73$), and postoperative GERD-HRQL scores were similar. One patient underwent laparoscopic myotomy for persistent symptoms with no improvement, and one patient underwent esophagectomy for a sigmoid esophagus and persistent symptoms despite adequate myotomy.

Conclusion A prior intervention does not seem to impact short-term clinical outcomes with POEM. Patients who had submucosal injections or small caliber dilations are similar to patients with no prior inventions; however, patients with a sigmoid-shaped esophagus and/or a prior myotomy require nearly double the operative time. Endoscopists undertaking POEM should consider these during their learning curve.

Keywords Achalasia · Per oral endoscopic myotomy (POEM) · Balloon dilation · Botulinum toxin · Myotomy · Outcomes

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Performance of a distal esophageal myotomy for the treatment of achalasia requires access to the submucosal layer of the esophageal wall. This potential space is accessed during laparoscopic modified Heller myotomy (LHM) by division of the longitudinal and circular muscle layers, whereas during per oral endoscopic myotomy (POEM), it is accessed by incising the mucosa and muscularis mucosae layers. Regardless of the approach, there is theoretical concern that prior intervention with esophageal dilation or submucosal injection of botulinum toxin could obliterate this potential space and impact the outcome of the procedure. The impact of prior interventions on the

performance of a LHM has been debated with studies showing no significant impact [1, 2] and other studies demonstrating longer hospital stay, increased perforation rates and worse outcomes and higher reoperation rates [3–5].

There is a paucity of similar data on the impact of these prior interventions on the conduct and outcomes of POEM [6–8]. Since POEM more so than LHM is dependent on accessing the submucosal space to create the space within which the surgical myotomy occurs, understanding the impact is important. Moreover, as more endoscopists embrace POEM for this uncommon disease, they may unnecessarily avoid these prior intervention patients during their initial experience and potentially slow their mastery of POEM. Therefore, we sought to review our experience and hypothesized that the effect of prior interventions on POEM would have minimal impact on clinical outcomes but may lengthen operative time.

Materials and methods

We performed a retrospective review of a prospectively maintained achalasia database and chart review of consecutive POEM procedures performed at Swedish Medical Center from July 2014 until March 2016 beginning with our first POEM patient. Patients were included if they had a diagnosis of achalasia or other dysmotility disorders based on history, radiographic findings and high-resolution manometry. Patients with prior dilations, botulinum injections, myotomies and other esophageal surgeries were included. We did not have any contraindication to POEM except inability to undergo general anesthesia. The institutional review board of Swedish Medical Center approved this study. Individual patient consent was waived due to the retrospective nature of the study.

To analyze the data, we grouped patients a priori based on our experience with LHM according to their anticipated difficulty and irrespective of their achalasia subtype. Three groups were created based on the patient's prior endoscopic interventions, history of esophageal surgery and radiographic findings on timed barium swallow or barium swallow:

- Group A (no prior interventions)—patients with an esophagus width less than 6 cm on imaging and without sigmoidal deformation or prior interventions.
- Group B (prior interventions)—patients with an esophagus width <6 cm on imaging, without sigmoidal deformation, but with prior balloon (<30 mm) or bougie dilations (<20 mm) and/or botulinum toxin injections.

- Group C (complex interventions)—patients with sigmoid-shaped esophagus defined as at least two turns, esophageal width >6 cm on imaging, prior myotomies/esophageal operations, or dilations using a large caliber balloon (30–40 mm).

All patients underwent a preoperative evaluation consisting of a detailed history and physical, upper endoscopy, timed barium study and high-resolution manometry. Prior to POEM, patients were placed on a liquid diet for 3 days with clear liquids only on the day prior to surgery. Nystatin 500,000 units swish and swallow was given four times a day for 3 days. Peri-operatively, patients were given standard antibiotic prophylaxis and dexamethasone 6–8 mg IV to reduce swelling. Postoperatively, patients underwent a water contrast and thin barium swallow on the first postoperative day. If satisfactory, patients were provided clear liquids for 24 h and advanced to full liquids for 7 days before solid food was introduced. In follow-up, all patients were recommended to undergo repeat testing consisted of upper endoscopy and Bravo pH testing and encouraged to repeat their high-resolution manometry at 6 months. A timed barium swallow was acquired at 12 months.

