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Retrospective Cohort Study

Efficacy and safety of peroral endoscopic myotomy after prior sleeve gastrectomy and gastric bypass surgery

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Abstract

BACKGROUND

Per-oral endoscopic myotomy (POEM) is safe and effective for the treatment of achalasia. There is limited data on performance of POEM in patients with altered upper gastrointestinal anatomy, especially after bariatric surgery. Outcomes in patients with prior sleeve gastrectomy have not been reported.

AIM

To assess the efficacy and safety of POEM in patients with prior bariatric surgery.

METHODS

A prospective POEM database was reviewed from 3/2017-5/2020 to identify patients who underwent POEM after prior bariatric surgery. Efficacy was assessed by technical success (defined as the ability to successfully complete the procedure) and clinical success [decrease in Eckardt score (ES) to ≤ 3 post procedure]. Safety was evaluated by recording adverse events.

RESULTS

Six patients (50% male, mean age 48 years) with a history of prior bariatric surgery who underwent POEM were included. Three had prior sleeve gastrectomy (SG) and three prior Roux-en-Y gastric bypass (RYGB). Four patients had achalasia subtype II and 2 had type I. Most (4) patients had undergone

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previous achalasia therapy. Technical success was 100%. Clinical success was achieved in 4 (67%) patients at mean follow-up of 21 mo. In one of the clinical failures, EndoFLIP evaluation demonstrated adequate treatment and candida esophagitis was noted as the likely cause of dysphagia. There were no major adverse events.

CONCLUSION

POEM is technically feasible after both RYGB and SG and offers an effective treatment for this rare group of patients where surgical options for achalasia are limited.

Key Words: Obesity; Bariatric surgery; Achalasia; Peroral endoscopic myotomy; Sleeve gastrectomy; Gastric bypass

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Core Tip: There is limited data on performance of per-oral endoscopic myotomy (POEM) in patients with altered upper gastrointestinal anatomy, especially after bariatric surgery. To our knowledge, performance and outcomes of POEM have not been reported after sleeve gastrectomy, which is the most common surgical bariatric procedure. Given the worldwide epidemic of obesity, gastroenterologists may be increasingly faced with achalasia after bariatric surgery, for which POEM may be a viable endoscopic option. Our results show that POEM can be safely performed for achalasia in the setting of prior bariatric surgery and offers a safe and effective treatment for these patients with limited surgical options.

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INTRODUCTION

Achalasia is a chronic debilitating condition with an incidence rate of approximately 1.07 per 100000 and likely much higher with increasing awareness and advancements in diagnostic tools for evaluation of dysphagia^[1]. It is characterized by loss of peristalsis of the esophageal body and failure of relaxation of the lower esophageal sphincter (LES). Traditional therapies include pneumatic dilation, endoscopic injection of botulinum toxin, and laparoscopic Heller myotomy (LHM), however per-oral endoscopic myotomy (POEM) has more recently emerged as a safe and effective treatment modality for achalasia^[2-5]. Randomized clinical trials have demonstrated treatment success with POEM (superior to PD^[6] and non-inferior to LHM^[7]) though with greater likelihood for reflux esophagitis^[8]. POEM can be successfully performed in patients who have had prior endoscopic interventions^[9] such as botulinum toxin injection and pneumatic dilation, previous POEM^[10], and even after LHM^[11]. There is limited data on performance of POEM in patients with altered upper gastrointestinal anatomy, especially after bariatric surgery.

Achalasia can result in dramatic weight loss and thus is not typically thought of as a disease that coexists with obesity. However, reports of achalasia occurring after bariatric surgery exist. Boules *et al*^[12] analyzed patients diagnosed with achalasia over a 12-year period and found a history of bariatric surgery in 3%. While in general the etiology of achalasia is unknown, in this clinical scenario it has been hypothesized that iatrogenic injury from bariatric surgery alters neuromuscular systems creating achalasia-like motility disorders^[13]. Additionally, obesity is a known risk factor for esophageal disorders, with approximately 50% of obese patients in one prospective cohort study demonstrating dysmotility on esophageal manometry^[14]. Given the worldwide epidemic of obesity, gastroenterologists may be increasingly faced with achalasia after bariatric surgery, for which POEM may be a viable endoscopic option.

