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Transoral incisionless fundoplication with or without hiatal hernia repair for gastroesophageal reflux disease after peroral endoscopic myotomy

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ABSTRACT

Background and study aims Gastroesophageal reflux disease (GERD) following peroral endoscopic myotomy (POEM) occurs in 40% to 60% of patients. There are limited data evaluating antireflux surgery or transoral incisionless fundoplication (TIF) for refractory post-POEM GERD.

Patients and methods In a single-center prospective cohort study, consecutive patients with medically refractory post-POEM regurgitation and/or GERD treated with TIF or combined laparoscopic hernia repair and TIF (cTIF) were evaluated. Baseline evaluation: GERD-Health Related Quality of Life (GERD-HQRL) and Reflux Symptom Questionnaire 7-day recall (RESQ-7) questionnaires, EGD, high-resolution manometry (HRM), 48-hour pH test off proton pump inhibitors (PPIs) and impedance planimetry of the esophagogastric junction (EGJ) to calculate the diameter distensibility index (EGJ-DI). A PPI was taken twice daily for 2 weeks after TIF and restarted later if required. Patients returned 9 to 12 months after treatment when all preoperative studies were repeated. Quality of life, pH studies and EGJ metrics before and after antireflux surgery were compared.

Results Seventeen patients underwent TIF (n = 2, 12%) or cTIF (n = 15, 88%) a mean 25±15 months after POEM. At follow-up a mean of 9±1 months after TIF/cTIF, patients required less frequent daily PPIs (n = 0.001), were more satisfied (P = 0.008), had improved GERD-HQRL (P = 0.001), less intensity and frequency of GERD (P = 0.001) and fewer reflux episodes (P = 0.04) by pH testing. There was no change in EGJ-DI, EGJ diameter, integrated relaxation pressure, % total time pH <4, or DeMeester score.

Conclusions TIF and cTIF for difficult-to-control post-POEM GERD appear safe, decrease PPI use and reflux episodes, and improve QOL without significant change in IRP, EGJ compliance, diameter or esophageal acid exposure time.

Introduction

Laparoscopic Heller myotomy (LHM) is the most common surgical procedure for achalasia and other motility disorders associated with a hypertensive lower esophageal sphincter (LES). This operation is usually performed concomitantly with a fundoplication to decrease the incidence of postoperative gastroesophageal reflux disease (GERD). Peroral endoscopic myot-

omy (POEM) is an incisionless endoscopic procedure that provides comparable symptom relief to LHM for treatment-naïve achalasia [1]. However, beause no antireflux procedure is routinely offered after POEM, post-procedure GERD is more common than LHM with fundoplication [2].

Patient-reported symptoms, response to proton pump inhibitor (PPI) therapy, and mild esophagitis on endoscopy are often insufficient to diagnose GERD in an average population [3]. Furthermore, patients with achalasia and other esophageal motility disorders may have discordant objective findings and reported symptoms of GERD after myotomy of the LES [4, 5, 6]. Therefore, objective testing by esophagogastroduodenoscopy or pH testing rather than patient-reported symptoms may be required to diagnose post-POEM GERD [7].

Accurate identification and determination of the severity of GERD after POEM is critical to triage patients to observation, dietary or lifestyle modifications, antisecretory therapy, surgery, or alternative treatments. Most patients, fortunately, experience only mild symptoms and respond well to conservative measures and/or PPIs [8]. However, some patients continue to experience symptomatic regurgitation, heartburn, or complications of esophagitis, such as strictures and require additional treatment options.

Mechanical treatment of refractory post-POEM GERD has included laparoscopic antireflux surgery [9], endoscopic full-thickness plication [10], and transoral incisionless fundoplication (TIF) [11, 12, 13]. However, studies evaluating the role of TIF in these patients are limited by small cohorts, retrospective study design, and limited assessment of quality of life (QOL) and objective measures of esophageal acid exposure and regurgitation. Furthermore, there have been no reports to date describing concomitant laparoscopic hiatal hernia/crural repair and TIF (cTIF) for the treatment of post-POEM GERD. Therefore, in this single-center prospective study, we report the use of TIF alone or cTIF for consecutive patients with refractory post-POEM GERD.

