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AGA Clinical Practice Update on Advances in Per-Oral Endoscopic Myotomy (POEM) and Remaining Questions—What We Have Learned in the Past Decade: Expert Review

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DESCRIPTION: This American Gastroenterological Association (AGA) Institute Clinical Practice Update (CPU) aims to review the available evidence and provide expert advice regarding advances in per-oral endoscopic myotomy (POEM). **METHODS:** This CPU was commissioned and approved by the AGA Institute CPU Committee and the AGA Governing Board to provide timely guidance on a topic of high clinical importance to the AGA membership and underwent internal peer review by the CPU Committee and external peer review through standard procedures of *Gastroenterology.* This review is framed around best practice advice points agreed upon by the authors, based on the current available evidence and expert opinion in this field. Because systematic reviews were not performed, these best practice advice statements do not carry formal ratings regarding the quality of evidence or strength of the presented considerations.

BEST PRACTICE ADVICE STATEMENTS

BEST PRACTICE ADVICE 1: Patients evaluated for POEM should undergo a comprehensive diagnostic workup, which includes clinical history and review of medications, upper endoscopy, timed barium esophagram, and high-resolution manometry. Endoscopic functional luminal impedance planimetry can be a useful adjunct test, particularly in cases when diagnosis is equivocal. **BEST PRACTICE ADVICE 2:** POEM, laparoscopic Heller myotomy, and pneumatic dilation are effective therapies for type I and type II achalasia; the decision between these treatment modalities should be based on shared decision making, taking into account patient and disease characteristics, patient preferences, and local expertise. POEM should be considered the preferred treatment for type III achalasia. **BEST PRACTICE ADVICE 3:** Patients with esophagogastric outflow obstruction alone and/or nonachalasia spastic disorders on manometry should undergo a comprehensive evaluation with correlation of symptoms. Evidence for POEM for these manometric findings are limited and should only be considered on a case-by-case basis after other less invasive approaches have been exhausted. **BEST PRACTICE ADVICE 4:** A single dose of antibiotics at the time of POEM may be sufficient for antibiotic prophylaxis. **BEST PRACTICE ADVICE 5:** POEM can be performed via either an anterior or posterior tunnel orientation, with comparable efficacy, safety, and rate of postprocedure reflux between these 2 approaches. Endoscopist's preferences and patient's surgical history, including prior laparoscopic Heller myotomy and/or POEM, should be considered when determining tunnel orientation. **BEST PRACTICE ADVICE 6:** The optimal length of the myotomy in the esophagus and cardia, as it pertains to treatment efficacy and risk for postprocedure reflux, remains to be determined. Adjunct techniques, including real-time intraprocedure functional luminal impedance planimetry, may be considered to tailor or confirm the adequacy of the myotomy. **BEST PRACTICE ADVICE 7:** The clinical impact of routine esophagram or endoscopy immediately post-POEM remains unclear. Testing can be considered based on local practice preferences, and in cases in which intraprocedural events or postprocedural findings warrant further evaluation. **BEST PRACTICE ADVICE 8:** Same-day discharge after POEM can be considered in select patients who meet discharge criteria. Patients with advanced age, significant comorbidities, poor social support, and/or access to specialized care should be considered for hospital admission, irrespective of symptoms. **BEST PRACTICE ADVICE 9:** Pharmacologic acid suppression should be strongly considered in the immediate post-POEM setting, given the increased risk of postprocedure reflux and esophagitis. **BEST PRACTICE ADVICE 10:** All patients should undergo monitoring for gastroesophageal reflux disease after POEM. Patients with persistent esophagitis and/or reflux-like symptoms despite proton pump inhibitor use, should undergo additional testing to evaluate for other etiologies besides pathologic acid exposure and management to optimize and achieve reflux control. **BEST PRACTICE ADVICE 11:** Long-term postprocedure surveillance is encouraged to monitor for progression of disease and complications of gastroesophageal reflux disease. **BEST PRACTICE ADVICE 12:** POEM may be superior to pneumatic dilation for patients with failed initial POEM or laparoscopic Heller myotomy; however, the decision among treatment modalities should be based on shared decision making between the patient and physician, taking into account risk of postprocedural reflux, need for repeat interventions, patient preferences, and local expertise.

Keywords: Per-Oral Endoscopic Myotomy; POEM; Achalasia; Esophagogastric Outflow Obstruction; EGJOO; Esophageal Dysmotility.

