The Pressure Is On

Optimizing Pneumatic Dilation for Achalasia

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KEYWORDS

- Esophagogastric junction outflow obstruction • Achalasia • Heller myotomy
- Peroral endoscopic myotomy • Esophagomyotomy • Dysphagia
- Pneumatic dilation • Chicago classification

KEY POINTS

- Pneumatic dilation, along with Heller myotomy and peroral endoscopic myotomy, is a treatment modality for achalasia with proven efficacy.
- A graded dilation method starting with a 30-mm balloon dilator and up-sizing as necessary has been shown to be effective in managing clinical symptoms of achalasia.
- Type III achalasia, younger age, and male gender are negative predictors for treatment success with pneumatic dilation.
- Pneumatic dilation remains a reasonable treatment option in patients with type I or II achalasia, without a severely dilated or tortuous esophagus, and in whom an outpatient treatment approach is preferred.

INTRODUCTION

In the most recent iteration of the Chicago Classification for diagnosis of esophageal motility disorders, disorders of esophagogastric junction (EGJ) outflow include achalasia types I-III and EGJ outflow obstruction (EGJOO).[1] Achalasia, characterized by a lack of coordinated esophageal body peristalsis and impaired lower esophageal sphincter (LES) relaxation, remains the prototypical primary esophageal motor disorder with robust prognostic and management data, while EGJOO requires further adjunctive testing to confirm the diagnosis as a primary motility disorder, followed by a tailored management plan.

The pathogenesis of achalasia remains incompletely understood, and no curative treatment is currently available. Management goals for achalasia remain largely palliative, focusing on the improvement of symptoms and esophageal emptying and

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Gastrointest Endoscopy Clin N Am 35 (2025) 651–663
https://doi.org/10.1016/j.giec.2025.02.006 giendo.theclinics.com

Abbreviations	
BOM	blown-out myotomy
CARS	Contents, Anatomy, Resistance, and Stasis
CSA	cross-sectional area
EGJ-DI	esophagogastric junction distensibility index
EGJ	esophagogastric junction
EGJOO	EGJ outflow obstruction
FLIP	functional lumen imaging probe
GERD	gastroesophageal reflux disease
LES	lower esophageal sphincter
PD	pneumatic dilation
POEM	peroral endoscopic myotomy
PPI	proton pump inhibitor
RCT	randomized controlled trial

prevention of complications. Potentially definitive LES-directed treatment options include pneumatic dilation (PD), laparoscopic Heller myotomy (LHM) with partial fundoplication, and peroral endoscopic myotomy (POEM). LHM involves surgical dissection of muscle fibers of the LES and is typically done along with a partial fundoplication (Dor or Toupet). First introduced in 2009, POEM has gained worldwide acceptance in recent years as another effective therapeutic option using an endoscopic approach to create a submucosal tunnel in the esophagus, through which the LES muscle fibers are dissected. PD, using a 30, 35, or 40 mm diameter, air-filled balloon to stretch the LES, offers an alternative to surgical approaches for treating achalasia. Nondefinitive treatment options for achalasia include oral medications and botulinum toxin injection.[2] Due to low efficacy and temporary nature of the latter treatment options, they are generally reserved for nonsurgical candidates or patients with limited life expectancy.

Despite the increasing enthusiasm for POEM, PD remains a viable and possibly favorable treatment option for some achalasia patients. In this review, the authors outline PD technique, efficacy, and complications in achalasia management, summarize available comparative data on efficacy and safety among treatment options and discuss patient selection strategies and future research considerations involving PD.

DISCUSSION

Technique

PD is performed after careful patient selection (see patient selection section) as an outpatient procedure by trained gastroenterologists in the endoscopy suite with fluoroscopic capability. Patients usually undergo general anesthesia sedation to control the risk of aspiration. To avoid retained food debris in the esophagus, especially in those with known esophageal dilatation and retention, a liquid-only diet up to 3 days prior to the procedure may be recommended.

