

Peroral Endoscopic Myotomy (POEM) Procedures



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DESCRIPTION

The use of peroral endoscopic myotomy (POEM) procedures (POEM, D-POEM, G-POEM, Z_POEM) has been proposed as an alternative to existing therapies for the treatment of achalasia, esophageal diverticula, gastroparesis and Zenker's diverticulum.

Esophageal Achalasia

Achalasia is a rare motility disorder of the esophagus and is defined by three elements: the reduction or absence of the primary peristaltic waves in the distal two thirds of the esophagus, incomplete or no relaxation of the lower esophageal sphincter (LES) during swallowing and increased resting LES tone. There is degeneration of the esophageal muscle and the nerves that control the muscles. The cause of primary or idiopathic achalasia is unknown. Secondary achalasia is due to diseases that cause esophageal motor abnormalities (e.g., Chagas disease, esophageal cancer, Fabry disease, amyloidosis). Men

and women are affected with equal frequency, with no racial predilection and achalasia is usually diagnosed in patients between the ages of 30 and 60 years. Symptoms of achalasia include dysphagia, heartburn, difficulty belching, chest pain, regurgitation of undigested food and liquid, and weight loss.

Achalasia is defined by aperistalsis and abnormal lower esophageal sphincter (LES) relaxation (integrated relaxation pressure [IRP] > 15 mmHg). The disorder is characterized monometrically by insufficient relaxation of the lower esophageal sphincter (LES) and loss of esophageal peristalsis; radiographically by aperistalsis, esophageal dilation, with minimal LES opening, “bird-beak” appearance, poor emptying of barium; and endoscopically by dilated esophagus with retained saliva, liquid, and undigested food particles in the absence of mucosal stricturing or tumor.

The three types of achalasia based on the Chicago Classification of patterns of esophageal pressurization on high-resolution manometry (HRM) (CC v3.0) include the following:

- **Type I (Classic Achalasia):** Incomplete LES relaxation, aperistalsis and absence of esophageal pressurization. Swallowing results in no significant change in esophageal pressurization and has 100% failed peristalsis with a distal contractile integral (DCI, an index of the strength of distal esophageal contraction) < 100 mmHg.
- **Type II:** Incomplete LES relaxation, aperistalsis and panesophageal pressurization in at least 20% of swallows. Swallowing results in simultaneous pressurization that spans the entire length of the esophagus. Type II achalasia has 100% failed peristalsis and pan-esophageal pressurization with ≥ 20 percent of swallows.
- **Type III (Spastic Achalasia):** Incomplete LES relaxation and premature contractions (distal latency [DL] < 4.5 seconds) in at least 20% of swallows. Swallowing results in abnormal, lumen-obliterating contractions or spasms. Type III achalasia has no normal peristalsis and premature (spastic) contractions with DCI >450 mmHg-sec-cm with ≥ 20 percent of swallows.

Treatment

The primary treatment objective for achalasia is to relieve obstruction in the distal esophagus by decreasing the resting pressure in the lower esophageal sphincter (LES) to a level at which the sphincter no longer impedes the passage of undigested food and liquid. Established treatment options include pharmacotherapy (e.g., injection of botulinum toxin into the esophagus, use of oral nitrates) or mechanical disruption of the muscle fibers of the LES by surgical interventions (i.e., endoscopic balloon dilation, surgical Heller myotomy [LHM] with or without fundoplication) to reduce the incidence of gastroesophageal reflux disease (GERD). LHM is the treatment of choice and has an 85%–90% effect in treating the condition. When a patient has dysphagia following surgical myotomy, the first suspicion is incomplete myotomy.

Laparoscopic Heller myotomy (LHM) has been the gold standard surgical approach for the past two decades. Myotomy (e.g., Heller myotomy) is a procedure that involves the

incision of the muscle fibers of the lower esophageal sphincter (LES) without disrupting the mucosal lining of the esophagus. It can be performed as an open or laparoscopic procedure.

Peroral endoscopic myotomy (POEM) is a novel endoscopic procedure that uses the oral cavity as a natural orifice entry point to perform myotomy of the lower esophageal sphincter (LES). This procedure is intended to reduce the total number of incisions needed and thus the overall invasiveness of surgery and will be discussed in this evidence review.

Peroral endoscopic myotomy (POEM) is a minimally invasive intervention that aims to treat achalasia. It is regarded as the endoscopic equivalent of Heller myotomy. The POEM technique involves guiding an endoscope through the esophagus, making an incision in the mucosa, creating a submucosal tunnel for access to the lower esophagus and gastroesophageal junction, and cutting the muscle fibers in the lower esophagus and proximal stomach. Internal incisions are closed with clips after myotomy is complete. The proposed advantage of POEM is that it can deliver a longer myotomy than pneumatic dilation or the Heller procedure. The length of myotomy from the esophageal to the gastric side can be adjusted on a case-by-case basis while achieving functional durability of traditional surgical myotomy. A longer myotomy may be more effective in controlling symptoms. POEM includes no anti-reflux procedure and can therefore result in gastroesophageal reflux disease (GERD).

POEM is a complex procedure, demanding skilled hands to avoid serious complications. Endoscopists should be able to recognize structures beyond mucosa, including vasculature nerves and the anatomy of the mediastinum. POEM should be performed in highly specialized centers by experienced endoscopists or surgeons.

Clinical Context and Therapy Purpose

The purpose of peroral endoscopic myotomy (POEM) in individuals who have esophageal achalasia is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with esophageal achalasia. Esophageal achalasia is characterized by reduced numbers of neurons in the esophageal myenteric plexuses and reduced peristaltic activity, making it difficult for patients to swallow food and possibly leading to complications such as regurgitation, coughing, choking, aspiration pneumonia, esophagitis, ulceration, and weight loss.

Interventions

The therapy being considered is peroral endoscopic myotomy (POEM). The POEM procedure involves tunneling an endoscope down the esophagus toward the esophageal-gastric junction. A surgeon performs the myotomy by cutting only the inner, circular

lower esophageal sphincter (LES) muscles through a submucosal tunnel created in the proximal esophageal mucosa.

Comparators

Comparators of interest include esophageal dilation, laparoscopic Heller myotomy (LHM), and botulinum toxin injection.

Esophageal dilation is performed in a graded approach, starting with a small balloon (typically 30 mm), then progressing to larger balloons (35 to 40 mm) 2 to 4 weeks later. The balloons are placed at the level of the gastroesophageal junction and inflated slowly, in order to tear the muscle fibers in a controlled manner. Esophageal perforations are a potential complication. Long-term studies have estimated that approximately one-third of patients may need a repeat procedure.