We also used four different quality-of-life metrics to assess esophageal function and capture potential side effects of the POEM procedure including Eckardt scores [9], Quality of Life in Reflux and Dyspepsia questionnaire (QOLRAD) [10], GERD-HRQL [11] and a modified Dakkak dysphagia severity score (DSS) [12]. These validated surveys have been described previously, but briefly Eckardt scores range from 0 to 12 with a lower score indicating improved quality of life, QOLRAD scores range from 1 to 7 with a higher score indicating better quality of life, GERD-HRQL scores range from 0 to 54 with a lower score indicating less GERD-type symptoms and DSS scores ranging from 0 to 45 with a higher score indicating improved swallowing function. These metrics were obtained preoperatively, at 2, 6 weeks and 6–12 month follow-up. Patients with missing information were contacted by phone for follow-up and underwent a standardized interview and scoring.

To determine the impact of prior interventions, we defined the following primary outcomes: operative time (scope insertion to scope withdrawal), myotomy length and length of procedure per cm myotomy (LOP/cm). The secondary outcomes were the four quality-of-life metrics, inadvertent mucosotomy rates and other complications. We defined a mucosotomy as a full thickness breach of the mucosa identified by passage of wire or inability to maintain the tunnel with water instillation or air insufflation and an identified injury when viewed from the esophageal or gastric lumen. Intraoperative data were collected and analyzed in all patients who underwent

successful completion of the POEM procedure. Both operative time and mucosotomy events were plotted out by procedure number and then divided into tertiles based on procedure number to determine whether learning curve had any influence on these two outcomes. Postoperative quality-of-life metrics were analyzed in patients with 6 or more weeks of follow-up.

POEM preparation and technique

The POEM team consisted of two thoracic surgeons (BL, RA), an interventional gastroenterologist (DS), and three esophageal fellows in training. A consistent operating room team was used. The physician team underwent a structured training program including a didactic, hands-on (explant and live models) and case observation POEM course followed by an additional live model laboratory with the entire POEM team [13]. An experienced proctor was present for the first three cases.

Our POEM technique is based on the stepwise procedure described by Dr. Swanstrom with some modifications [14]. Briefly, upper endoscopy was performed to evacuate any residual debris and establish baseline measurements of the proximal and distal extent of the high-pressure zone (HPZ). The myotomy began 2 cm above the proximal high-pressure zone and extended 2 cm past the distal extent. A small longitudinal mucosotomy was made approximately 5 cm above the intended upper extent of the myotomy at the 2–3 o'clock position after a submucosal wheal was raised. The submucosal tunnel was developed with hydrodissection and electrocautery using electrosurgical water jet knife (Erbe, Marietta, GA, USA). In addition to marking the distal extent of the myotomy with concentrated methylene blue, we passed a pediatric endoscope along side the primary scope into the stomach and via retroflection confirmed that the myotomy extended onto the cardia. The mucosotomy was closed with either endoscopic clips (Boston Scientific, Marlborough, MA, USA) or endoscopic sutures (Apollo Endosurgery, Austin, TX, USA).

The lower esophageal sphincter was assessed prior to myotomy and after myotomy by placement of the endoluminal functional lumen imaging probe (EndoFLIP, Crospon, Galway, Ireland) catheter. We considered our myotomy to be complete when the waist of the image from the imaging probe was negated and endoscopically the sphincter would easily open with insufflation by the endoscope.

Capnoperitoneum and pneumothorax were monitored closely with anesthesia using peak airway pressure, abdominal examination and the presence of hemodynamic alterations. The stomach was deflated first to assess for resolution. If there were persistent elevations in airway pressure and/or the abdomen was taut, we performed needle decompression of the abdomen below the left subcostal margin. The presence of pneumothorax was considered if this did not resolve the problems.

Statistical analysis was performed by IBM-SPSS software (Version 17). Continuous variables were compared before and after surgery within groups using a student's t test. The comparison between groups was made with an analysis of variance calculation. Categorical variables were compared via Pearson's Chi-square test. Statistical significance was defined as a p value equal to 0.05 or less.

Results

A POEM procedure was initiated in 39 patients, and 38 patients successfully underwent POEM from July 2014 till March 2016. The indication for POEM was achalasia Type I (10), Type II (19) and Type III (7) and other dysmotility disorders such as EGJ outflow obstruction (2) and Jackhammer esophagus (1). After grouping, 19 patients were placed into Group A, 11 patients into Group B and 8 patients into Group C. Baseline clinical characteristics for each group are found in Table 1.