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Achalasia after bariatric surgery represents a technical challenge for surgical repair. LHM is difficult in this population due to post-surgical anatomy and adhesions^[15,16]. In addition, the advantage of combining an anti-reflux procedure during LHM is lost since fundoplication is not feasible after bariatric surgery. POEM after Roux-en-Y gastric bypass (RYGB) has been described in small case series^[17,18] with reasonably high technical and clinical success rates and acceptable rates of acid reflux. Performance and outcomes of POEM have not been reported after sleeve gastrectomy (SG), which is the most common bariatric procedure and more likely than RYGB to result in acid reflux^[19]. As rates of obesity and bariatric surgery continue to increase, data on the feasibility of POEM after SG will become more important. To address this gap, we assessed efficacy and safety of POEM for achalasia after bariatric surgery.

MATERIALS AND METHODS

Patient cohort

The study was performed at a tertiary care academic medical center. The prospective POEM database at the University of Colorado Hospital was reviewed to identify patients with a prior history of bariatric surgery who underwent POEM between 3/2017-5/2020. Achalasia was diagnosed by high resolution manometry (HRM) meeting Chicago Classification version 3.0 criteria for Achalasia (type 1, 2 or 3). Pre procedure symptom assessment was performed using the validated Eckardt score (ES) which measures symptoms in 4 categories (dysphagia, regurgitation, chest pain, weight loss) according to frequency (0-3)^[20,21] with higher scores indicating more severe symptoms. Patient demographics and clinical data including radiologic examination, diagnostic testing, endoscopy and surgery reports were recorded. This study was approved by the Institutional Review Board.

Endoscopic and post procedure protocol

Patients were asked to stay on a liquid diet for 2 d before the procedure to allow adequate esophageal clearance for visualization during POEM and to minimize risk of adverse events. All procedures were performed in the supine position in the endoscopy unit under general anesthesia with endotracheal intubation. Technique for POEM was as previously described^[22,23]. A posterior submucosal tunnel with a posterior myotomy in the 5 o'clock position was performed with the T-type Hybrid knife (ERBE USA, Marietta, GA, United States). Bleeding during the procedure was treated with the dissection knife and/or Coagrasper (Olympus America, Center Valley, PA, United States). The mucosal incision was closed with endoscopic clips (Quick Clip Pro, Olympus America, Center Valley, PA, United States).

As per routine practice in our unit, patients were admitted after their procedure for overnight observation and underwent an esophagram the following morning. If there was no evidence of leak on esophagram patients were started on a clear liquid diet and discharged home. All patients were prescribed one week of oral antibiotics, typically amoxicillin with clavulanic acid (or ciprofloxacin and metronidazole if allergic to penicillin) upon discharge. All patients received a phone call within 72 h after their procedure as per our endoscopy unit protocol to assess for early adverse events. Follow-up data on symptoms and adverse events were obtained from clinical encounters or phone calls through the end of the study period (6/2020). Patients who had recurrent symptoms or asymptomatic individuals who were logistically able to return for endoscopic evaluation underwent upper endoscopy and endoluminal functional lumen imaging probe (EndoFLIP). Reflux esophagitis was categorized according to the Los Angeles Classification and grade C or D were considered significant as per the Lyon consensus^[24]. The 16-cm EndoFLIP EF-322N balloon catheter (Medtronic, Minneapolis, MN, United States) was used and a post procedure DI > 2.8 mm²/mmHg at 60 mL was considered as adequate treatment^[25].