Laparoscopic Heller myotomy is a minimally invasive procedure in which the thick muscle of the lower esophagus and the upper stomach is cut to open the tight LES. The procedure involves 5 small incisions to insert the camera and surgical instruments. Reported success rates are high (>90%), with a 5-year follow-up study showing an 8% rate of symptom recurrence.

Endoscopic botulinum toxin is injected with a sclerotherapy needle approximately 1 cm above the esophagogastric junction. The complication rate is low and approximately 80% of patients experience immediate symptom relief. The effect diminishes over time, with more than 60% of patients reporting recurrent symptoms at 1 year.

Outcomes

The general outcomes of interest are symptom relief and treatment-related morbidity.

Symptom relief may be measured by the Eckardt score, which is comprised of 4 major symptoms of achalasia: dysphagia, regurgitation, retrosternal pain, and weight loss. Each symptom receives a score from 0 (none) to 3 (severe), for a maximum score of 12. Total scores of 4 or greater represent treatment failure.

Treatment-related morbidity of concern is the development of gastroesophageal reflux disease (GERD). Gastroesophageal reflux disease risk is high with this procedure because POEM involves ablating the LES without adding any type of anti-reflux mechanism. Additional complications include thoracic effusion, subcutaneous emphysema, and esophagitis.

Symptom relief may be experienced shortly following the procedure. Assessment of durability of relief requires a follow-up of months to years.

Peroral Endoscopic Myotomy (POEM) for Adult Patients with Achalasia

Review of Evidence

Randomized controlled trials (RCTs) have compared peroral endoscopic myotomy (POEM) to laparoscopic Heller myotomy with Dor fundoplication (LHD) for the treatment of achalasia. The studies concluded that POEM is noninferior to laparoscopic Heller myotomy with Dor fundoplication with shorter operative times and minimal serious adverse events. Another RCT compared the efficacy of POEM to pneumatic dilation as the initial treatment of patients with treatment-naïve achalasia with a clinically significant treatment success rate at two years in the POEM group. Numerous case studies, systematic reviews and systematic reviews with meta-analysis have been published investigating POEM for the treatment of achalasia.

In 2020, Costantini et. al., conducted a propensity score case-control study that compared POEM to laparoscopic Heller myotomy with Dor fundoplication (LHD) for the treatment of esophageal achalasia. Patients (n=280) that had primary achalasia (types I to III) were enrolled in the study and received either LHD (n=140) or POEM (n=140) at specialized centers. The primary outcome measured treatment success which was defined as an Eckardt score ≤ 3 . Secondary outcomes included: basal lower esophageal sphincter (LES) pressure and integrated relaxation pressure (IRP) based on high-resolution manometry (HRM) findings; presence of reflux esophagitis based on endoscopy findings; and esophageal acid exposure. Treatment success was assessed two, six and 12 months after surgery, and every two years. Esophagitis was measured by endoscopy at six (POEM group only) and 12 months after the operation and then recommended every 24 months. Esophageal HR manometry and 24-h pH monitoring (according to DeMeester) were performed six months after the surgical procedure. Study results stated that POEM required a significantly shorter operation time and postoperative stay compared to LHD ($p < 0.001$). No mortality was recorded in either group. There was not a significant difference between groups in severe procedure related complications ($p = 0.33$). At a median follow-up of 24 months for POEM and 31 months for LHD, there was not a significant difference in clinical success ($p < 0.12$). Four years after the treatment, the probability to have symptoms adequately controlled was $> 90\%$ for both groups ($p = 0.2$). HR-Manometry showed a similar reduction in the LES pressure; 24-h pH-monitoring showed a significant abnormal exposure to acid in 38.4% of POEM patients, as compared to 17.1% of LHD patients ($p < 0.01$) and esophagitis was found in 37.4% of the POEM and 15.2% of LHD patients ($p < 0.05$). Study limitations included the study design and potential bias due to latent variables that can remain after matching. Additionally, the results may not represent those achievable by centers with less experience with the procedures. The authors concluded that POEM provides the same midterm results as LHD. However, there was a higher incidence of postoperative GERD in the POEM group.

In 2019, Werner et. al., conducted a prospective, multicenter, randomized, open label, noninferiority trial that compared peroral endoscopic myotomy (POEM) with laparoscopic Heller's myotomy (LHM) plus Dor's fundoplication in patients with

symptomatic idiopathic achalasia. Patients (n=221) in the modified intention-to-treat population were randomly assigned to undergo either POEM (n=112) or LHM plus Dor's fundoplication (n=109). Adults 18 years or older with symptomatic achalasia and a medical indication for surgical myotomy or pneumatic dilation were eligible for inclusion in the trial if they had an Eckardt symptom score > 3 and had findings on preinterventional manometry that were consistent with the diagnosis of achalasia (classified as types I to III). Eligible patients who had previously undergone endoscopic treatment were included. The primary outcome was clinical success at the two-year follow-up, defined as an Eckardt symptom score of ≤ 3 without the use of additional treatments, using a noninferiority margin of -12.5 percentage points. Secondary measurements included adverse events, esophageal function, Gastrointestinal Quality of Life Index score and gastroesophageal reflux. Clinical data were collected at three, six, 12-, and 24-months follow-up. Patient-reported outcomes were assessed by means of telephone calls, mail, or follow-up appointments by dedicated trial personnel who were aware of the treatment-group assignments. Objective evaluation by means of endoscopy, manometry, and esophageal pH monitoring (at least one week after the discontinuation of a proton-pump inhibitor) was planned at three and 24-months. Clinical success at the two-year follow-up was observed in 83.0% of patients in the POEM group and 81.7% of patients in the LHM group, which was not clinically significant (p=0.007 for noninferiority). Serious adverse events occurred in 2.7% of patients in the POEM group and 7.3% of patients in the LHM group. Improvement in esophageal function and Gastrointestinal Quality of Life Index from baseline to 24 months did not differ significantly. At three- and 24-months reflux esophagitis was assessed by endoscopy, 57% of patients in the POEM group and 20% of patients in the LHM group had reflux esophagitis and at 24 months, the corresponding percentages were 44% and 29%. Author noted limitations included: the surgeons were more experienced in performing LHM plus Dor's fundoplication than the endoscopists were in performing POEM, treatment effects on postoperative pain or on the use of pain medications was not analyzed and the study was unblinded. Because of the unblinded nature there was a potential source of bias given that the primary end point was based on patients' reports of symptoms; however, objective assessment by manometry corroborated the primary finding. The authors concluded that POEM was noninferior to LHM plus Dor's fundoplication in controlling symptoms of achalasia at two years. Gastroesophageal reflux was more common among patients who underwent POEM than among those who underwent LHM.