The prior interventions in Group B ($N = 11$) consisted of 6 patients who were only dilated with savory dilators or small caliber balloons. Five patients underwent submucosal injections of botulinum toxin including 1 patient who underwent injection 4 times separate times. In Group C ($N = 8$), there were 6 patients with a sigmoid-shaped esophagus including two had also undergone a prior laparoscopic myotomy and fundoplication. One patient underwent large caliber balloon dilation to 35 mm, and one patient underwent tracheoesophageal fistula repair during infancy just below the level of the carina as well as multiple prior abdominal surgeries.

The overall operative times (Table 2) were comparable between Groups A and B, but patients in Group C experienced significantly longer operative times with almost twice the time at 210 min ($p \leq 0.001$). These findings were also seen when the length of procedure was assessed by myotomy length (LOP/cm of myotomy) with Group C also experiencing a significantly higher LOP/cm myotomy value at 33.2 min per cm of myotomy ($p = 0.01$).

The overall inadvertent mucosotomy rate was 21 % with all but one closed uneventfully with endoscopic clips. This Group A patient underwent stent placement at the GEJ to cover the mucosotomy. The stent was removed on POD#2, and a swallow study was performed on POD#4 showing no leak. Mucosotomy rates were highest in Group A with 6 of 19 (31.6 %), followed by Group B with 1 of 11 (8.3 %) and Group C with 1 of 8 (11.1 %) ($p = 0.46$). There were no leaks on postoperative imaging studies. Further analysis of

Table 1 Demographics

Characteristic	Group A N = 19	Group B N = 11	Group C N = 8	p value
Age	58 (49–61)	60 (52–63.3)	55 (44–68)	0.89
Gender M/F	11/8	4/7	5/3	0.62
BMI (median)	25.1	25	27.2	0.83
(IQR)	(23–32.5)	(22.7–34.7)	(23.7–30.7)	
ASA 1-2	11 (57.9 %)	9 (81.8 %)	4 (50 %)	0.36
ASA 3	8 (42.1 %)	2 (18.1 %)	4 (50 %)	
Follow-up (weeks)	35	25.3	33.7	0.62
(IQR)	(12.3–46.9)	(22.7–34.7)	(12.4–47.5)	

BMI body mass index, *ASA* American Society of Anesthesiology class, *IQR* interquartile range

Table 2 Operative data

Metric	Group A N = 19	Group B N = 11	Group C N = 8	p value ANOVA
Operative time (min) (IQR)	133 (120–148)	132 (121–150.5)	210.5 (186.3–282)	<0.001
LOP/cm myotomy (IQR)	20.8 (19.3–24.6)	22 (19.2– 25.3)	33.2 (31.9–46.7)	0.01
Length of myotomy (cm) (range)	6 (6–7)	6 (6–7)	6 (6–7)	0.73
# Endoscopic clips (range)	7 (5–9)	7 (5–8)	7 (6–11)	0.73

LOP length of procedure, *IQR* interquartile range

the 8 mucosotomies revealed that 6 of 8 occurred at or below the high-pressure zone of the GEJ. Bleeding was associated with an inadvertent mucosotomy in 2 of 8 injuries (Table 3).

When operative time was plotted by consecutive procedure number, operative times were generally clustered between the interquartile range of 124.5–171.5 min (median time 146 min). Group C was clustered at or above the third quartile of 171.5 min where as Group A was clustered around the first quartile with the exception of 2 patients who experienced a mucosotomy requiring closure. Group B operative times were all below the third quartile limit (Fig. 1). Mucosotomies occurred throughout the time period of the study with an even distribution in Group A between the tertiles (Fig. 2).

An insufflation needle to decompress the capnoperitoneum was utilized liberally at first and was noted to be highest in Group A with 10 of 19 (52.6 %) requiring decompression and lowest in Group C with 3 of 8 (37.5 %) (p = 0.9). Needle decompression was successful immediately and well tolerated by all patients without any sequelae.