Outcomes and definitions

The main outcomes were efficacy (technical and clinical success) and safety of POEM after prior bariatric surgery. Technical success was defined as the ability to successfully complete submucosal tunneling and endoscopic myotomy of the lower esophagus across the esophagogastric junction (EGJ) and at least 2 cm into the cardia. Clinical success was defined as symptom relief with an ES ≤ 3, which is the most widely used metric for assessing clinical outcomes in achalasia^[26]. Intraprocedural and post procedural adverse events were recorded as per published ASGE criteria^[27]. Descriptive statistics were used to report continuous variables and time to event data.

RESULTS

Six patients (50% male, mean age 48 years) with a history of prior bariatric surgery (3 SG, 3 RYGB) who underwent POEM were included (Table 1). Patients had either achalasia subtype 1 (33%) or 2 (67%). Four patients (67%) had undergone prior therapies for achalasia: One patient had prior Heller myotomy, one had botulinum toxin injection and aborted Heller myotomy due to adhesions found during surgery, two patients had previous botulinum toxin injection, and two patients had no previous treatment for achalasia. Mean ES before POEM was 7.6 (range 4-10). POEM was performed at a mean of 84.8 mo after bariatric surgery (range 8-165). The mean myotomy length was 9.3 cm with 2.2 cm extension into the cardia (Table 2). Mean procedure duration was 79.8 min (Range 47-105). During submucosal tunneling in post SG patients, there was appreciable tortuosity and scarring near the EGJ and in one case surgical sutures were encountered and left intact while complete myotomy was performed around them. (Figure 1). Technical success was achieved in all cases (100%).

Clinical success was achieved in 4 (67%) patients (2 SG and 2 RYGB) at a mean follow-up time of 21 mo (1.5-37) (Table 3). One of the clinical failures was in a patient with previous SG whose endoscopic evaluation post-POEM demonstrated recurrent candida esophagitis (white exudates confirmed on pathology) thought to be the cause of persistent dysphagia. EndoFLIP evaluation demonstrated EGJ distensibility index (DI) of 10.2 mm²/mmHg at 60 mL balloon inflation, consistent with adequate treatment. The second clinical failure occurred in a patient with prior RYGB who had a follow up evaluation by telephone and reported ongoing symptoms however despite multiple attempts to schedule her for endoscopic evaluation and further workup she was lost to follow up. Three patients underwent routine post POEM endoscopy (all of whom had prior SG) and LA grade A/B reflux esophagitis was seen in two patients and candida esophagitis in the third patient as described.

There were no intra-procedural adverse events. Esophagram on post-procedure day 1 showed no leak and patients were discharged from the hospital. One patient presented to the emergency room 5 days later due to chest pain and had a negative workup and was discharged home. There were no other adverse events.

DISCUSSION

Our results show that POEM can be safely performed for achalasia in the setting of prior bariatric surgery and offers a viable treatment for these patients with limited surgical options. In addition, to the best of our knowledge, POEM after SG has not been previously reported.

The main disadvantage of POEM over LHM is that it may cause acid reflux in up to 40% of patients^[8]. There have been several published case reports of POEM performed after RYGB^[28-30]. In the largest series to date with 10 patients, none experienced regurgitation and the six patients who underwent pH testing had normal results^[18]. The present study included 3 patients who had history of RYGB and none developed clinical symptoms of acid reflux during the follow up period. SG is known to promote acid reflux likely as a result of EGJ disruption (more obtuse EGJ insertion angle) and specifically when there is > 80% reduction in gastric capacity^[31]. In theory after SG it might be preferable to combine achalasia therapy with anti-reflux treatment through a traditional surgical approach with concomitant Heller myotomy and fundoplication. However, fundoplication is not feasible after SG so surgery no longer offers this benefit over an endoscopic approach. In the 3 patients who had POEM after prior SG, 2 had endoscopic evidence of mild (grade A/B) esophagitis during the follow up period.