In 2019, Ponds et. al., conducted a multicenter randomized control trial that compared the efficacy of POEM to pneumatic dilation as the initial treatment of patients with treatment-naïve achalasia (types I to III). Patients (n=133) were randomized to receive POEM (n=67) or pneumatic dilation (n=66). The study included adults aged 18–80 years with newly diagnosed achalasia, an Eckardt score > 3, and no previous treatment. The primary outcome measured treatment success at the two-year follow-up. Treatment success was defined as a reduction in the patient's Eckardt score to ≤ 3 and the absence of severe complications or need for re-treatment. Secondary outcomes were measured at three months, one year, and two years after initial treatment and included the following: Eckardt score, basal lower esophageal sphincter (LES) pressure and integrated relaxation

pressure (IRP) based on high-resolution manometry (HRM) findings, esophageal stasis and diameter evaluated by timed barium esophagogram, complication rate, the rate of endoscopic or surgical re-treatment, presence of reflux esophagitis based on endoscopy findings, esophageal acid exposure, reflux symptoms, PPI use, and general health-related (physical and mental aspects) and achalasia-related quality of life. Of the 133 randomized patients, 130 underwent treatment and were included in the analysis (n=64/POEM, n=66/pneumatic dilation) with 126 (95%) completing the study. Four patients were lost to follow-up. The treatment success rate, after two years of follow-up was 92% in the POEM group and 54% in the pneumatic dilation group, a clinically significant difference of 38% (p<0.001). Reflux esophagitis occurred significantly more often in the POEM group compared to the pneumatic dilation group (p=0.002). No significant differences were observed in Eckardt score, IRP and basal LES pressure, barium column height and diameter, or quality of life after post hoc adjustment for multiple comparisons. Two serious adverse events, including one perforation, occurred after pneumatic dilation, while no serious adverse events occurred after POEM. Author noted limitations included: a strict intention-to-treat analysis was not performed, the start time for follow-up was treatment initiation rather than randomization resulting in follow-up time differences (24 months for the POEM group vs 24.5 months for the pneumatic dilation group). Additionally, the study was unblinded without long term results beyond two years. The authors concluded that the findings support consideration of POEM as an initial treatment option for patients with achalasia.

In 2018, Li et. al., conducted a single center study that analyzed the long-term results of POEM, with an emphasis on POEM failures and associated risk factors. Included patients (n=564) had esophageal achalasia which was diagnosed by established methods such as clinical symptoms, barium swallow, EGD, manometry, and/or chest CT scan. The primary outcome measured the clinical success rate of POEM (Eckardt score \leq 3). The secondary outcomes included procedure-related adverse events (AEs), lower esophageal sphincter (LES) pressure on manometry pre- and post-POEM, reflux symptoms, reflux esophagitis on EGD, and procedure parameters such as operation time, length of hospital stay, and myotomy length. Patients were scheduled to follow-up at one month, three months, six months, one year postoperatively and yearly afterward. Follow-up included a symptom assessment, physical examination, and objective tests including EGD and barium esophagram. A total of 144 patients were lost to follow-up. Major perioperative AEs occurred in 6.4% (36 patients) which included delayed mucosal barrier failure, delayed bleeding, hydrothorax, pneumothorax (all of whom had received air rather than CO2 insufflation). After initiation of CO2 insufflation, the AE rate dropped to 2.4%. After a median follow-up of 49 months (range, 3–68), the Eckardt score and lower esophageal sphincter (LES) pressure were significantly decreased (p<0.05; p<0.05, respectively). Fifteen failures occurred within three months, 23 between three months and three years, and 10 after three years. The estimated clinical success rates at one, two, three, four, and five years were 94.2%, 92.2%, 91.1%, 88.6%, and 87.1%, respectively. Clinical reflux occurred in 37.3% of patients (155/416). Author noted limitations included a high loss-to-follow-up rate, poor patient compliance at diagnostic tests, and difficulties in accessing records from outside hospitals. These limitations resulted in a

lack of in-depth analysis of causes of POEM failures, especially regarding the role reflux played. Additionally, the center did not have CO₂ insufflator for the entire study resulting in high gas-related AEs.

In 2018, Schlottmann et. al., conducted a systematic review and meta-analysis to compare the outcomes of oral endoscopic myotomy (POEM) and laparoscopic Heller myotomy (LHM) for the treatment of esophageal achalasia. Studies that investigated POEM or LHM with at least 20 patients and a follow-up greater than nine months were included. The primary outcome measures were improvement of dysphagia and post-treatment gastroesophageal reflux disease (GERD). A total of 53 studies investigating LHM (n=5834) and 21 studies on POEM (n=1958) met inclusion criteria. Studies were primarily case series and retrospective reviews. There were five randomized control trials investigating LHM (n=25–138). The one randomized controlled trial that included POEM was a comparison of two different surgical techniques. Mean follow-up was significantly longer for LHM studies (41.5 mos. vs. 16.2 mos.) (p<0.0001). Predicted probabilities for improvement in dysphagia at 12 months were 93.2% for POEM and 91.0% for LHM (p=0.01) and 92.7% and 90.0%, respectively, at 24 months (p=0.01). Average improvement of dysphagia was 93.2% for POEM and 87.7% after LHM. Patients undergoing POEM were more likely to develop GERD symptoms (p<0.0001), GERD evidenced by erosive esophagitis (p<0.0001) and GERD evidenced by pH monitoring (p<0.0001). The estimated odds of GERD symptoms increased by a factor of 1.16 with a 12 month increase in follow-up time. On average, length of hospital stay was 1.03 days longer after POEM (p=0.04). Since morbidity and mortality were extremely low for both procedures, statistical analysis could not perform. Although short-term symptom relief was significantly better with POEM, the authors noted that the absolute difference between the groups was only 5.5% and conclusion regarding superiority should be viewed with caution. Limitations of the studies include the retrospective study designs, lack of prospective comparative studies, and short-term follow-ups following POEM procedure.