Patients and methods

Patient selection and study design

This Institutional Review Board-approved prospective study (ClinicalTrials.gov NCT04306380) evaluated consecutive patients between 2018 and 2022 at Indiana University Health Hospital in Indianapolis with medically refractory post-POEM GERD and treated with TIF alone or cTIF with at least 6 months follow-up after antireflux surgery. Standard evaluation at our institution before POEM includes high-resolution impedance esophageal manometry (HRM), functional lumen imaging probe (FLIP) of the gastroesophageal junction (GEJ), and Eckardt score calculation (ES).

Each motility disorder was characterized after manometry by the Chicago Classification version 3.0 [12]. A FLIP catheter was inserted during preoperative EGD, and volumetric distension to 50 mL was performed to calculate the esophagogastric jejunal distensibility index (EGJ-DI) [14]. All POEM procedures were performed by two gastroenterologists and included myotomy in the proximal-to-distal direction extending approximately 2 cm into the gastric cardia. Patients were instructed to use a PPI twice daily for 2 weeks at discharge with the option to restart only for apparent persistent symptoms of GERD.

Follow-up after POEM

Between 9 and 12 months after POEM, all patients were offered same-day repeat HRM, ES calculations, FLIP of the EGJ, and ambulatory wireless pH testing after cessation of all antisecretory therapy for at least 1 week [7, 15]. For same-day testing, unsedated HRM was performed initially, followed 1 to 2 hours later by EGD, FLIP measurement, and placement of the wireless capsule (Bravo, Medtronic, Minneapolis, Minnesota, United States). When all tests could not be performed on the same day, these were all completed within 1 month. The severity of endoscopic esophagitis was graded by the Los Angeles Classification [16], and the retroflexed appearance of the GEJ was assessed by the Hill Classification [17]. After endoscopy and pH testing, the diagnosis of GERD was determined using the Lyon consensus criteria, namely total time acid exposure time > 6% or LA Grade C or D esophagitis [18].

Patients with objective evidence of post-POEM GERD and class A or B esophagitis were offered lifestyle changes and once-daily PPI medications. If a once-daily PPI was inadequate to control symptoms or initial testing showed class C or D esophagitis, then twice-daily PPI was prescribed.

Criteria for antireflux surgery

Inclusion criteria for antireflux surgery to treat post-POEM regurgitation or GERD were: 1) GERD as determined using the Lyon consensus criteria [18]; 2) desire to stop or decrease medications when PPI-dependent or; 3) symptoms were inadequately controlled with high-dose PPIs and/or lifestyle changes. Exclusion criteria included: 1) body mass index ≥ 40; 2) LA class C or D esophagitis despite at least twice-daily PPIs; 3) esophageal stricture; and 4) previous foregut surgery requiring intestinal resection, reduction, or diversion (i. e., bariatric surgery). Concomitant laparoscopic hiatal hernia/crural repair and TIF (cTIF) were considered for a Hill Grade III-IV GE junction and/or hiatal hernia ≥2 cm. A solo TIF procedure was considered for a Hill Grade I-II GE junction and hernia ≤2 cm. Patients who agreed to undergo cTIF or TIF consented for both the procedures and research study.

Consented patients completed a GERD Health Related Quality of Life (HRQL) Questionnaire [19] and Reflux Symptom Questionnaire 7-day recall (RESQ-7) questionnaire [20] before surgery. The GERD-HQRL is a 16-question survey that evaluates the severity and impact of heartburn and regurgitation and overall satisfaction with the present condition. The RESQ-7 is a 13-symptom questionnaire that assesses the frequency and intensity of four components (heartburn, regurgitation, burping, and hoarseness/cough/dysphagia).