Over the last few decades, the procedure has been standardized with the use of the Rigiflex balloon system (Boston Scientific, Boston, MA).[3] The balloon is a 10 cm polyethylene polymer mounted on a flexible catheter and comes in 3 inflation diameters: 30, 35, and 40 mm. It is noncompliant, inflating maximally to its designated diameter regardless of inflation pressure. The procedure begins with the introduction of an endoscope to clear fluid and retained debris before a careful evaluation of the LES on forward and retroflexed view. Retroflexion in the stomach is especially important to rule out pseudoachalasia from malignancies, especially gastric cardia cancer. A

guidewire is then placed, and the PD balloon is advanced over the guidewire toward the EGJ with fluoroscopic guidance.

Centering the PD balloon at the EGJ is a key step in performing a successful PD. This can be accomplished by visualizing the waist created by the tight EGJ on the expanding balloon under fluoroscopy and adjusting the radiopaque markers on the PD balloon catheter to match this location. Four radiopaque markers are present on the balloon shaft to help define its upper, middle, and lower borders during fluoroscopy. The 2 closely spaced middle makers mark the center of the balloon (Fig. 1A). Balloon location can also be assessed with side-by-side endoscopic visualization. Some endoscopists use additional methods to confirm accurate balloon location, as demonstrated in Fig. 1B, C. In this case, the EGJ location was first identified endoscopically and marked with external markers (paperclips in this case). The PD balloon middle markers are adjusted to match the location of the paperclips on fluoroscopic examination.

After accurately positioning the PD balloon, the balloon is inflated with a hand-held air pump until the desired pressure (typically 7–15 pounds per square inch [p.s.i.]) is reached or until the balloon waist (from sphincter constriction) has completely effaced on fluoroscopy. The insufflation is maintained for a duration of 30 to 60 seconds, while the endoscopists secure the catheter firmly outside of the mouthguard so that the balloon location remains stable.[3] Afterward, the balloon is deflated and withdrawn, and the endoscope is reinserted to examine the esophagus for signs of bleeding or mucosal damage. In post-procedure, patients are monitored for at least 30 to 60 minutes. Post-PD recovery includes monitoring for signs of perforation and for pain assessment. If there are clinical suspicions for perforation, an upright esophagram may be performed to rule out a leak.

Although the techniques for PD have become fairly standardized in recent years, practices on initial choice of balloon size and subsequent escalation of therapy (eg, use of larger balloon or converting to surgical management) in nonresponders or partial-responders vary, often depending on availability of fluoroscopy-equipped procedure rooms, insurance concerns, and local availability of surgical treatment expertise. A reasonable treatment algorithm based on avoidance of complication

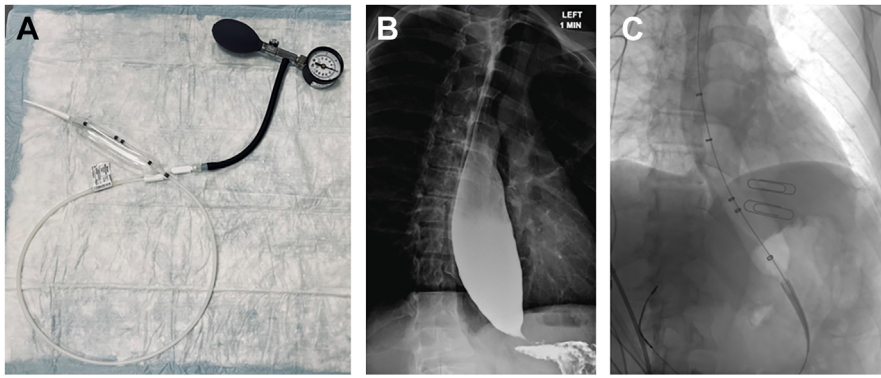

Fig. 1. (*A*) A Rigiflex balloon system (Boston Scientific, Boston, MA) with an attached air pump and pressure gauge. (*B* and *C*) An example of a patient with type II achalasia. (*B*) The patient's barium esophagram with bird's beak appearance in the distal esophagus. In (*C*), an inflated pneumatic dilation balloon is seen on fluoroscopy across the patient's EGJ. The middle balloon markers are positioned at the level of the paper clips (external markers for EGJ location), thus centering the balloon at the EGJ.