In 2018, Fernandez-Ananin et al., conducted a systematic review of the literature to evaluate the optimal treatment (i.e., repeat laparoscopic myotomy, pneumatic dilatation, POEM) when surgical myotomy fails. Failure was defined as the reappearance of symptomatology (e.g., dysphagia, chest pain, regurgitation, cough, heartburn). A total of 37 studies met inclusion criteria including: four studies (n=87) investigating pneumatic dilatation (PD), 166 patients who underwent revisional surgery (11 studies) and 36 patients treated by POEM (five studies). Studies were primarily retrospective in design. Studies with patients treated for achalasia who had failed a surgical myotomy were included. Exclusion criteria were studies with insufficient data to verify the results of the treatment performed, as well as those that used a treatment modality different from those mentioned; case reports; systematic reviews; non-English studies, and animal studies. The primary outcome measure was synthesizing the current possibilities of treatment after laparoscopic myotomy failure in patients with achalasia and how to define its benefits and its results. The secondary outcome was to define an algorithm of action for the patients in whom evidence fails after the Heller myotomy and determine the order of

their choice. PD failure (n=87) was caused by incomplete myotomy combined with fibrosis in seven patients and one case was an incomplete myotomy without fibrosis. The cause of failure was not defined in other studies. The mean time between detection of myotomy failure and initiation of PD treatment was four months. The mean number of PDs performed to achieve the absence of symptoms was 2.5 (range: 1–3). The mean interval between dilations was 26 months (range: 0–144). The success rate with PD was 89%. Regarding LHM the cause of failure (n=93) was due to incomplete myotomy (n=64), fibrosis (n=23) or both (n=6). PD prior to re-laparoscopic Heller myotomy (LHM) was used in 64% of patients. The reported re-LHM operative time in six studies was an average of 177 minutes (range: 111–240). The conversion rate to open surgery was 6%. Hospital stays ranged from 2–8 days (mean four days). Follow-up time ranged from 6–63 months (mean 26.3 months). The success rate ranged from 69%–100%, although there was great variability in the exposure of the data. Regarding POEM the time between surgical myotomy and POEM ranged from 11–134 months (mean 98 months). PD was performed prior to POEM in 80% of patients. Operative time ranged from 62–175 minutes (mean 99 minutes). The mean hospital stay was 2.1 days. The success rate was 98.4% and the follow-up time ranged from 3–10 months (mean 7.4). The initial procedure chosen by the majority of the authors (67%) after the ineffectiveness of the surgical myotomy was PD. Fourteen re-LHM patients (14%) had mucosal perforation and one had a pneumothorax. Two studies did not address complications. Complications following POEM included: one mucosal perforation, two subcutaneous emphysema, four mediastinal emphysema, four pneumothorax and three pneumoperitoneum. The authors noted that the best treatment for failure of myotomy is prevention in the prior surgery (pre-operative functional study, extended myotomy and correct antireflux procedure). Laparoscopic re-myotomy was considered a safe technique but endoscopic surgeries can be used without significantly increasing the risk of perforation. The analysis was limited by the lack of available studies; small heterogeneous patient populations (n=2–58); heterogeneity of studies by intervention; short-term follow-ups; and lack of comparative studies.

In 2016, Akintoye et. al., conducted a systematic review and meta-analysis to assess the safety and efficacy of peroral endoscopic myotomy (POEM) for the treatment of achalasia. The primary outcome measure was the proportion of patients with an Eckardt score of ≤ 3 after the procedure. Secondary measures were the mean Eckardt score, manometry parameters, timed barium esophagogram, and weight change postoperatively. All studies reporting clinical outcomes after POEM were eligible for inclusion. Exclusion criteria included: animal studies, case reports with < 5 patients, commentaries or general reviews, conference abstracts, and overlapping publications from the same center. Thirty-six studies (n=2373) met inclusion criteria (nonrandomized prospective studies and retrospective reviews). Overall, compared to baseline there was a significant improvement in the Eckardt score, manometry, and timed barium esophagogram postoperatively ($p < 0.05$). Clinical success (Eckardt score ≤ 3) was achieved in 98% of patients. The mean Eckardt score prior to treatment was 6.9 ± 0.15 compared to 0.77 ± 0.10 at one month, 1.0 ± 0.10 at six months and 1.0 ± 0.08 at 12 months. There was a significant decrease in manometry score within six months post-POEM ($p < 0.05$). The

average heights of the barium column following a timed barium esophagogram (a simple technique for evaluating esophageal emptying in patients with achalasia) were 14 ± 2.3 and 9.7 ± 1.9 cm at one and five minutes, respectively. The column heights decreased to 4.2 ± 0.77 and 2.6 ± 0.72 cm at one and five minutes, respectively, following POEM. Average weight gain (six studies; n=488) 5.4 ± 0.73 kg after a mean follow-up of 7.4 months. Adverse events included: mucosal injury (4.8%), esophageal perforation (0.2 %), substantial bleeding requiring interventions (0.2 %), subcutaneous emphysema (7.5 %), pneumothorax (1.2 %), pneumomediastinum (1.1 %), pneumoperitoneum (6.8 %) and pleural effusion (1.2 %). After a mean follow-up of eight months the rates of symptomatic gastroesophageal reflux was 8.5%, esophagitis on EGD 13% and abnormal acid exposure following a 24-hour pH monitoring study 47%. Limitations include the heterogeneity of the study populations and POEM techniques, missing data, variable follow-up times and significant heterogeneity in the primary outcomes, limiting the generalizability of the results. The authors concluded that POEM appears to be safe and effective based on the current evidence and warrants consideration as first-line therapy when an expert operator is available.

Summary of Evidence

Based on review of the peer reviewed medical literature peroral endoscopic myotomy (POEM) can be performed in most patients who have symptomatic, monometrically proven primary idiopathic achalasia. POEM has been endorsed as a primary treatment for type I and II achalasia (as an alternative to pneumatic dilation and surgical myotomy) and a preferred treatment for type III achalasia by major society guidelines. Clinical success is defined as a post-treatment Eckardt score of ≤ 3 and/or a >50 percent decrease in the lower esophageal sphincter (LES) pressure. The efficacy and safety of POEM has been compared with that of laparoscopic Heller myotomy (LHM) and pneumatic dilation. The short-term success rate of POEM for achalasia, 82 to 100 percent, is comparable to that of laparoscopic Heller myotomy and superior to that of pneumatic dilation. Longer-term studies revealed success rates of 78 to 88 percent at two to five years. POEM also appears to be a viable treatment option for patients who develop recurrent or persistent symptoms after other treatments of achalasia, such as pneumatic dilatation, botulinum toxin injection, or surgical myotomy. Based on current literature, patients with achalasia should be informed that POEM and LHM are equally effective in relieving swallowing difficulties but POEM results in more reflux and LHM has more adverse events. Thus, the choice may depend on available local resources and patient/surgeon preference.

The following are contraindications in which patients for the treatment of achalasia should not undergo POEM:

- Severe erosive esophagitis (signs and symptoms of erosive esophagitis: difficult or pain when swallowing, sensation of something being stuck in the back of the throat, burning feeling in the throat, chest pain, heart burn, hoarseness, chronic cough, and blood in vomit)
- Severe coagulation disorders
- Liver cirrhosis with portal hypertension

- Prior therapy that may compromise the integrity of the esophageal mucosa or lead to submucosal fibrosis (e.g., radiation, endoscopic mucosal resection, or radiofrequency ablation).