Laparoscopic surgery

All patients underwent general anesthesia, and one thoracic surgeon performed all laparoscopic procedures. An intraoperative esophagogastroduodenoscopy (EGD) was performed to evaluate the hiatal hernia. Laparoscopic repair was performed

with three or four 5-mm and one or two 12-mm ports. After exposing the hiatus, the distal esophagus was circumferentially mobilized, preserving the anterior and posterior vagus nerves. Dissection was continued into the mediastinum to mobilize the distal esophagus, assuring the GEJ is 3 cm below the hiatus without tension. The short gastric vessels were not routinely divided. A posterior cruroplasty was performed with interrupted suturing. Insufflation was released, and a repeat EGD was performed to confirm a satisfactory reduction of the paraesophageal hernia. Ports were then removed, incisions closed, and the patient was placed in a partial lateral decubitus position to complete the TIF.

TIF 2.0 procedure

All procedures were performed by a single operator under general anesthesia, as previously described [21]. EGD was first performed to evaluate the location of the GE junction, hernia size, GEJ Hill Grade, and the presence of any esophagitis. Next, a 54F bougie dilation of the upper esophageal sphincter was performed. The EsophyX device (Endogastric Solutions, Redmond, Washington, United States) was loaded onto a standard upper endoscope and advanced into the distal stomach. The device was rotated to the 11 o'clock (posterior wall), 1 o'clock (anterior wall), and 5 to 7 o'clock (greater curve) positions where six, six, and eight polypropylene fasteners were placed, respectively. Additional fasteners were placed as necessary to create a 240- to 270-degree fundoplication with a ≥2 cm high-pressure zone.

Follow-up after antireflux surgery

Patients undergoing laparoscopy were admitted to the surgical service and discharged when pain control, bowel function, and oral intake were deemed adequate. Solo TIF patients were considered for same-day discharge. All patients were given a PPI twice daily for 2 weeks after discharge and instructed to restart only for recurrent symptoms. Patients were phoned 1 and 2 weeks after TIF to assess for short-term adverse events (AEs).

Between 9 and 12 months after antireflux surgery, all patients were offered HRM, ES calculations, FLIP of the EGJ, ambulatory wireless pH testing off antisecretory therapy, and updated GERD-HRQL and RESQ-7 questionnaires off PPIs.

Study outcomes and definitions

The primary outcome assessed was a change of GERD-HRQL and RESQ-7 questionnaires at before and after TIF or cTIF. Secondary outcomes included procedure technical success, AEs, PPI use, and change in grade of esophagitis, EGJ-DI, integrated relaxation pressure (IRP), and pH data (DeMeester score, number of reflux episodes, and proportion of time with pH <4) before and after treatment.

Statistical analysis

Continuous variables are described as means±standard deviations or medians with ranges. Dichotomous variables are described as proportions. Paired *t*-tests for continuous outcomes and McNemar's exact test for dichotomous variables were used to test for differences in patient-reported outcomes and objective tests between the two time-points. The signed-Rank test was used to determine if LA Grade improved over time. P <0.05 was used to determine significance. All analyses were performed using SAS v9.4 (Cary North Carolina, United States).

Results

Study population

During the study period, 498 POEMs were performed and 17 consecutive patients (3.4%) (9 female, mean age 60±7 yrs.; ▶ **Table 1**) underwent TIF alone (n = 2, 12%) or cTIF (n = 15, 88%) for medically refractory post-POEM GERD. The most common indication for POEM was type 2 achalasia (n = 6, 35%). A hiatal hernia measuring a mean 2.7±1.2 cm before POEM was present in three of 17 (18%) before POEM. Two patients with a hernia did not undergo Heller myotomy due to a required long esophageal myotomy for esophageal spasm and the other with achalasia was not a candidate for laparoscopic surgery.