Since its introduction into clinical practice more than a decade ago, per-oral endoscopic myotomy (POEM) has become a mainstream treatment for achalasia. Multiple

Abbreviations used in this paper: **EGJ, esophagogastric junction; EGJOO, esophagogastric outflow obstruction; FLIP, functional luminal impedance planimetry; GERD, gastroesophageal reflux disease; HRM, high-resolution manometry; IRP, integrated relaxation pressure; LES, lower esophageal sphincter; LHM, laparoscopic Heller myotomy; PD, pneumatic dilation; POEM, per-oral endoscopic myotomy; PPI, proton pump inhibitor; RCT, randomized controlled trial.**

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observational studies and randomized trials have consistently supported the clinical efficacy and safety profile of POEM and its favorable performance compared with both laparoscopic Heller myotomy (LHM) and pneumatic dilation (PD).[1,2] Yet many questions remain unanswered, despite the widespread adoption of POEM. For one, the role of POEM for nonachalasia esophageal disorders remains to be determined. From a technical standpoint, the optimal approach to the myotomy and its impact on both clinical success and its effect on post-POEM reflux has not been elucidated. Similarly, there is significant heterogeneity in terms of pre- and post-POEM patient evaluation and management, stemming from limited high-quality evidence and lack of expert consensus. The intent of this document was to provide an update on the role of POEM for esophageal motility disorders and offer practical guidance in terms of key questions that remain to be answered. This expert review serves as an update to the prior American Gastroenterological Association Clinical Practice Update on this topic released in 2017.[3] A summary of our suggested approach to patients being evaluated for POEM is shown in Figure 1.

Preprocedure Evaluation and Indications for Per-Oral Endoscopic Myotomy

Best Practice Advice 1: Patients evaluated for POEM should undergo a comprehensive diagnostic workup, which includes clinical history and review of medications, upper endoscopy, timed barium esophagram, and high-resolution manometry. Endoscopic functional luminal impedance planimetry (FLIP) can be a useful adjunct test, particularly in cases when diagnosis is equivocal.

A comprehensive evaluation is paramount in patients to confirm the diagnosis before consideration of POEM. A detailed clinical history helps establish the quality and severity of symptoms that may be best treated with POEM. Endoscopy (esophagogastroduodenoscopy), esophagram, and high-resolution manometry (HRM) are well-established tests for the evaluation of patients before POEM. Endoscopic findings suggestive of poor esophageal clearance may include frothy retained secretions[4] and a puckered gastroesophageal junction. A careful retroflexed examination during esophagogastroduodenoscopy is mandatory to exclude any irregularities that may suggest pseudoachalasia. Retention of barium on esophagram can show structural changes and confirm outflow obstruction. Timed barium esophagram and administration of a 13-mm barium tablet may elicit more subtle evidence for narrowing at the esophagogastric junction (EGJ) and can also be useful to monitor disease severity and postintervention effect.[5] HRM remains the gold standard for the diagnosis of achalasia. Defining the subtype of achalasia according to the current Chicago classification system 4.0[6] is crucial for phenotype-directed treatment to ensure optimal patient outcome (Figure 2). Nonetheless, it should be noted that although HRM tends to be more reliable for the diagnosis of achalasia compared with other esophageal motility disorders, considerable expertise is still required for its interpretation and integration into the clinical scenario. FLIP is a useful adjunct test that may confirm and complement HRM findings (Figure 2).[8] Impaired EGJ opening, as assessed by low distensibility index on FLIP, can be suggestive of a diagnosis of achalasia in select cases otherwise not conclusively proven manometrically.[8] In all, multiple tests should be considered to comprehensively characterize anatomy and function, correlate with symptomatology, and guide treatment decisions.

Best Practice Advice 2: POEM, LHM, and PD are effective therapies for type I and type II achalasia; the decision among these treatment modalities should be based on shared decision making, taking into account patient and disease characteristics, patient preferences, and local expertise. POEM should be considered the preferred treatment for type III achalasia.