The evidence is sufficient to determine this technology results in an improvement in net health outcomes in the treatment of individuals with diagnosed achalasia and those with recurrent or persistent symptoms of achalasia.

Peroral Endoscopic Myotomy (POEM) for Pediatric Patients with Achalasia

Review of Evidence

In 2021 Zhong et. al., published an updated systematic review and meta-analysis evaluating clinical outcomes of peroral endoscopic myotomy (POEM) for the treatment of achalasia in children. The review included 11 studies published between January 2009 to June 2020 (N=389; 222 boys). The mean age of the patients ranged from 5.5 to 15.2 years with symptom duration ranging from 1.7 to 26.4 months. The pooled technical success (completion of the POEM procedure successfully) was achieved in 385 children (97.4%; 95% CI, 94.7% to 98.7%) and the pooled clinical success (decrease in Eckhardt score to ≤ 3 during follow-up) was achieved in 343 children (92.4%; 95% CI, 89% to 94.8%). The Eckhardt score was significantly reduced by 6.76 points following POEM (95% CI, 6.18 to 7.34; $p < .00001$). Regarding adverse events, the pooled major adverse event rate was 12.8% (95% CI, 4.5% to 31.5%) with a pooled gastroesophageal reflux rate of 17.8% (95% CI, 14.2% to 22%). The authors concluded that POEM was effective and safe for treating children with achalasia; however, all included studies in the analysis were observational in nature.

In 2019, Lee et. al., conducted a systematic review and meta-analysis to evaluate the safety and efficacy of peroral endoscopic myotomy (POEM) in children. Studies that conducted POEM in pediatric patients age < 18 years were included. Studies were excluded if they had a non-pediatric population; no clear diagnostic or clinical evaluation of achalasia (e.g., Eckardt scoring system, esophageal manometry, barium X-ray, upper endoscopy); and/or were non-human studies, case-reports, editorials, and review papers. Twelve studies (n=142) met inclusion criteria and included eight case series and four retrospective cohort studies. Three of the studies were published conference abstracts. Primary outcome measures included the Eckardt score and lower esophageal sphincter (LES) pressure before and after POEM. Secondary outcome measures were the clinical success rate and adverse events. Follow-ups ranged from 1-36 months (median 14 months). Compared to baseline, there was a significant reduction in mean Eckardt scores by 6.88 points ($p < 0.001$) and a decrease in LES pressure by 20.73 mmHG ($p < 0.001$). At least 93% of the patients experienced improvement or resolution of achalasia symptoms. Adverse events included mucosal injury (n=7), esophageal tear (n=1), esophageal leak (n=1), focal atelectasis (n=2), pneumoperitoneum (n=13), pneumothorax (n=4), pneumonitis/pneumonia (n=15), pleural effusion (n=9), subcutaneous or mediastinal emphysema (n=25), retroperitoneal CO₂ (n=2), fever (n=1), and severe-postoperative pain (n=2). There were also cases of clinical reflux symptoms after POEM such as

heartburn (n=2), regurgitation (n=11), and reflux esophagitis (n=5). Most events were minor and self-limiting. Limitations of the studies included: small patient populations; short-term follow-ups; retrospective study designs and conference abstracts; no comparators; missing data; and heterogeneity of the procedure. Randomized controlled trials comparing POEM to established treatment options are needed to establish the safety and efficacy of POEM for the treatment of achalasia in pediatric patients.

In 2019, Nabi et. al., published a retrospective study assessing peroral endoscopic myotomy (POEM) for the treatment of children with achalasia. Forty-four patients ≤ 18 years old and weighing ≥ 10 kg who were diagnosed with achalasia between 2013 and 2018 were included. POEM was successfully performed in 43 patients (technical success 97.72%). Eleven (25.6%) children experienced intra-operative adverse events, including retroperitoneal CO₂ (n=7), capnoperitoneum (n=3), and mucosal injury (n=1). Clinical success at 1, 2, 3, and 4 years of follow-up was 92.8%, 94.4%, 92.3%, and 83.3%, respectively. The study was limited by its retrospective design, the lack of confirmation of GERD in about half the patients, and the small number of patients who completed 3 or more years of follow-up.

In 2017, Miao et.al. published a retrospective, single-center study of POEM for the treatment of pediatric achalasia. Twenty-one children (aged 11 months to 18 years) diagnosed with achalasia and treated between 2014 and 2016 were included. Mean follow-up time was 13.2 months. No severe adverse events were reported, and for all patients, difficulty in feeding or swallowing was significantly alleviated or resolved. By 1 month after POEM, all Eckardt scores were < 3 and by 6 months were 0.75 on average (average pre-operative score: 7.18; $p < .001$). At 6 months, an average weight gain of 2.7 kg was observed. Four patients had gastroesophageal reflux and 2 had concomitant gastroesophageal reflux and reflux esophagitis at 3 months follow-up. No limitations to the study were reported.

Summary of Evidence

For pediatric patients who have achalasia who receive peroral endoscopic myotomy (POEM), the evidence includes nonrandomized studies and systematic reviews. The studies reported treatment success for POEM based on decreases in Eckardt scores and lower esophageal sphincter (LES) pressure. No randomized controlled trials (RCTs) have been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome in this population of individuals.

Diverticular Peroral Endoscopic Myotomy (D-POEM)

Esophageal diverticula are rare outpouchings of the esophagus that can cause dysphagia, regurgitation, chest pain and aspiration pneumonia as they progress. Interventional treatment should be considered for symptomatic cases. Surgical resection of the diverticulum has traditionally been considered to be the only curative option. The D-POEM technique is unique in that, through the creation of submucosal tunneling, the cricopharyngeus muscle or the diverticular septum can be methodically exposed, allowing for careful complete septotomy under direct endoscopic visualization. The D-

POEM technique for the treatment of esophageal diverticula has only been reported in limited case reports.

Clinical Context and Therapy Purpose

The purpose of diverticular peroral endoscopic myotomy (D-POEM) in individuals who have esophageal diverticula is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with esophageal diverticula.

Interventions

The therapy being considered is diverticular peroral endoscopic myotomy (D-POEM). The D-POEM technique is unique in that, through the creation of submucosal tunneling, the cricopharyngeus muscle or the diverticular septum can be methodically exposed, allowing for careful complete septotomy under direct endoscopic visualization.