EGD before TIF showed a hiatal hernia in all 17 (100%), measuring a mean 1.7±0.8 cm. Hill Grade GEJ was classified as 2 in 8 (47%), 3 in 8 (47%), and 4 in 1 (6%). The mean time between POEM and TIF was 25±15 months. At least once-daily PPI use was required in all 17 patients (100%) and was taken for a mean of 1.5±1.1 years before antireflux therapy.

TIF and cTIF

Due to a hiatal hernia and/or widened GE junction, laparoscopic hernia reduction and/or crural repair was required in 15 of 17 patients (88%) before TIF. Two patients underwent solo TIF. Technical success during TIF and laparoscopy was 100%. During TIF, a mean 24±4 fasteners were placed to create a 240-degree (n = 8, 47%) or 270-degree (n = 9, 53%) wrap and a mean 2.7 ±0.6 cm high-pressure zone. No AEs were noted following endoscopy or surgery. Both solo TIF patients were discharged on the same day. The 15 who underwent laparoscopy were discharged after 1 day (n = 11) or 2 days (n = 4).

Follow-up after TIF and cTIF

Before scheduled post-procedure follow-up, two (11%) with solid food dysphagia required 45F or 48F bougie dilation within 2 months of TIF, and one died 4 months after cTIF of unrelated causes. At follow-up endoscopy, the fundoplication was intact in nine (53%) and loose in eight (47%). A recurrent hernia was seen in four (24%) measuring 1 cm in three and 2 cm in one.

For the primary study outcome at follow-up a mean of 9±1 months after TIF/cTIF (▶ **Table 2**), patients reported more satisfaction with their present condition (P = 0.008) and improved total (P = 0.001), heartburn (P = 0.005), and regurgitation (P <0.001) GERD-HQRL scores. The frequency of hoarseness, coughing, or dysphagia by RESQ-7 was not different between the two groups (P = 0.11). However, by RESQ-7 the total intensity and frequency of the other assessed symptoms each improved after intervention (▶ **Table 2**).

For secondary study outcomes, patients required less frequent daily PPIs (100% vs. 20%; P = 0.001), had fewer reflux episodes (p = 0.04) by pH testing, and improved LA Grade esophagitis (P = 0.004) at follow-up evaluation. However, there was no

▶ **Table 1** Baseline characteristics and results of TIF in 17 patients undergoing TIF alone (n = 2) or combined TIF (cTIF) with laparoscopic hiatal hernia repair (n = 15) for PPI-dependent post-POEM GERD.

Characteristic	Results
Mean (± SD) age	60.4±6.7
Gender, n (%)	
▪ Female	9 (53)
▪ Male	8 (47)
Mean (± SD) BMI	29.6±4.6
Indication for POEM, n (%)	
▪ Type 2 achalasia	6 (35)
▪ Hypercontractile esophagus	4 (24)
▪ Esophageal spasm	3 (18)
▪ EGJ outflow obstruction	3 (18)
▪ Type 3 achalasia	1 (5)
Mean (± SD) myotomy length (cm)	11.4±4.3
Daily PPI use (n, %)	17 (100)
Mean (± SD) duration PPI use (yr)	1.5±1.1
Time from POEM to TIF (mo)	24.7±15
Hiatal hernia before surgery (n, %)	17 (100)
Mean (± SD) size (cm)	1.7±0.8
Hill Grade GEJ classification, n (%)	
▪ 2	8 (47)
▪ 3	8 (47)
▪ 4	1 (6)
Mean (±SD) TIF duration (min)	62.1±18.5
Mean (±SD) fasteners placed	23.6±3.6
High-pressure zone after TIF (cm)	2.7±0.6
Hospitalization (n, %), days)	
▪ 0	2 (12)
▪ 1	11 (65)
▪ 2	4 (24)

PPI, proton pump inhibitor; BMI, body mass index; PPI, proton pump inhibitor; POEM, peroral endoscopic myotomy; EGJ, esophagogastric junction; GEJ, gastroesophageal junction; GERD, gastroesophageal reflux disease; TIF, transoral incisionless fundoplication; SD: standard deviation.