There were no major or serious complications in any of the groups. However, we did make several observations. One patient in Group C had prominent vessels in the submucosal tunnel and intragastric space. Even with cautery forceps, we encountered significant bleeding of approximately 200 mL, which was controlled uneventfully and did not require transfusion. One patient with sigmoid-shaped esophagus, but no prior interventions, was aborted due to difficulty accessing the submucosal space. Her esophagus was short, and her entry site was chosen just at a large proximal bend of her tortuous esophagus. We were unable to lift the mucosa safely and aborted after
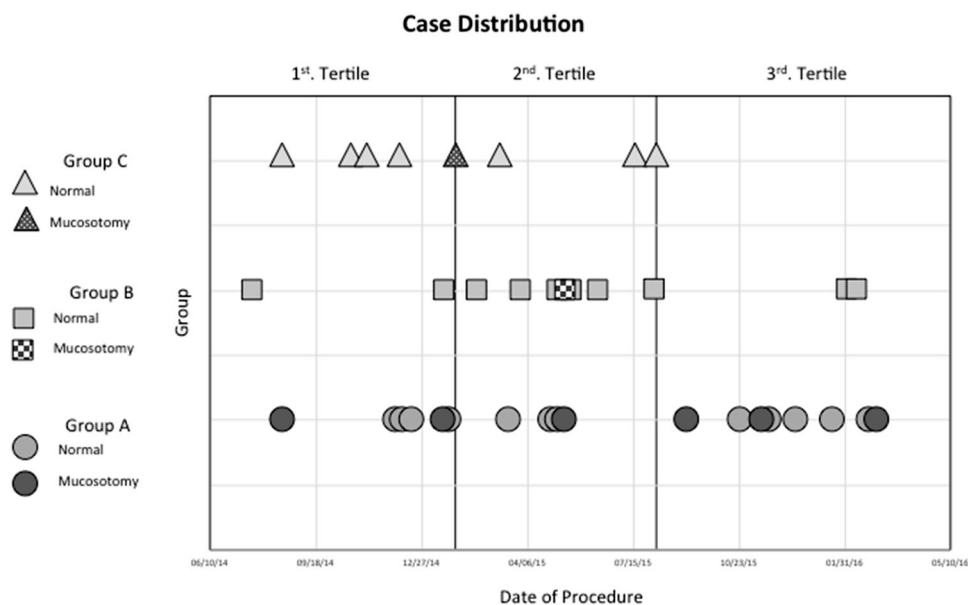
Table 3 Complications and reoperations

Events	Group A N = 19	Group B N = 11	Group C N = 8	p value
Mucosotomy	6 (31.6 %)	1 (9.1 %)	1 (12.5 %)	0.46
Needle decompression	10 (52.6 %)	5 (45.5 %)	3 (37.5 %)	0.9
Complications	Stent	None	None	na
Reinterventions	0	0	Esophagectomy Lap Heller	na
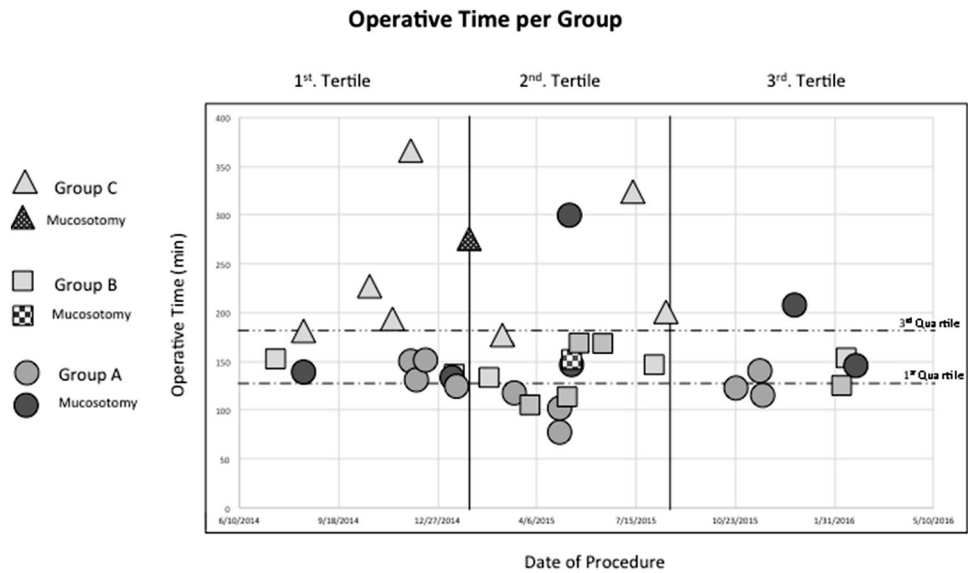
significant attempts. She underwent uneventful closure of
the incision in the mucosa. She then underwent successful
laparoscopic Heller myotomy and partial fundoplication
during the same hospitalization where we noted that the
submucosal space was similarly obliterated.