The presence of esophageal outflow obstruction at the EGJ and esophageal aperistalsis unifies the achalasia subtypes and directs interventional therapies to the lower esophageal sphincter (LES). PD, laparoscopic myotomy with partial fundoplication (LHM), and, more recently, POEM have all been demonstrated to be safe and effective in multiple studies. Data from high-level randomized controlled trials (RCTs) have demonstrated excellent outcomes for both LHM and PD.[9,10] POEM has been found to be superior to PD and noninferior to LHM in separate multicenter RCTs.[1,2]

Multiple studies have demonstrated that achalasia treatment outcomes vary among the sub-types. Achalasia types I and II are differentiated by the respective absence or presence of esophageal body pressurization with test swallows. However, type III achalasia is characterized by spastic body contractions capable of luminal obliteration regardless of pressurization. Studies consistently show that symptoms associated with type III achalasia appear best palliated with a myotomy tailored to the proximal extent of esophageal body spasm rather than confined to the LES alone.[11,12] As opposed to a laparoscopic approach, POEM provides the advantage of unlimited proximal extension of the myotomy,[13] although long-term outcomes on "long myotomies" are limited.

Best Practice Advice 3: Patients with esophagogastric outflow obstruction (EGJOO) alone and/or nonachalasia spastic disorders on manometry should undergo a comprehensive evaluation with correlation of symptoms. Evidence for POEM for these manometric findings are limited and should only be considered on a case-by-case basis after other less invasive approaches have been exhausted.

Current standards identify EGJOO by an elevated median integrated relaxation pressure (IRP) in both the supine and upright positions and elevated intrabolus pressure in at least 20% of supine swallows on HRM.[6] By itself, EGJOO is not pathognomonic for any diagnosis and should not, in isolation, be used to justify any permanent intervention. Rather EGJOO is a manometric finding that is associated with a multitude of alternative causes, such as obesity,