▶ **Table 2** Comparison of Quality-of-Life Metrics before and after TIF or cTIF for PPI-dependent post-POEM GERD

Characteristic	Pre TIF	Post TIF	p value
GERD-HQRL off PPIs			
▪ Mean (±SD) Total HQRL score (n = 13)*	47.4±17.1	17.4±19.7	0.001
▪ Mean (±SD) Heartburn score (n = 13)*	20.3 (6.6)	8.4 (10.5)	0.005
▪ Mean (±SD) Regurgitation score (n = 13)*	20.3 (7.8)	6.2 (7.3)	<0.001
Satisfied with present condition (n, %) (n = 15)*			
▪ Yes	0/15 (0.0)	8/15 (53.3)	0.008
▪ No or Neutral	15/15 (100.0)	7/15 (46.7)	
RESQ7 – Frequency			
▪ Heartburn (n = 16)*	3.0 (1.3)	1.5 (1.6)	0.003
▪ Regurgitation (n = 16)*	3.3 (1.2)	1.4 (1.5)	<0.001
▪ Hoarseness, Coughing, Dysphagia (n = 16)*	2.6 (1.3)	1.8 (1.7)	0.112
▪ Burping (n = 16)*	3.9 (1.4)	2.4 (2.4)	0.049
▪ Total (n = 16)*	3.1 (1.0)	1.6 (1.4)	0.001
RESQ7 – Intensity			
▪ Heartburn (n = 16)*	3.0 (1.2)	1.4 (1.5)	<0.001
▪ Regurgitation (n = 16)*	3.2 (1.2)	1.3 (1.4)	<0.001
▪ Hoarseness, Coughing, Dysphagia (n = 16)*	2.6 (1.4)	1.5 (1.3)	0.005
▪ Burping (n = 16)*	3.1 (1.4)	1.5 (1.8)	0.008
▪ Total (n = 16)*	3.0 (0.9)	1.4 (1.2)	<0.001

* Comparisons only made in patients who had both pre-TIF and post-TIF testing for variable
Table 2 Abbreviations: PPI: proton pump inhibitor, POEM: peroral endoscopic myotomy; GERD: gastroesophageal reflux disease; TIF: transoral incisionless fundoplication; HQRL: Health Related Quality of Life Questionnaire; GERD-HQRL: GERD Health Related Quality of Life Questionnaire; RESQ-7 Reflux Symptom Questionnaire 7-day recall (RESQ-7) questionnaire.

change in EGJ-DI or EGJ diameter at 40 mL or 50 mL balloon inflation, and no difference was noted in either IRP or % total time pH <4 or Demeester score following TIF or cTIF (▶ **Table 3**).

Discussion

In this single-center prospective study, TIF and cTIF for PPI-refractory post-POEM GERD and regurgitation appear safe, decrease PPI use, reflux episodes, grade of esophagitis, and improve QOL. These interventions, however, did not change IRP, EGJ compliance, or acid exposure time in patients tested.

Previous smaller single-center [11] and multicenter [12] retrospective studies have reported that TIF alone for refractory GERD after POEM is feasible, safe, decreases PPI use [13, 14], and improves quality-of-life metrics [14]. Recently, Benias et al. [13] reported that same-session POEM and TIF in five patients was safe and feasible and eliminated GERD by pH testing in four of five patients tested. When these data are added to the current study, it appears that TIF and cTIF in selected patients may be considered for treatment of recalcitrant GERD following POEM.