Comparators

Comparators of interest include diverticulectomy and flexible endoscopic diverticulotomy.

Outcomes

The general outcomes of interest are symptom relief and treatment-related morbidity.

Symptom relief may be experienced shortly following the procedure. Assessment of durability of relief requires a follow-up of months to years.

Summary Of Evidence

Studies in the peer-reviewed literature investigating diverticular peroral endoscopic myotomy (D-POEM) are primarily in the form of small prospective studies with patient populations ranging from 11–25 with follow-up of 12 months. Larger prospective studies with longer follow-up are needed to assess the efficacy and safety of D-POEM. There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of DPOEM for the treatment of esophageal diverticula or any other indication.

Gastric Peroral Endoscopy Myotomy (G-POEM)

Gastroparesis (GP) is a chronic motility disorder defined as a functional disorder with objective delayed gastric emptying in the absence of a mechanical obstruction. The symptoms of gastroparesis include nausea, vomiting, early satiety, belching, bloating, and/or upper abdominal pain. Initial management of gastroparesis consists of dietary modification, optimization of glycemic control and hydration, and pharmacologic therapy with prokinetic and antiemetic medications. Patients who are refractory to medical therapy may require surgical interventions in the forms of tube gastrostomy, subtotal gastrectomy, or pyloroplasty. Surgical pyloroplasty (e.g., Heineke-Mikulicz pyloroplasty) can lead to sustained improvement of symptoms in patients with refractory gastroparesis.

The POEM procedure has been adapted to be performed in the stomach (G-POEM) is a proposed, less invasive alternative treatment of severe gastroparesis that is refractory to medical therapy in selected patients. G-POEM consists of creating a prepyloric submucosal tunnel extending to the pylorus before dissecting circular and oblique muscle bundles, as per the peroral endoscopic myotomy (POEM).

Clinical Context and Therapy Purpose

The purpose of gastric peroral endoscopy myotomy (G-POEM) is in individuals who have gastroparesis (GP) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with gastroparesis (GP).

Interventions

The therapy being considered is peroral endoscopy myotomy (G-POEM). G-POEM consists of creating a prepyloric submucosal tunnel extending to the pylorus before dissecting circular and oblique muscle bundles, as per the peroral endoscopic myotomy (POEM).

Comparators

Comparators of interest include tube gastrostomy, subtotal gastrectomy, or pyloroplasty.

Outcomes

The general outcomes of interest are symptom relief and treatment-related morbidity.

Symptom relief may be experienced shortly following the procedure. Assessment of durability of relief requires a follow-up of months to years.

Review of Evidence

A number of prospective observational studies (n=13–80 patients) and systematic reviews with meta-analysis (n=9–22 studies/196–322 patients) have evaluated the efficacy and safety of G-POEM in treating refractory gastroparesis. These studies have been limited by short-term follow-up of 1–18 months and lack of RCT's. The studies used the Gastroparesis Cardinal Symptom Index (GCSI) and gastric emptying scintigraphy (GES). GCSI measures the following symptoms: nausea, retching, vomiting, stomach fullness, inability to finish a meal, excessive fullness, loss of appetite, bloating and abdominal distension. GES measures half gastric-emptying time, retention at two and four hours. Larger and longer-term studies with active treatment comparators are needed to fully evaluate the effectiveness and safety of G-Poem for refractory gastroparesis

In 2021, Vosoughi et. al. conducted an international prospective trial at five tertiary centers (four USA, one South America) that investigated the efficacy and safety of G-POEM in patients with refractory gastroparesis. Adults (n=80) with refractory gastroparesis were included in the study, the mean age was 49.3±14.9 with 57 (71.3%)

females. The most common etiology of gastroparesis was idiopathic (n=33, 41.3%), followed by postsurgical (n=28, 35%) and diabetic (n=19, 23.8%). The primary outcome measured clinical success of G-POEM which was defined as at least one score decrease in Gastroparesis Cardinal Symptom Index (GCSI) with $\geq 25\%$ decrease in two subscales, at 12 months. Secondary outcomes evaluated safety, change in quality of life and change in gastric retention over the course of the study. The GCSI Score and subscales, adverse events (AEs) and 36-Item Short Form questionnaire of quality of life were evaluated at baseline and one, three, six and 12 months after G-POEM. A gastric emptying study was performed before and three months after the procedure. Five patients were lost to follow-up with 75 patients (94%) completing the 12-month follow-up. Clinical success at one month, three months, six months and 12 months following G-Poem were 57.5%, 61.5%, 60.3% and 56%, respectively. At 12 months, the GCSI Score (including subscales) improved moderately after G-POEM ($p < 0.05$). Clinical success rate at 12 months was generally not significant across gastroparesis subtypes ($p = 0.913$). There was a significant improvement in the majority of the quality-of-life aspects both at 12 months and over time. Physical functioning, role limitation due to physical health and bodily pain, showed no significant change. Three months after G-POEM, GES was performed in 53 of the 80 patients (66%). Gastric retention at four hours decreased significantly at three months from baseline, which resulted in GES improvement in 64.2% (34 of 53 cases). Mild procedure-related AEs occurred in five (6%) patients. Author noted limitations included the lack of a control group and the inability to sufficiently control important confounding variables, such as the use of prokinetics could be a major threat to the study's internal validity. Lastly, gastric emptying was not evaluated at 12 months after the study and several patients were not available for repeat gastric emptying study at three months post procedure. The authors concluded that G-POEM is a safe procedure but showed only modest overall effectiveness in the treatment of refractory gastroparesis. Further studies are required to identify the best candidates for G-POEM; unselective use of this procedure should be discouraged. No health disparities were identified by the investigators.

In 2020, Spadaccini et al. evaluated the efficacy and safety of G-POEM for refractory gastroparesis (GP) in a systematic review and meta-analysis. The authors noted that symptomatic improvement was achieved after 83.9% of procedures. When comparing the mean values of pre- and post-procedural gastric emptying scintigraphy (GES), there was a significant decrease of the gastric retention percentage at two and four hours $74.9\% \pm 5.2\%$ versus $52.5\% \pm 10.8\%$ ($p < 0.001$) and $44.1\% \pm 13.0\%$ versus $20.6\% \pm 9.5\%$ ($p = 0.006$). Limitations included short term follow-up and the lack of head-to head comparison with either surgical or endoscopic pylorus directed therapies. Additionally, G-POEM is a relatively new technique and long-term data on symptom relief are still lacking. The authors concluded that G-POEM appears to be a promising approach for GP in terms of safety and efficacy outcomes in the short term.