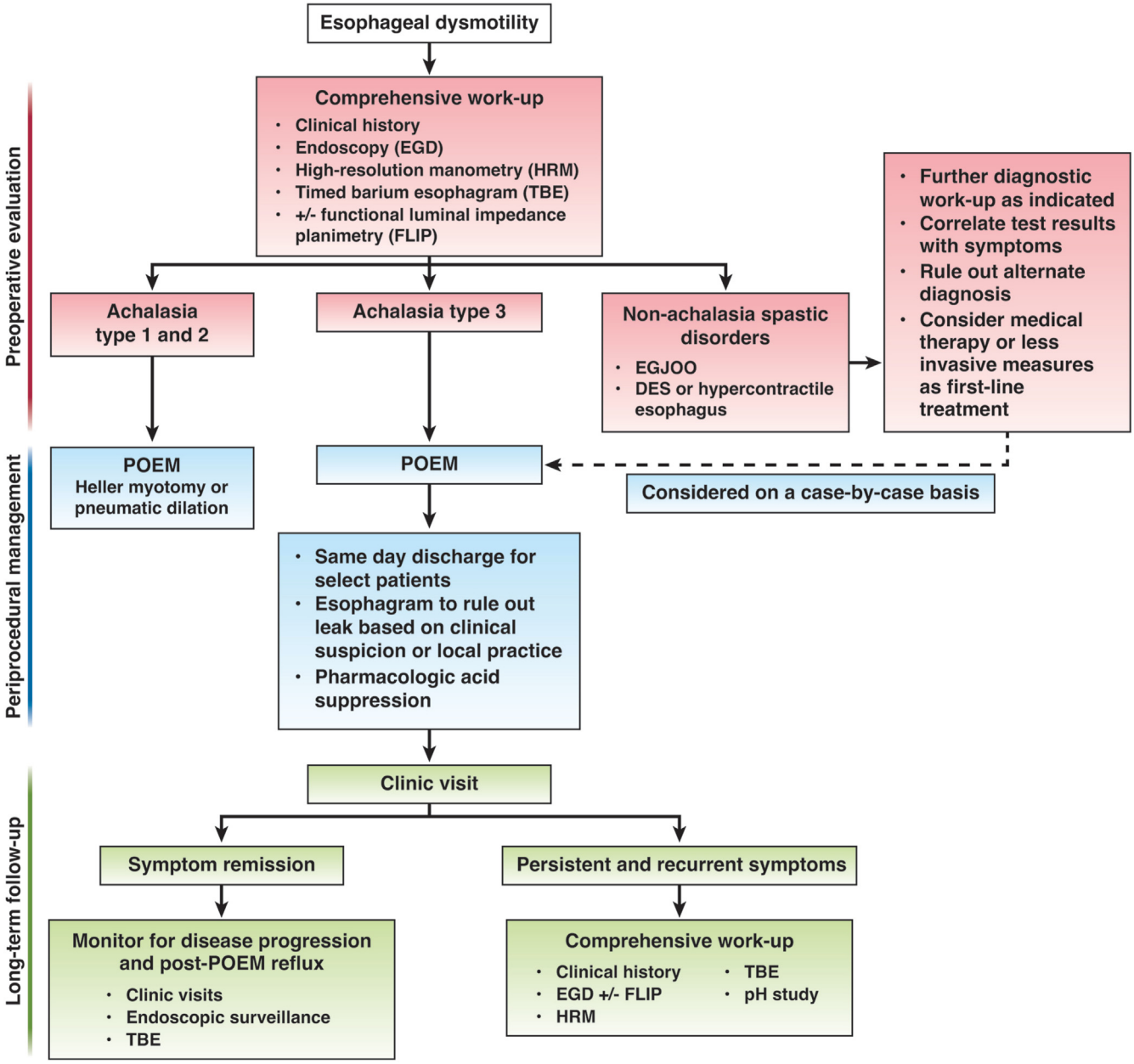

Figure 1. Flow chart summarizing the role of POEM in the evaluation and management of patients with esophageal motility disorders.

obstructive hiatal hernia, gastroesophageal reflux disease (GERD), external compression, sub-mucosal masses, medications (ie, opiates), and manometric artifact.[14] It is important to make the distinction between manometric and clinically relevant diagnoses of EGJOO and other non-achalasia spastic motility disorders (eg, diffuse esophageal spasms and hypercontractile esophagus). Careful consideration of potential false positives, as well as confirmatory compliance testing (eg, impedance planimetry, timed barium esophagram, and pH study) to exclude GERD and document symptomatic delayed esophageal emptying are mandatory. In all, the role of POEM for EGJOO and other nonachalasia spastic motility disorders is not well-defined; hence, we strongly suggest that less invasive alternatives (ie, medical therapy, botulinum toxin injections, and endoscopic dilation) be exhausted before consideration of POEM in very selected cases. Studies evaluating POEM in EGJOO alone are limited due to the rarity of the disease limiting even high-volume centers to only a few patients annually. However, several small studies have suggested reasonable outcomes in carefully selected patients.[15,16] Importantly, the reported long-term success rates for POEM in EGJOO (80%–85%) appear somewhat lower compared with POEM for the classic achalasia sub-types.[16]