▶ **Table 3** Comparison of PPI use, Esophagitis, pH studies, Esophagogastric Junction Distensibility Index, and Integrated Relaxation pressures before and after TIF or cTIF for PPI-dependent post-POEM GERD

Characteristic	Pre TIF	Post TIF	p value
Daily PPI use (n, %)*	n = 17 17/17 (100)	n = 15 3/15 (20)	0.001
LA Grade esophagitis off antisecretory therapy* (n, %)	n = 17	n = 14	0.004
▪ none	2 (12)	7 (50)	
▪ A	0 (0)	2 (14)	
▪ B	7 (41)	4 (29)	
▪ C	6 (35)	1 (7)	
▪ D	2 (12)	0 (0)	
Mean (±SD) Total time reflux episodes (n = 11)*	90.5±46.9	49.3±32.3	0.04
Mean (±SD) % Total time pH<4 (n = 11)*	16.9±10.3	13.2±11.4	0.32
Mean (±SD) Total Time DeMeester score (n = 11)*	56.4±32.5	42.2±35.3	0.14
FLIP at 40 ml (n = 13)*			
▪ Mean (±SD) EGJ Diameter (mm)	12.9 (2.0)	13.2 (2.1)	0.57
▪ Mean (±SD) EGJ-DI	6.0 (2.5)	5.9 (3.1)	0.56
FLIP at 50 ml (n = 13)*			
▪ Mean (±SD) EGJ Diameter (mm)	15.4±2.5	16.2±1.8	0.22
▪ Mean (±SD) EGJ-DI	5.0±2.3	5.8±3.0	0.64
▪ Mean (±SD) IRP (n = 12)*	6.0±4.4	6.6±6.0	0.86

*Comparisons only made in patients who had both pre-TIF and post-TIF testing for the variable
Abbreviations: PPI: proton pump inhibitor, FLIP: functional lumen imaging probe; POEM: peroral endoscopic myotomy; EGJ: esophagogastric junction; EGJ-DI: Esophagogastric Junction Distensibility Index; GERD: gastroesophageal reflux disease; TIF: transoral incisionless fundoplication; IRP: integrated relaxation pressure

In the current study, 15 of 17 patients (88%) had a hiatal hernia ≥ 2 cm, a widened diaphragmatic crura or axial diameter of the GE junction (Hill Grade III or IV valve), or both anomalies that required surgical repair before fundoplication. Therefore, these 15 patients underwent laparoscopic surgery before same-session TIF (cTIF) to decrease loosening or slippage that might occur from endoscopic fundoplication alone. Although the cTIF procedure has been previously reported [22, 23] for the treatment of GERD, the current study, to our knowledge, represents the first description of its use for PPI-resistant post-POEM GERD. Because combining the two procedures simultaneously appears feasible, safe, and efficacious in our experience, we believe that cTIF may increase the opportunity to treat refractory GERD in patients with GEJ anatomy not amenable to endoscopic fundoplication alone. Furthermore, this approach may optimize the reproducibility and individual flexibility of the fundoplication while minimizing risk of post-procedure dysphagia and gas-bloat.

Decreasing post-POEM GERD may be attempted by intraprocedural modifications (i. e., myotomy technique or fundoplication), post-POEM lifestyle and medications, or post-POEM endoscopic and/or surgical therapy to the GEJ. For procedural modifications, a single report suggested that preservation of the GEJ sling fibers during POEM may decrease the development of GERD [24], but other modifications of the myotomy technique do not appear beneficial [25, 26, 27]. Because POEM technique modification does not appear to reliably lower the incidence of GERD, most research has focused on outcomes of concomitant fundoplication or post-POEM interventions. When considering therapy to decrease post-POEM GERD, we advocate that post-POEM GERD should be confirmed by objective testing [7] to exclude functional heartburn or reflux hypersensitivity. GERD after POEM appears to be responsive to PPIs in most patients [8] and the diagnosis of severe (LA grade C-D) esophagitis in these patients is rare [2, 7, 8]. Although the incidence of esophagitis and PPI use after POEM is higher than after Heller myotomy with fundoplication [2, 28], esophageal acid exposure time is similar 2 years after intervention [24]. Therefore, post-POEM testing, judicious use of PPIs, and intervention with endoscopic and/or surgical techniques after endoscopic myotomy may be preferred to concomitant POEM and fundoplication [13, 29, 30]. In our study, the mean time between POEM and TIF was 25±15 months, which reflected the length of time required for attempted medical management of symptoms and diagnostic/preoperative testing. Further feasibility and safety studies are required to dictate the timing of antireflux surgery in these patients.