The overall median length of follow-up was 26.9 weeks
(IQR = 4.7–39.9) with all groups demonstrating signifi-
cant improvements in the subjective outcomes (Table 4).
Eckardt scores improved after POEM across each group
with postoperative scores ranging from 0.5 to 2 ($p = 0.2$).
QOLRAD and GERD-HRQL scores significantly improved
in Groups A and C, whereas Group B was less distin-
guished and although it showed numerical improvement
for both QOLRAD and GERD-HRQL scores; this did not

attain statistical significance. When compared among all
groups, the postoperative QOLRAD and GERD-HRQL
scores did not differ significantly. Preoperative dysphagia
was more severe in Group C patients at 0.75 ($p = 0.008$),
but after POEM, swallowing function improved signifi-
cantly within the groups with no difference across the
groups ($p = 0.57$).

In the follow-up period, 2 patients in Group C under-
went further procedures for persistent symptoms. The
patient with a history of tracheoesophageal fistula repair
required laparoscopic Heller myotomy for persistent dys-
phagia and delayed emptying on timed barium swallow
despite adequate myotomy assessed by endoscopy and
manometry. His symptoms did not improve significantly

Table 4 Subjective quality-of-life outcomes

Quality of life	Group A N = 19	Group B N = 11	Group C N = 8	ANOVA p value pre/post
Eckardt				
Pre-op	6 (6–8)	8 (5–8.5)	6 (6–7.5)	0.73
Post-op	1 (0.5–1)	2 (0–4)	0.5 (0–2.5)	0.2
p value	<0.001	<0.001	<0.001	
Dysphagia severity				
Pre-op	15 (7–28)	19 (14–29)	0.75 (0–2.6)	0.008
Post-op	37 (27.8–45)	36.5 (22.8–42.4)	34.3 (30.3–37.5)	0.57
p value	0.002	0.29	0.002	
QOLRAD				
Pre-op	4.1 (3.9–5.2)	3.4 (3–5.3)	4.6 (2.5–5.1)	0.93
Post-op	6.5 (5.9–7)	6.3 (4.7–6.9)	6.9 (6.7–7)	0.61
p value	<0.001	0.16	0.08	
GERD-HRQL				
Pre-op	13 (8–27)	15 (13–17)	20 (11–28)	0.91
Post-op	5 (1.5–7)	6 (3.8–16)	1 (11–28)	0.11
p value	0.02	0.5	0.05	

All values are median with interquartile range (IQR)

after the second operation, and he developed reflux esophagitis. One patient with end-stage esophageal function underwent esophagectomy for continued dysphagia, weight loss and an abnormal timed barium swallow. This patient refused a recommendation for esophagectomy from an experienced esophageal surgeon 5 years prior to presenting to our group. The procedure was undertaken as a last resort prior to esophagectomy and resulted in a noticeable loosening in the LES based on distensibility measurements and endoscopic assessment. However, continued stasis and symptoms led the patient to agree to esophagectomy.

Discussion

The primary finding in this study of the initial 38 consecutive POEM procedures is that patients with no prior interventions and an esophageal width <6 cm had similar operative and clinical outcomes to patients who had undergone small caliber dilations and submucosal injections of botulinum toxin, whereas patients with a sigmoid-shaped esophagus, esophageal width >6 cm, prior esophageal surgery and large caliber balloon dilation (>30 mm) had significantly longer operative outcomes, but similar complication rates and short-term clinical outcomes.

Overall, these results support the findings in several other studies [6–8] that prior interventions do not appear to have a significant impact on the operative time of the

POEM procedure, the complication rate or the short-term outcomes. However, endoscopists should be prepared for the difficult submucosa space because these series identify patients who have been particularly challenging after prior interventions. For example, Orenstein et al. [6] described a challenging case after multiple submucosal injections and dilations that led to a 2-cm distal mucosotomy that required stent placement and prolonged hospitalization. Furthermore, the vascularity of the tunnel can also present a challenge not only during the case as we experienced with significant blood loss during one case but also post-operatively as described by Sharata et al. [7] who had to clip an intramural bleed on postoperative day one.