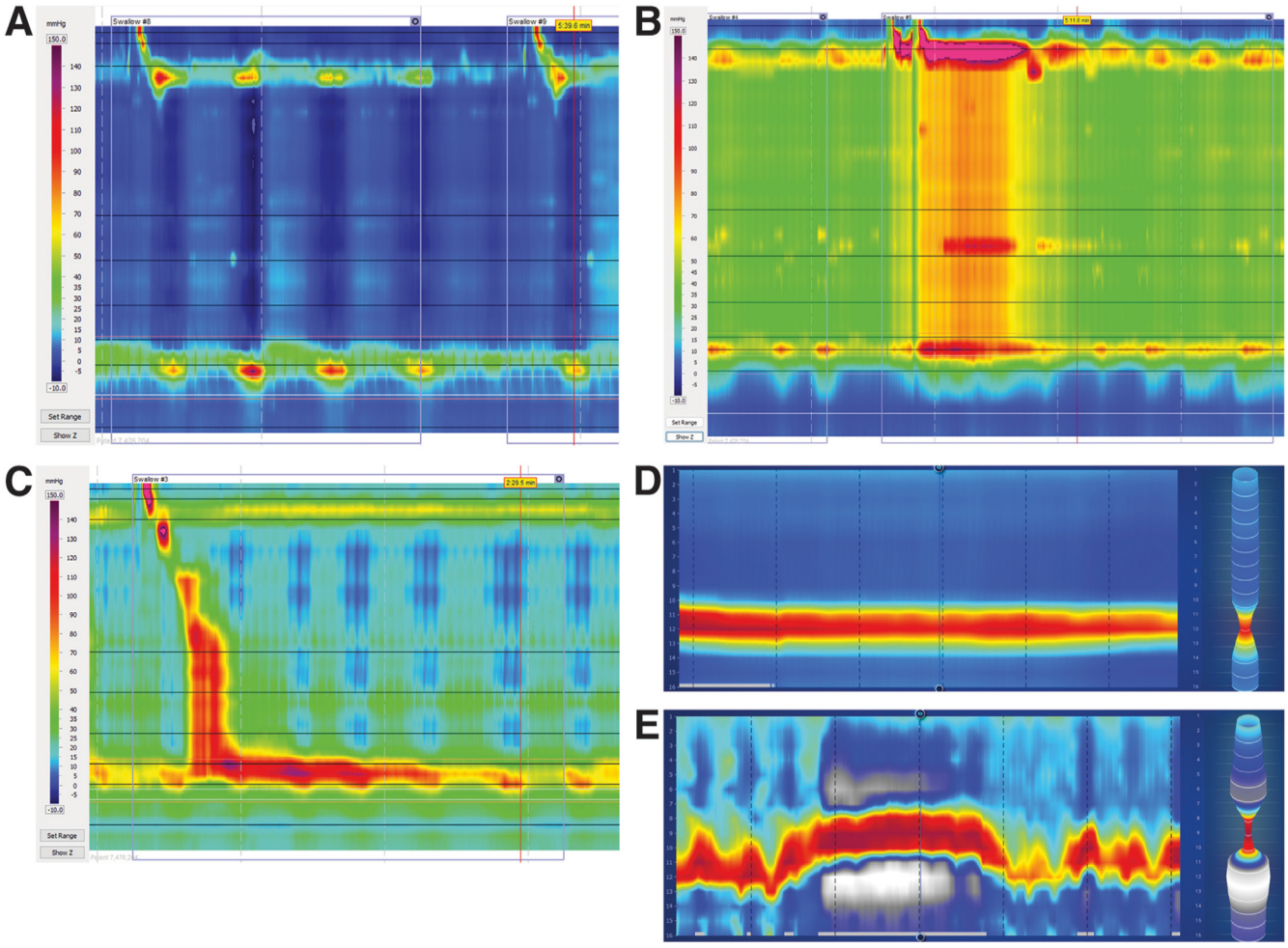

Figure 2. Representative images from HRM studies from patients with achalasia. (*A*) Type 1 achalasia with absent contractility and an elevated IRP. In this case, the median IRP was 19 mm Hg. Type 2 achalasia has an elevated IRP, 100% failed swallows, and presence of pan-esophageal pressurization in ≥20% of swallows, as shown in the HRM image in panel *B*. In this case, the median IRP was 61 mm Hg and there was pan-esophageal pressurization in 100% of swallows. Type 3 achalasia demonstrates an elevated IRP with abnormal swallows characterized by at least 20% premature contractions, as shown in panel *C*, which in this swallow had a distal latency of 3.8 seconds. This case had a median IRP of 51 mm Hg.[6] FLIP with the 16-cm 322N catheter demonstrates both EGJ metrics and esophageal topography. Reduced EGJ opening and absent contractility as seen classically in achalasia and EGJ outflow obstruction is shown in panel *D*. In this case, the diameter was 7.4 mm, distensibility was 1.2 mm^2/mm Hg, and the pressure was 37 mm Hg at the 60-mL fill volume, as shown here and the maximum diameter in this case was 11.2 mm at the 70-mL fill volume. A sustained occluding contraction, as shown in panel *E*, is indicative of a spastic-reactive contractile response, which may be seen in type III achalasia or other motility disorders with spastic features.[7]

Periprocedural Antibiotics and Procedural Considerations

Best Practice Advice 4: A single dose of antibiotics at the time of POEM may be sufficient for antibiotic prophylaxis.

The POEM procedure is associated with a potential risk of contamination, as the mediastinum and peritoneum may be exposed to luminal contents and commensal organisms of the oropharynx and upper gastrointestinal tract after myotomy. As such, prophylactic antibiotics are traditionally administered. Data on specific guidelines on the role and extent of antibiotic prophylaxis before and after POEM are lacking; hence, there is significant variability in clinical practice. A survey study of POEM experts demonstrated that although prophylactic antibiotics are universally initiated before or at the start of the procedure, antibiotic regimens and duration of antibiotics after POEM varies significantly (range, 1–7 days).[17] A recent RCT of 124 patients comparing the efficacy of single-dose vs short-course prophylactic antibiotics demonstrated no significant differences between the 2 groups in markers of inflammation, transient bacteremia, or infectious sequelae at day 5 after POEM.[18] Overall, the incidence of infection after POEM is low among patients on prophylactic antibiotics. The most appropriate antibiotic regimen and duration should be determined on a case-by-case basis, taking into consideration antibiotic-related adverse events, including allergic reactions, local antibiotic