There were two patients who did not meet criteria for clinical success at 1 year. The first was a 68-year-old male with a history of SG and an initial ES of 6. This patient noted dramatic improvement after POEM with ES 0 at 6 mo but subsequently developed recurrent dysphagia and regurgitation. Upper endoscopy demonstrated candida esophagitis that was treated with fluconazole resulting in mild improvement in symptoms. Post POEM EndoFLIP findings indicated adequate treatment at the LES (DI 10.2 mm²/mmHg) suggesting that candida infection was potentially causing the symptoms. An alternative possibility for clinical failure is a secondary achalasia from a more distal obstructive process related to the sleeve analogous to the scenario described after lap-band^[32,33]. Notably, this patient's pre POEM manometry demonstrated a dual high-pressure zone at the EGJ which could be consistent with a hiatal hernia or with increased pressure distal to the EGJ (*i.e.*, at the sleeve). Additional

Table 1 Clinical characteristics of patients with a history of bariatric surgery who underwent peroral endoscopic myotomy

Case	Age Sex	Type of bariatric surgery	Pre-POEM Eckardt Score	Achalasia subtype	IRP (normal < 15)	Prior achalasia treatment ¹	Months from bariatric surgery to POEM
1	54 M	SG	9	1	NA ²	Heller myotomy	47
2	68 M	SG	6	2	22.2	Botulinum toxin injection	71
3	53 F	SG	7	1	23.7	Botulinum toxin injection; Heller myotomy ³	165
4	43 F	RYGB	10	2	21.2	None	96
5	31 M	RYGB	4 ⁴	2	28	Botulinum toxin injection	8 ⁴
6	37 F	RYGB	10	2	36	None	122

¹Standard endoscopic dilation ≤ 20 mm was not considered as a prior achalasia treatment.

²Probe was not able to be passed beyond the esophagogastric junction, however there was complete aperistalsis consistent with achalasia with prior treatment with Heller myotomy.

³Aborted due to adhesions.

⁴Achalasia diagnosis preceded bariatric surgery. In all other cases achalasia was diagnosed after bariatric surgery. Eckardt score comprised of dysphagia (2) and regurgitation (2) without weight loss. M: Male; F: Female; SG: Sleeve gastrectomy; RYGB: Roux-en-Y gastric bypass; ES: Eckardt Score; IRP: Integrated relaxation pressure of the lower esophageal sphincter (mmHg) as measured by high-resolution esophageal manometry. POEM: Peroral endoscopic myotomy; NA: Not available.

Table 2 Procedural data for peroral endoscopic myotomy

POEM Procedural data (n = 6)	Mean (range)
Submucosal Tunnel length, cm	12.3 (11-14)
Myotomy length, cm	9.3 (9-10)
Extension of myotomy into cardia, cm	2.2 (2-3)
Clips, number	5 (3-7)
POEM time, min	79.8 (47-105)

POEM: Peroral endoscopic myotomy.

testing is in progress to elucidate the exact cause for continued symptoms. This case highlights the importance of close collaboration between the endoscopist and esophageal motility expert performing the diagnostic workup.

The second clinical failure was a 43-year-old female with history of RYGB and comorbidities including depression, chronic pain, fibromyalgia, and migraines. This patient was evaluated at our esophageal multidisciplinary clinic and it was unclear if her symptoms were purely related to achalasia or multifactorial. POEM was performed for documented achalasia type II with predominant symptoms of dysphagia and regurgitation (ES 10). Although she did not have clinical success with POEM, symptoms shifted towards less dysphagia and regurgitation, and more chest pain and weight loss. These findings are unusual and highlight the possibility that other underlying conditions may be contributing to ongoing symptoms, especially in bariatric patients with coexistent comorbidities. As highlighted in this case, objective evaluation such as EndoFLIP, HRM, and pH testing should be performed in patients with clinical failure, to determine if symptoms are related to ineffective POEM or other causes.