Based on our case complexity grouping, we expected to see a higher rate of mucosotomies occurring in more complex cases particularly Group C, yet we had more mucosotomies in our most straightforward group—Group A. Instinctively, we assumed that this might be due to the learning curve but the occurrences are distributed evenly between the tertiles (Fig. 2). We are not sure why we had more mucosotomies in Group A, which we assume to be straightforward. There are two potential explanations. First, creation of the tunnel at the GEJ is observed to be a tighter space which puts the mucosa closer to the cautery. This may explain why most of our mucosotomies have occurred at the GEJ. We have learned from others that division of the circular fibers at the GEJ creates more space and potentially could lessen our mucosotomy rate with more experience. Second, bleeding was associated with the others and may be a factor. We have been more judicious

about identifying submucosal vessels and cauterizing them with the grasping forceps. We have observed that bleeding obscures the anatomy, and if it requires cautery on both the mucosal and muscular sides to control bleeding potentially, this will create a mucosal defect.

Our study differs from the prior studies in several ways. First, we separated the use of dilation based on likelihood of impact on the submucosal space. The use of a balloon larger than 30 mm or a traditional pneumatic achalasia dilation balloon is designed for disruption of muscle fibers and as such likely has a greater effect on the submucosal space. Comparatively, a smaller caliber dilation (<30-mm balloon or 20-mm bougie) has little impact on the muscular layer or the submucosal space. Thus, we elected to place the patients undergoing pneumatic dilation into our higher complexity Group C for this study. Second, in Group C, we also included the sigmoid-shaped esophagus reasoning that it represents more advanced disease, and mucosal inflammation from stasis would create scarring and vascularity. Although there is no difference in clinical outcome in this group, the operative times are longer. It is possible that the longer operative times for Group C reflect our learning curve, but the prior studies also appear to be including their initial series of POEM cases. These times are likely to improve with more experience but separating out these more complex cases identifies a more advanced disease process and provides a more realistic expectation of the case complexity.

The short-term outcomes of POEM reported in these same studies are compelling, but they remain short-term outcomes with median follow-up ranging from 3 to 10 months. The question remains whether the longer-term outcomes will remain as good. The 3-year results of POEM in a series of 500 patients where 40 % had a prior intervention suggest that outcomes are at least durable for that period, although the outcomes were not specifically broken out for prior interventions [15]. However, the long-term results from patients undergoing LHM with prior interventions provide some reason for caution. Portale et al. [5] analyzed 248 LHM divided into three groups: no interventions (203), pneumatic dilation 19 and botulinum toxin (22) + dilation (4) at a mean follow-up of 41 months. In this series, prior botulinum toxin injections resulted in less relief of dysphagia and when botulinum toxin was combined with dilation, the resolution of dysphagia was worse. Similarly, Smith et al. [4] analyzed 154 out of 209 patients that underwent prior interventions. Intraoperative perforations were more common at 9.7 versus 3.6 % ($p < 0.05$); pulmonary symptoms and dysphagia were more common at 10.4 versus 5.4 % ($p < 0.05$) in early follow-up in the prior intervention group. Furthermore symptomatic failure requiring further treatment occurred in 19.5 % of pretreated patients versus 10.1 % of untreated patients ($p < 0.05$).

The utility of the groupings we used to compare our results provided an unintended observation. We believe that this grouping might have several future purposes. First, it may be useful for endoscopists beginning to adopt POEM to determine which patients might be expected to have a longer procedure time based on the patient's characteristics determined preoperatively. This may guide surgeons initiating their POEM practice toward cases that may be easier for them initially. Second, it might be used to counsel patients about their clinical outcomes because even though there seemed to be no difference in clinical outcomes, two of our patients in Group C went on to additional surgery because of a more advanced disease process. Lastly, this grouping system could be used in future studies allowing more consistent comparison of results across different studies though it requires some validation.

There are several limitations to our study. First, the sample size is small, and therefore, it is difficult to make definitive conclusions. Nevertheless, these results are similar to other series evaluating prior interventions. Second, our clinical results are short term, and we cannot make any comment about how prior interventions or inadvertent mucosotomies influence the medium or long-term outcomes. Lastly, these procedures represent our initial experience and the inadvertent injuries and operative times will likely decrease with greater experience.

Conclusion

A prior intervention does not seem to impact short-term clinical outcomes with POEM. Patients who have had submucosal injections or small caliber dilations respond similarly to patients with no prior inventions; however, patients with a sigmoid-shaped esophagus, forceful pneumatic dilation and/or a prior myotomy appear to require nearly double the operative time. Endoscopists undertaking POEM should consider these groupings of patients when selecting patients for POEM especially during their learning curve.

Compliance with ethical standards

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