Previous reports [11, 12]and the current study demonstrate that TIF and cTIF improve QOL and decrease PPI use in refractory GERD after POEM. These findings are similar to a meta-analysis [31] of three randomized trials [32, 33, 34] which concluded that when compared with PPIs, TIF decreased PPI use and improved QOL for the treatment of GERD unrelated to POEM. In the 11 patients tested in our study, we also found that cTIF and TIF decreased reflux events. TIF has also been demonstrated in standard GERD patients to decrease reflux events compared with sham treatment or PPIs [32, 33, 35]. These findings also suggest that patients with regurgitation-predominant GERD may benefit the most from TIF or cTIF.

We found no significant change in acid exposure time for the 11 patients tested which may reflect either limited durability or the intentionally limited fundoplication (240–270 degrees) performed in these patients without adequate peristalsis. Limiting fundoplication after POEM was designed to minimize the risk of dysphagia. Accordingly, only two patients required bougie dilation after intervention for solid food dysphagia. In addition, there were no cases of gas-bloat syndrome in our population. However, we found that eight of 17 fundoplications were loose and 4 or 17 patients had recurrent hernias at follow-up endoscopy. We hypothesize that the antireflux valve by the lim-

ited fundoplication in our patients minimizes regurgitation and, therefore, improves QOL but may be of insufficient strength or durability to decrease esophageal acid exposure time. Future studies will be required with placement of more fasteners (to improve durability) to create a fundoplication of ≥300 degrees to attempt to decrease esophageal acid exposure time without increasing resultant post-fundoplication symptoms (like dysphagia or gas-bloat) in the post-POEM population.

We found that that crural repair and/or fundoplication did not alter mean IRP or EGJ-DI in patients tested. Thus, these variables may not need to be evaluated in these patients. Rather, quality-of-life measurement, EGD and esophageal pH studies off PPIs may optimize care after antireflux surgery in POEM patients.

A recent prospective, randomized, sham-controlled trial found that endoscopic full-thickness plication in PPI-dependent patients after POEM decreases symptoms and PPI usage [10]. Therefore, additional options may be available to treat these patients besides fundoplication and/or hernia reduction.

The current study is the largest prospective study that evaluates the role of endoscopic fundoplication (TIF) for treating post-POEM, PPI-refractory GERD and is the only report on treatment with cTIF in these patients. Furthermore, objective manometry, pH testing, and QOL questionnaires were completed in most patients, providing crucial information about the efficacy of therapy. Nevertheless, our study has two primary limitations. First, the sample size was small. However, medically refractory GERD after POEM remains a rare phenomenon, as illustrated by the fact that this sample size required 5 years to accrue and comprised only 3.4% of POEMs performed during the study period. Second, there is no comparative group of patients treated with either continued PPIs or another antireflux procedure.

Conclusions

In conclusion, TIF and cTIF for medically refractory post-POEM GERD appear safe, decrease PPI use and reflux episodes, and improve QOL after intervention. These therapies do not significantly change IRP, EGJ compliance, or acid exposure time. Further evaluation in larger studies is required to further define the role of TIF, cTIF, or other interventions in these patients.

Conflict of Interest

John DeWitt (consultant: Boston Scientific, Inc., APM Therapeutics, Inc, Vyaire Medical, Inc; Grant Support: Vyaire Medical, Inc.), Sarah Stainko (none), Anthony Perkins (none), Mohammad A. Al-Haddad (Consultant: Boston Scientific, Inc Grant support: Cook Medical, Amplified Sciences, Inc, Creatics, LLC), Thomas J. Birdas (none), Mimi Ceppa (none), Hala Fatima (none)

Clinical trial

Trial registry: ClinicalTrials.gov (http://www.clinicaltrials.gov/)
Registration number (trial ID): NCT04306380
Type of Study: Prospective, cohort study

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