It would be quite unusual for achalasia patients to develop obesity requiring bariatric surgery. Indeed, most published reports indicate that achalasia developed *after* bariatric surgery. One proposed theory is that iatrogenic injury during bariatric surgery may promote development of achalasia. This chronology was true for most patients in the present study except for one who had known achalasia preceding RYGB, a sequence that has only been demonstrated in a small number of cases^[17]. This

Table 3 Outcomes of patients with a history of bariatric surgery who underwent peroral endoscopic myotomy

Case	Type of bariatric surgery	Technical success	Clinical success	Post-POEM Eckardt score	Adverse events	Follow up, mo	Endoscopy findings	Medical comorbidities
1	SG	Yes	Yes	3	No	37	Grade A esophagitis	HTN, HLD
2	SG	Yes	No	6	Minor ¹	21	Candida esophagitis; EndoFLIP DI: 10.2 ²	COPD, TIA, OSA, HTN, type 2 diabetes
3	SG	Yes	Yes	2	No	13	Grade B esophagitisEndoFLIP DI: 5.1 ³	None
4	RYGB	Yes	No	10	No	21	NA	Major depressive disorder, chronic migraines
5	RYGB	Yes	Yes	2	No	33	NA	None
6	RYGB	Yes	Yes	2	No	1.5	NA	Hypothyroidism

¹ER visit for chest pain 5 d after procedure with negative workup.

²EndoFLIP: Esophagogastric junction distensibility index, 60 mL: 10.2 mm²/mmHg; dysphagia and clinical failure likely related to candida esophagitis.

³EndoFLIP: Esophagogastric junction distensibility index, 60 mL: 5.1 mm²/mmHg. SG: Sleeve gastrectomy; RYGB: Roux-en-Y gastric bypass; POEM: Peroral endoscopic myotomy; HTN: Hypertension; HLD: Hyperlipidemia; COPD: Chronic obstructive pulmonary disease; TIA: Transient ischemic attack; OSA: Obstructive sleep apnea; NA: Not available.

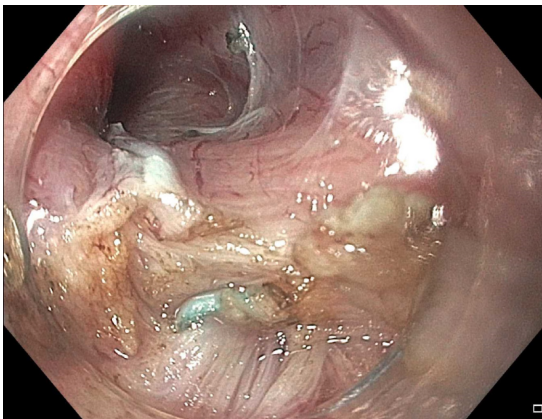


Figure 1 Surgical sutures seen in submucosal tunnel near gastroesophageal junction during myotomy.

patient had been planned to undergo Heller myotomy at the time of bariatric surgery but for unknown reasons this was not done at their local hospital. The best management of concomitant achalasia and obesity is unclear as it is uncommon for these two conditions to co-exist. Oviedo *et al*^[34] reported an interesting case of a young female with obesity and achalasia who chose POEM followed by SG (instead of LHM with RYGB) mainly due to risk of malabsorption in the context of a future planned pregnancy. Recent data suggests that esophageal motility disorders in bariatric patients may be underrecognized or a possible consequence postoperatively, therefore we suggest considering motility testing prior to surgery to assess for silent disease^[35]. Given the increasing number of bariatric procedures being performed for obesity, surgeons and endoscopists will likely be faced with similarly challenging situations as reported here. Additionally, as POEM gains widespread acceptance for management of achalasia, endoscopists will need to adapt current procedural techniques to unique cases such as surgically altered anatomy. These cases demonstrate that although technically challenging, POEM can be performed after bariatric surgery including sleeve gastrectomy and may be potentially safer than repeat surgery.