resistance, and risk of secondary infections. Although a one-time antimicrobial prophylaxis may be sufficient and equivalent in efficacy to a short course; data specifically evaluating differences in infectious adverse events between these 2 approaches are still needed. There are currently no significant data supporting routine antifungal prophylaxis. Incidental esophageal candidiasis identified at the time of the procedure should be treated with a full course of antifungal therapy (usually 14–21 days), but should not necessarily preclude proceeding with POEM.

Best Practice Advice 5: POEM can be performed via either an anterior or posterior tunnel orientation, with comparable efficacy, safety, and rate of postprocedure reflux between these 2 approaches. Endoscopist's preferences and patient's surgical history, including prior LHM and/or POEM, should be considered when determining tunnel orientation.

The POEM procedure can be performed via a so-called anterior (2 o'clock) or posterior (5 o'clock) approach (Figure 3). Besides shorter procedure time with a posterior tunnel during POEM, RCTs and a recent meta-analysis of 18 studies with 1247 patients have failed to demonstrate differences in clinical success, adverse events, and post-POEM reflux rates between the 2 approaches.[19] Both approaches to POEM appear to be equally effective in the short and mid-term. However, it should be noted that interpretation of these data is limited by short follow-up, and considerable heterogeneity in myotomy length, objective pH testing, and outcome definitions. The decision to proceed with an anterior or posterior POEM should depend largely on the endoscopist's preference and patient characteristics. Among patients with prior surgery, including LHM or POEM, we strongly suggest opting for an approach opposite in orientation from the site of prior surgery, given the likelihood of extensive fibrosis in that same plane.

Best Practice Advice 6: The optimal length of the myotomy in the esophagus and cardia, as it pertains to treatment efficacy and risk for postprocedure reflux, remains to be determined. Adjunct techniques, including real-time intraprocedure FLIP, may be considered to tailor or confirm the adequacy of the myotomy.

The initial technique of POEM described by Inoue and colleagues[20] suggested an esophageal and gastric myotomy length of 7–8 cm and 2–3 cm, respectively. These metrics were based primarily on adequacy of relieving LES pressure and in reference to conventional surgical myotomy length.[21] However, the length of the myotomy during POEM has continued to evolve, particularly given advancements in HRM and better appreciation for manometric subtypes of achalasia. Furthermore, the use of FLIP may potentially offer a more pragmatic and objective real-time measure of EGJ distensibility. It was suggested recently that extending the myotomy just beyond the LES by 1–2 cm may be sufficient to normalize EGJ distensibility, without potentially incurring in additional increased risk for post-POEM reflux associated with a longer gastric myotomy.[22]

Although a long esophageal myotomy based on HRM findings is often suggested for patients with achalasia type III, the optimal esophageal myotomy length for types I and II achalasia remains to be determined. An RCT comparing short (<5 cm) and long (6–10 cm) esophageal myotomies found similar efficacy, safety profile, and incidence of GERD in patients with types I and II achalasia, with reduced procedure time with a shorter myotomy.[23] It has been theorized recently that the myotomy is a point of weakness in the esophagus, which becomes vulnerable to retained contractions and a potential risk factor for developing a blown-out myotomy after LHM and POEM.[24] Hence, it is conceivable that limiting the length of the esophageal myotomy, while ensuring complete myotomy at the EGJ, may potentially reduce the risk of blown-out myotomy. Larger trials and extended follow-up periods, coupled with robust methods for diagnosing GERD and precise techniques for measuring myotomy length, are essential before specific recommendations regarding the length of esophagogastric myotomy can be recommended. Studies evaluating the role of FLIP in directing intraoperative myotomy thickness and length based on esophageal distensibility are currently underway.

Immediate Postprocedural Care

Best Practice Advice 7: The clinical impact of routine esophagram or endoscopy immediately post-POEM remains unclear. Testing can be considered based on local practice preferences, and in cases in which intraprocedural events or postprocedural findings warrant further evaluation.