In 2020, Yan et al. also used a systematic review and meta-analysis that evaluated the efficacy and safety of G-POEM for refractory gastroparesis (GP) using the GCSI scale and GES. The authors noted that the technical success rate was 100%. After G-POEM,

patients reported significant changes in GCSI score ($p < 0.0001$), GCSI reduction ($p < 0.0001$), gastric emptying scintigraphy at four hours (GES-4h) ($p < 0.00001$), and GES time (GET) reduction ($p < 0.00001$). The intra-procedure complication rate was 5.1 %, including capnoperitoneum (seven cases) and accidental mucotomy (five cases). The post-procedure complication rate was 6.8 %, including abdominal pain (three cases), bleeding (three cases), ulcer (one case), difficulty swallowing (one case) and others (eight cases). Both intra and post-procedure complications were easily managed by conservative or endoscopic treatments. Limitations noted by the authors included: the quality of the included studies was relatively low, studies had a high risk of bias, lack of RCT's, and heterogeneity between studies was significant, probably due to the mismatching of baseline information. The authors concluded that the outcome of this meta-analysis is significant, caution is still needed to draw a conclusion as to whether G-POEM can be a complete treatment for the treatment of gastroparesis.

In 2019, Aghaie Meybod et al. conducted a systematic review and meta-analysis that concluded that treating refractory gastroparesis with G-POEM results in a high rate of clinical success and low rate of adverse events. The clinical success weighted pool rates (WPR) were 82%. The post procedure mean values of GCSI were reduced significantly at five days ($p < 0.001$) when compared to pre-procedure GCSI. The mean values of gastric emptying were significantly decreased 2–3 months after the procedure ($p < 0.05$). Author noted limitations included the small patient population of the included studies and high level of heterogeneity in the secondary outcome measures. This finding could be attributed to different inclusion criteria in the studies. The authors also noted that G-POEM is a relatively new technique and the studies that reported outcomes have short follow-up duration.

Summary of Evidence

There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of G-POEM for the treatment of refractory gastroparesis or any other indication. Larger prospective randomized controlled studies with longer follow-up are needed to assess the efficacy and safety of G-POEM. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Zenker Peroral Endoscopic Myotomy (Z-POEM)

A Zenker's diverticulum (ZD), or pharyngeal pouch, is an outpouching that occurs at the junction of the lower part of the throat and the upper portion of the esophagus. The pouch forms because the muscle that divides the throat from the esophagus, the cricopharyngeal (CP) muscle, fails to relax during swallowing. Symptoms of ZD include dysphagia, regurgitation, and its associated complications. Symptomatic ZD is more prominent in males (ratio 1:5) and typically seen in middle-aged adults and older adults in their seventh or eighth decade of life. The occurrence of ZD shows geographical variation and has been described more frequently in Northern Europe, North America, and Australia than in Southern Europe, Japan, or Indonesia.

The available treatment modalities include open surgery, rigid endoscopy, and flexible endoscopy. Z-POEM which is also known as submucosal tunneling endoscopic septum division (STESD) is a modified peroral endoscopic myotomy (POEM) technique. This technique eliminates direct dissection of the CP septum and, instead, involves dissecting a submucosal tunnel around the septum to achieve a complete myotomy. The procedure is indicated for treating small (< 2 cm) ZD because the small pocket may disappear after the myotomy is performed.

Clinical Context and Therapy Purpose

The purpose of Zenker peroral endoscopic myotomy (Z-POEM) is in individuals who have Zenker's diverticulum (ZD), or pharyngeal pouch to provide a treatment option that is an alternative to or an improvement on existing therapies.

Symptoms of ZD include dysphagia, regurgitation, and its associated complications.

Populations

The relevant population of interest is individuals with Zenker's diverticulum (ZD), or pharyngeal pouch.

Interventions

The therapy being considered is Zenker peroral endoscopic myotomy (Z-POEM). Z-POEM which is also known as submucosal tunneling endoscopic septum division (STESD) is a modified peroral endoscopic myotomy (POEM) technique. This technique eliminates direct dissection of the CP septum and, instead, involves dissecting a submucosal tunnel around the septum to achieve a complete myotomy. The procedure is indicated for treating small (< 2 cm) ZD because the small pocket may disappear after the myotomy is performed.

Comparators

Comparators of interest include open surgery, rigid endoscopy and flexible endoscopy.

Outcomes

The general outcomes of interest are symptom relief and treatment-related morbidity.

Symptom relief may be experienced shortly following the procedure. Assessment of durability of relief requires a follow-up of months to years.

Summary of Evidence

Studies in the peer-reviewed literature investigating Z-POEM are primarily in the form of retrospective studies. Large, well-designed, controlled trials showing long-term safety and efficacy are lacking. There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of ZPOEM for the treatment of dysphagia or any other indication. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Practice Guidelines and Position Statements

American College of Gastroenterology (ACG)

The American College of Gastroenterology (ACG) updated their clinical guideline: Diagnosis and Management of Achalasia in 2020 which includes the following recommendations:

- Peroral endoscopic myotomy (POEM) or laparoscopic Heller myotomy (LHM) is more effective for type III achalasia when compared to pneumatic dilatation (PD)
- POEM and PD have comparable symptom improvement in patients with types I or II achalasia
- POEM and LHM have comparable symptom improvement in patients with achalasia
- POEM is a safe option in patients with achalasia who have failed PD or LHM
- POEM is associated with a higher incidence of GERD when compared to LHM with fundoplication or PD

In 2013, the American College of Gastroenterology (ACG) clinical guideline: Management of Gastroparesis which states the following under the section for surgical options for GERD: “The usage of current endoscopic therapy or transoral incisionless fundoplication cannot be recommended as an alternative to medical or traditional surgical therapy (Strong recommendation, moderate level of evidence)”

American Gastroenterological Association (AGA)

In 2017, the American Gastroenterological Association (AGA) issued a clinical practice update by the committee of the American Gastroenterological Association on the use of per-oral endoscopic myotomy in achalasia proposes the following recommendations:

1. In determining the need for achalasia therapy, patient-specific parameters (Chicago Classification subtype, comorbidities, early vs late disease, primary or secondary causes) should be considered along with published efficacy data;
2. Given the complexity of this procedure, POEM should be performed by experienced physicians in high-volume centers because an estimated 20–40 procedures are needed to achieve competence
- 3 If the expertise is available, POEM should be considered as primary therapy for type III achalasia;
4. If the expertise is available, POEM should be considered as treatment option comparable with laparoscopic Heller myotomy for any of the achalasia syndromes; and
5. Post-POEM patients should be considered high risk to develop reflux esophagitis and advised of the management considerations (potential indefinite proton pump inhibitor therapy and/or surveillance endoscopy) of this before undergoing the procedure.