It should be mentioned that POEM after bariatric surgery is technically challenging due to surgically altered anatomy with concurrent tortuosity, angulation and scarring, and presence of surgical sutures in the dissection plane. However, careful dissection was feasible. The orientation of the submucosal dissection with reference to the mucosa on one side and the muscle on the other, and direction of the tunnel was

constantly checked to ensure safe tunneling without mucosal injury. Also, the reduced gastric lumen in the setting of RYGB or SG did not affect the technical feasibility of performing POEM.

We also acknowledge the limitations of this study. This was a single center series with a small number of patients which may limit generalizability. However, POEM for achalasia after bariatric surgery is a rare clinical scenario with limited reports and therefore sharing each case is valuable. For patients who develop achalasia in the short-term period after bariatric surgery when they have not yet reached their nadir, application of the Eckardt score should take into context ongoing intentional post-operative weight loss. All patients in our series had reached their weight loss nadir except potentially patient number 5 who had POEM 8 mo after RYGB. However, his Eckardt score (4) comprised of dysphagia (2) and regurgitation (2) without weight loss contributing to the ES. Another limitation is the lack of HRM/EndoFLIP and esophageal pH testing in all patients after POEM. This information would be helpful especially in patients with SG which is associated with increased acid reflux, though we did not find any significant grade C/D esophagitis in these patients. Additionally, post-POEM testing was only performed in some patients since these cases were performed at a tertiary referral center, and thus due to geographic distance and insurance restrictions not all patients were able to follow up at our institution. To mitigate this limitation, we communicated with all patients by phone to obtain symptom assessment. Lastly, this study was performed at a tertiary academic medical center with an established POEM program and results may not be applicable to other centers. Due to the technical complexity associated with these cases, we suggest that POEM after bariatric surgery should be performed by endoscopists with significant experience in standard POEM.

CONCLUSION

In the past 2 decades, the age-adjusted prevalence of obesity in the United States increased from 30.5% to 42.4% and severe obesity nearly doubled from 4.7% to 9.2%^[36]. This increase is coupled with a parallel 10.8% increase in utilization of bariatric surgery from 2017 to 2018 alone^[19]. Therefore this clinical scenario of achalasia post bariatric surgery may become more common. As more evidence accumulates regarding the safety and efficacy of POEM, these cases add to the growing scientific literature regarding performance of POEM in surgically altered anatomy. In conclusion, these cases demonstrate the safety and feasibility of POEM after RYGB and SG.

ARTICLE HIGHLIGHTS

Research background

Per-oral endoscopic myotomy (POEM) is a safe and effective treatment for achalasia, but in patients with prior bariatric surgery the altered gastrointestinal tract anatomy can pose a technical challenge.

Research motivation

Currently there is sparse published data on efficacy and feasibility of POEM in patients with prior Roux-en-Y gastric bypass (RYGB) and no published reports in patients with prior sleeve gastrectomy (SG).

Research objectives

To describe the safety, feasibility and clinical outcomes of POEM in patients with history of bariatric surgery.

Research methods

Six patients with prior bariatric surgery who underwent POEM for achalasia were included. Technical success defined as the ability to successfully complete the procedure and clinical success defined as a post procedure Eckardt score ≤ 3 were evaluated. Adverse events were recorded for safety outcomes.

Research results

Six patients (50% male, mean age 48 years) with a history of prior bariatric surgery (3 RYGB, 3 SG) underwent POEM. Four patients had Achalasia Type II and two had Achalasia Type I. Technical success was 100%. Clinical success was achieved in 4 (67%) patients at mean follow-up of 21 mo. One clinical failure was likely a result of candida esophagitis causing dysphagia since EndoFLIP demonstrated adequate myotomy. There were no major adverse events.

Research conclusions

POEM is technically feasible after both RYGB and SG and offers an effective treatment for this rare group of patients where surgical options for achalasia are limited.

Research perspectives

Future prospective studies are needed to compare outcomes in patients undergoing POEM after RYGB *vs* SG and to define predictors for clinical success.

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