There is a lack of evidence and standardization on the postprocedural care of patients after POEM. Most aspects of postprocedural care have been adapted largely from our initial POEM experience and surgical practices. Traditionally, patients are generally admitted for at least 24 hours to monitor and evaluate for potential adverse events, even if the patient is asymptomatic. During this observation period, an esophagram and/or endoscopy are often performed to evaluate for leaks or other potential complications before advancement of diet and consideration for discharge.[17,20,25] However, the clinical benefit of these practices remains questionable. Routine esophagram can be associated with high false-positive rates, low specificity, and poor correlation with clinically significant outcomes.[26] Reliance solely on routine esophagram findings to identify potential adverse events, primarily post-POEM leaks, may lead to unnecessary additional testing and even missed delayed complications. Given that most complications are often identified at the time of the procedure, postprocedural testing should be driven primarily by clinical suspicion.

Best Practice Advice 8: Same-day discharge after POEM can be considered in select patients who meet discharge criteria. Patients with advanced age, significant comorbidities, poor social support, and/or access to specialized care should be considered for hospital admission, irrespective of symptoms.

Current data indicate that same-day discharge may be safe and feasible after POEM.[25,27] In 2 retrospective studies in which discharge criteria included postprocedure

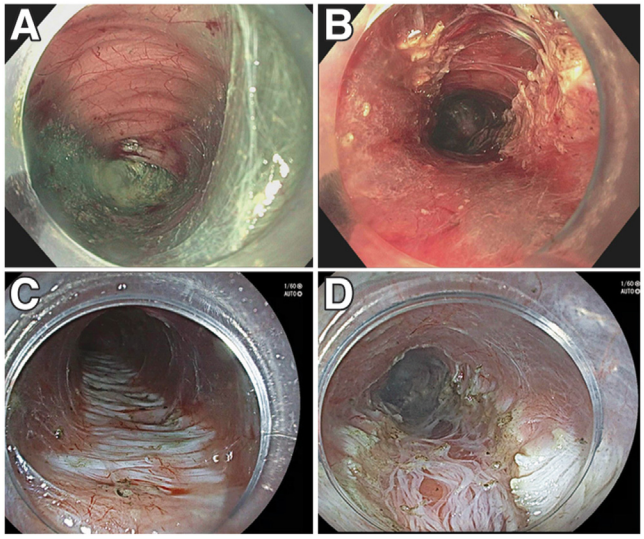

Figure 3. Endoscopic images of submucosal tunnel and myotomy along an anterior (*A*, *B*) vs posterior approach (*C*, *D*), respectively.

tolerance of oral fluids and good pain control, same-day discharge was achieved in 62%–79% of the patients without postdischarge complications documented on follow-up.[27,28] Hence, same-day discharge of select patients after POEM appears to be an important resource and cost-saving strategy. Currently, there are no standardized discharge protocols or specific criteria for safe same-day discharge, which is imperative before widespread adoption. In our opinion, patients should only be considered for same-day discharge if there are no intraprocedural issues that require postprocedural observation and if patients tolerate oral fluids and have minimal symptoms of nausea or pain that can be managed with oral medications. We strongly suggest that patients who undergo same-day discharge are contacted within 24–48 hours after the procedure to assess for any adverse events. Lastly, we suggest that patients with advanced age, significant comorbidities, poor social support, and/or access to specialized care should be considered for hospital admission, irrespective of symptoms.

Evaluation, Management of Post–Per-Oral Endoscopic Myotomy Reflux, and Long-Term Surveillance

Best Practice Advice 9: Pharmacologic acid suppression should be strongly considered in the immediate post-POEM setting, given the increased risk of postprocedure reflux and esophagitis.

GERD is perhaps one of the main voiced concerns for POEM. Nonetheless, it should be emphasized that GERD is common among patients who undergo endoscopic or surgical myotomy with disruption of the LES. The rate of abnormal acid exposure and esophagitis after POEM ranges between 41%–56% and 41%–65%, respectively.[1,2] Notably, one-quarter of these patients are asymptomatic and reliance on symptoms alone is insufficient. Hence, initiation of empiric acid suppression should be strongly considered in all patients after POEM. Although there is no consensus on the most appropriate regimen, most expert centers initiate patients on pharmacologic acid suppression in the immediate healing period and continue therapy for at least 3–6 months until further re-evaluation.

Best Practice Advice 10: All patients should undergo monitoring for GERD after POEM. Patients with persistent esophagitis and/or reflux-like symptoms despite proton pump inhibitor (PPI) use should undergo additional testing to evaluate for other etiologies besides pathologic acid exposure and management to optimize and achieve reflux control.