associated with larger balloon size is a graded approach where a 30 mm balloon is used initially, followed by 35 mm, and subsequently 40 mm dilation only if symptoms persist (Fig. 2).[4]

Follow-up

If there are no signs of perforation after PD, the patient is given liquids by mouth and discharged with the advice to advance diet slowly beginning with a soft mechanical diet until follow-up. A proton pump inhibitor (PPI) is typically recommended in the short term to promote healing and control gastroesophageal reflux following disruption of the LES. Follow-up symptom assessment may occur after 4 to 6 weeks, but as early as 1 to 3 weeks in some practices, and may be accompanied by a timed barium esophagram to compare with pretreatment assessment of esophageal clearance.

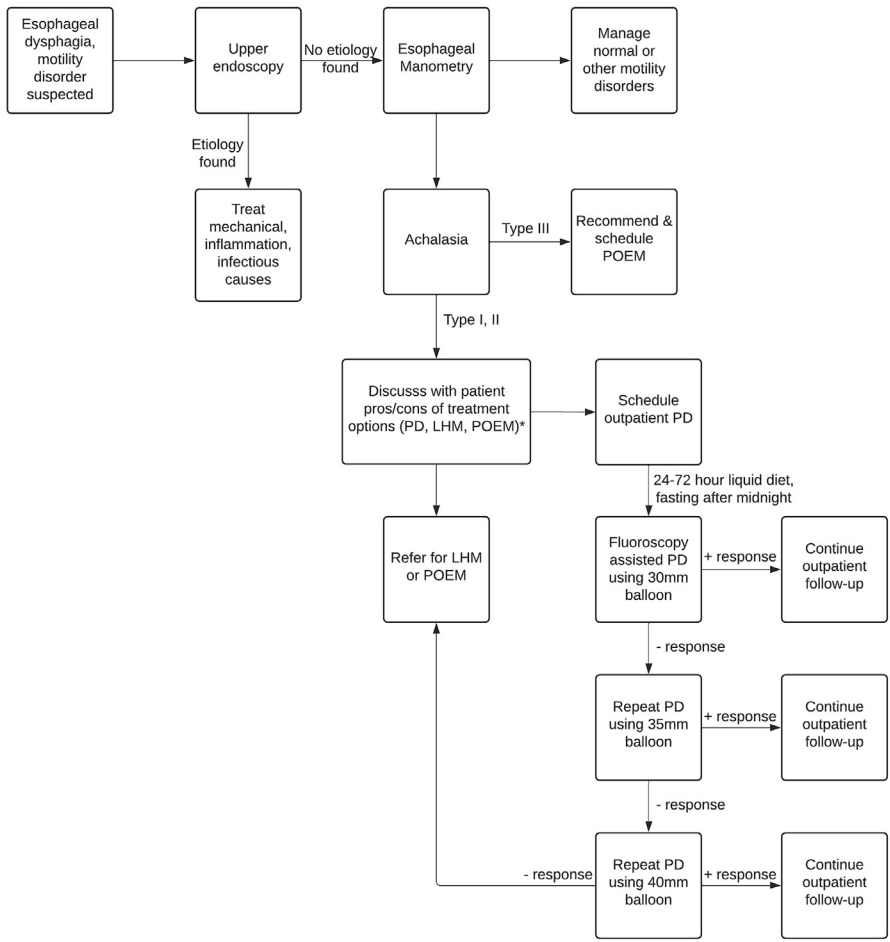

Fig. 2. A proposed pneumatic dilation algorithm using a graded approach where a 30 mm balloon is used initially, followed by 35 mm and 40 mm only if symptoms persist. BTx, botulinum toxin injection; EGJOO, esophagogastric junction outflow obstruction; LHM, laparoscopic Heller myotomy; PD, pneumatic dilation; POEM, per-oral endoscopic myotomy. *see Table 1.