The AGA concluded that POEM appears to be safe and effective in the short-term but that long-term durability of POEM are not yet available. Existing uncontrolled reports

suggested efficacy of POEM is equal to or superior to LHM but more likely to result in post-treatment reflux.

American Society of Gastrointestinal and Endoscopic Surgeons (ASGE)

In 2020, the American Society of Gastrointestinal and Endoscopic Surgeons (ASGE) issued an evidence-based guideline on the management of achalasia. Based on their evaluation, ASGE issued the following recommendations:

- Laparoscopic Heller myotomy, pneumatic dilation, and POEM are effective treatments for patients with achalasia. Achalasia type, local expertise, and patient preference should be used to decide between these treatments (strong recommendation based on high-quality evidence).
- POEM is the preferred treatment for management of patients with type III achalasia (weak recommendation, very-low quality evidence).
- Patients with failed initial myotomy (POEM or laparoscopic Heller myotomy), should undergo pneumatic dilation or redo myotomy using either the same or an alternative technique (weak recommendation based on very-low quality evidence).
- POEM patients should be counseled regarding the increased risk of postprocedure reflux compared with pneumatic dilation and laparoscopic Heller myotomy (weak recommendation based on low-quality evidence).
- POEM and laparoscopic Heller myotomy are comparable treatment options for management of patients with achalasia types I and II (weak recommendation based low-quality evidence).

The guideline noted that POEM is an intricate endoscopic procedure that requires advanced endoscopic skills, knowledge of surgical anatomy, and expertise in submucosal endoscopy and management of adverse events, such as bleeding, perforation, and leakage.

These 2020 ASGE guidelines were endorsed by the American Neurogastroenterology and Motility Society and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES).

International Society for Diseases of the Esophagus

In 2018, the International Society for Diseases of the Esophagus published guidelines on the diagnosis and management of achalasia. The Society convened 51 experts from 11 countries, including several from the United States, to systematically review evidence, assess recommendations using the GRADE system, and vote to integrate the recommendations into the guidelines (>80% approval required for inclusion). Table 1 summarizes POEM recommendations.

Table 1. Recommendations for the Treatment of Achalasia

Recommendation	LOR	GOR
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POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to Heller myotomy.	Conditional	Very low
POEM is an effective therapy for achalasia both in short- and medium-term follow-up with results comparable to pneumatic dilations.	Conditional	Low
Pretreatment information on GERD, nonsurgical options (pneumatic dilation), and surgical options with lower GERD risk (Heller myotomy) should be provided to patient.	Good practice	NA
POEM is feasible and effective for symptom relief in patients previously treated with endoscopic therapies.	Conditional	Very low
POEM may be considered an option for treating recurrent symptoms after laparoscopic Heller myotomy.	Conditional	Low
Appropriate training (in vivo/in vitro animal model) and proctorship should be considered prior to a clinical program of POEM.	Good practice	NA

GERD: gastroesophageal reflux disease; GOR: grade of recommendation; LOR: level of recommendation; NA: not applicable; POEM: peroral endoscopic myotomy.

Regulatory Status

POEM uses available laparoscopic instrumentation and, as a surgical procedure, is not subject to regulation by the U.S. Food and Drug Administration.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policy

- [Pharmacy Policy](#)
 - [05.01.02 Neuromuscular Blocking Agents](#)
- [02.01.03 Ambulatory Esophageal pH Monitoring](#)

Peroral endoscopic myotomy (POEM) may be considered **medically necessary** when **ALL** of the following criteria are met:

- The individual is age 18 years or older; **and**
- The diagnosis of achalasia has been confirmed by a positive esophageal manometry, EGD or barium swallow; **and**
- Eckardt symptom score is >3; **and**
- The individual does not have one of the following conditions that would be considered a contraindication to the POEM procedure:
 - Erosive esophagitis (signs and symptoms of erosive esophagitis: difficult or pain when swallowing, sensation of something being stuck in the back of the throat, burning feeling in the throat, chest pain, heart burn, hoarseness, chronic cough, and blood in vomit)
 - Coagulation disorders (e.g., hemophilia, Von Willebrand disease, clotting factor deficiencies, hypercoagulable states, and deep venous thrombosis)
 - Liver cirrhosis with portal hypertension
 - Prior therapy that may compromise the integrity of the esophageal mucosa or lead to submucosal fibrosis (e.g., radiation, endoscopic mucosal resection, or radiofrequency ablation).

Peroral endoscopic myotomy (POEM) may be considered **medically necessary** for individuals aged 18 years and older with recurrent or persistent achalasia following other treatments (pneumatic dilation, Botox injections or Heller myotomy) with an Eckardt symptom score >3 and no contraindications indicated above.

A repeated peroral endoscopic myotomy (POEM) may be considered **medically necessary** for individuals aged 18 years and older with recurrent symptoms after a prior POEM procedure on the opposite site of the esophagus with an Eckardt symptom score >3 and no contraindications indicated above.

Peroral endoscopic myotomy (POEM) for individuals 18 years and older not meeting the above criteria and for all other indications is considered **investigational** because the evidence is insufficient to determine the effects of this technology on net health outcomes

Peroral endoscopic myotomy (POEM) for individuals under the age of 18 for the treatment of achalasia and for any other indication is considered **investigational** because the safety and/or effectiveness of this service cannot be established by the available published peer reviewed literature.

The following peroral endoscopic myotomy (POEM) procedures are considered **investigational** for all indications, because the evidence is insufficient to determine the effects of this technology on net health outcomes:

- Diverticular peroral endoscopic myotomy (D-POEM)
- Gastric peroral endoscopic myotomy (G-POEM)
- Zenker peroral endoscopic myotomy (Z-POEM)

Policy Guidelines

Eckardt Symptom Score

The Eckardt symptom score (ESS) is most frequently used for the evaluation of symptoms, stages, and efficacy of achalasia treatment. The ESS is a 4-item self-report scale measuring weight loss, chest pain, regurgitation, and dysphagia. Each item is graded on a score of 0 to 3 with a maximum score of 12. Score greater than or equal to 3 are considered active achalasia.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 43180 Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (e.g., Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed
- 43497 Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM])
- 43499 Unlisted procedure, esophagus
- 43999 Unlisted procedure, stomach

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POLICY HISTORY

Date	Reason	Action
December 2022	Annual Review	Policy Revised
December 2021	Annual Review	Policy Revised
December 2020	Annual Review	Policy Revised
December 2019	Annual Review	Policy Revised
December 2018		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
 Medical Policy Analyst
 PO Box 9232
 Des Moines, IA 50306-9232

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