Best Practice Advice 11: Long-term postprocedure surveillance is encouraged to monitor for progression of disease and complications of GERD.

Achalasia is a chronic condition. Endoscopic surveillance should be strongly considered for all patients post POEM to monitor for disease progression and to identify potential complications from asymptomatic GERD. Specific intervals for endoscopy have not been established and this remains an area of ongoing investigation. FLIP may also be integrated into the endoscopic procedure to assess the EGJ opening. Some programs suggest alternating esophagram and endoscopy to monitor for structural changes, clearance of the esophagus, and mucosal changes. The goal of implementing a surveillance plan is to ideally tailor interventions that may delay or thwart progression to end-stage achalasia. Furthermore, it is well known that patients with achalasia have a higher risk for esophageal cancer compared with the general population.[29] In a recent cohort study of 9314 patients, those with achalasia had a 5-fold higher (hazard ratio, 4.6; 95% CI, 2.3–9.2) risk for esophageal cancer compared with patients without achalasia.[29] Although it is not currently implemented routinely or endorsed, the considerable risk for esophageal cancer in individuals with achalasia provides support for endoscopic surveillance.

Follow-up endoscopy and/or pH monitoring should be strongly considered in all patients for the objective evaluation of abnormal acid exposure. Testing for postprocedural acid reflux is generally performed 6–12 months after POEM. It should be noted that reflux symptoms after POEM may not necessarily be due to acid reflux, and objective evaluation may help discern pathologic acid exposure from other conditions, including nonreflux esophageal acidification due to stasis of food, acid fermentation, and visceral hypersensitivity.[30]

Objective assessment of acid exposure can be performed with pH monitoring with or without impedance. Off-PPI therapy pH monitoring should be performed if the presence of GERD is in question. Conversely, if GERD has already been established or in the setting of esophagitis (Los Angeles Classification grade B or higher), then testing on PPI may help determine the adequacy of acid suppression. Optimal management of GERD includes confirmation of patient adherence to PPI therapy, which should ideally be taken 30–60 minutes before meals to ensure adequate absorption and activation. Review of diet and lifestyle

counseling and implementation of adjuncts, such as alginate products, are helpful in mild cases or for breakthrough symptoms. Potassium competitive acid blockers may be a preferred alternative to PPIs in the future for the management of difficult to treat erosive esophagitis.[31]

A small number of patients may require an antireflux procedure (ie, endoscopic or surgical fundoplication) after confirmation of the presence of GERD; exclusion of other etiologies; and despite optimization of diet, lifestyle, and medical therapy. Importantly, long-term data after POEM suggest that reflux esophagitis and abnormal acid exposure decreases with time, indicating ongoing healing and remodeling of the LES after POEM.[32] Hence, we tend to favor a stepwise approach in the evaluation and management of post-POEM reflux.

Management After Failed Initial Myotomy

Best Practice Advice 12: POEM may be superior to PD for patients with failed initial POEM or LHM; however, decision between treatment modalities should be based on shared decision making between the patient and physician, taking into account risk of post-procedural reflux, need for repeat interventions, patient preferences, and local expertise.

Despite the effectiveness of POEM and LHM in providing durable clinical response for most patients with achalasia; approximately 10%–15% may experience persistent or recurrent symptoms on follow-up.[9] It is imperative that these patients undergo a comprehensive evaluation, which, at a minimum, should include repeat esophagogastroduodenoscopy, HRM, and timed barium esophagram. The efficacy and safety of PD, LHM, or POEM for patients with initial failed myotomy has been studied, with variable results.[33] To date, there has only been 1 randomized trial comparing PD with POEM in patients after failed LHM where POEM demonstrated a notable higher success rate (62% vs 27%).[34] In addition, there was no significant difference between POEM and PD regarding esophagitis, reflux symptoms, PPI use, and rate of serious adverse events. In all, POEM appears to be a safe and effective approach for patients with previously failed LHM or POEM. Nonetheless, the decision between treatment modalities should be individualized, taking into account the etiology for the failed myotomy, local expertise, patient characteristics, and preferences.

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Author Contributions
All authors contributed in the review of the literature, drafting of the best practice advice statements, writing and critical appraisal of the final manuscript.

Conflicts of interest
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