Diet may be further advanced to a normal diet, albeit eating slowly and drinking fluids liberally. Patients should be reminded that all LES-directed therapies including PD are not curative in nature, and an improvement, but not normalization, of eating is expected. Long-term minor dietary limitations and lifestyle adjustments such as nighttime head of bed elevation are often needed despite a successful PD. Patients with refractory symptoms, especially those associated with poor esophageal emptying, may warrant a repeat PD with a larger balloon (see **Fig. 2**). Failure to respond to the largest balloon may warrant reconsideration of the achalasia diagnosis or referral for LHM, POEM, or, in extreme cases, esophagectomy.

Efficacy

Treatment naïve patients

Achalasia treatment efficacy in most studies is defined as change in symptom score (eg, Eckardt score). The reported efficacy of PD varies among studies depending on dilation protocol, patient selection, and balloon size.

Boeckxstaens and colleagues conducted a pivotal multicenter randomized controlled trial (RCT), also known as the European Achalasia Trial, comparing PD with LHM in 201 newly diagnosed patients with achalasia. The standardized PD protocol initially began with a 35 mm balloon; however, this was quickly revised to start with a 30 mm balloon after multiple perforations occurred (4 out of the initial 13). Repeat dilation with a 35 mm or 40 mm balloon was offered in nonresponders to the 30 or 35 mm balloon after 1 to 3 weeks. Each of the 201 patients underwent at least 2 dilations. The authors reported a clinical success rate of PD (Eckardt score $\leq$3) of 90% and 86% at the 1 and 2 year marks, comparable to that of LHM (93% and 90%).[5] The 5 year follow-up assessment of the European Achalasia Trial again demonstrated no significant difference in clinical success rates between PD and LHM (82% and 84%), respectively (P = .92, log-rank test), although 25% of patients with PD required redilation during the follow-up period.[6] The recently published 10 year follow-up data from this trial again showed similar efficacy (74% and 74%, P = .84).[7]

The efficacy of PD and POEM in achalasia was compared by Ponds and colleagues[8] in a multicenter RCT that revealed short-term success of 54% with PD, compared to 92% with POEM (P<.001) at 2 year follow-up. The large difference in PD treatment success in this versus the European Achalasia trial is attributable to the difference in dilation protocol. In this trial, patients in the PD group were dilated with a single series of 30 to 35 mm dilators (no 40 mm dilators were used), and subsequent need for repeat dilation was considered treatment failure. Treatment success at 5 year was 40% in the PD group and 81% in the POEM group (P<.0001).[9]

Not surprisingly, one key factor affecting PD treatment outcome is the balloon size used. In a systematic review and meta-analysis including 10 studies with 643 patients, PD with a 30 mm or 35 mm balloon gave comparable mean success rates of 81% and 79%, respectively. A series of dilations up to 40 mm had a greater success rate of 90%. Complications of perforation, however, occurred most often during initial dilations and significantly more often using the 35 mm balloon than the 30 mm balloon (3.2 vs 1.0%, P = .027). A subsequent 35 mm balloon PD was found to be safer than an initial dilation with a 35 mm balloon (0.97 vs 9.3% perforations, P = .0017). Based on this, the most efficient and safe dilation strategy for achalasia patients is a graded approach starting with a 30 mm balloon dilation, followed by an elective 35 mm dilation and 40 mm dilation only when there is insufficient symptom relief.[10]

Multiple studies have demonstrated variable treatment outcomes depending on the achalasia subtype. Types I and II achalasia respond well to PD, while type III achalasia has been shown to respond best to myotomy tailored to include the proximal extent of

esophageal body spasm rather than confined to the LES. Rohof and colleagues[11] found the greatest success rate with PD in type II achalasia (96%), followed by type I (56%), then type III (29%). In the subgroup analysis of the 10 year follow-up of the European Achalasia Trial, PD was superior to LHM for type II achalasia ($P = .03$), and there was a trend ($P = .05$) toward LHM outperforming PD for type III achalasia.[7] In a systematic review and meta-analysis using data from 75 studies (8 RCTs, 27 prospective cohort studies, and 40 retrospective studies), manometric subtype, along with age and sigmoid deformity of the esophagus were factors affecting treatment outcomes.[12] Type III achalasia was an important predictor of PD treatment failure.

Patient age has also been found to associate with treatment response in patients with achalasia undergoing PD in several studies.[12–15] Eckardt and colleagues[16] stratified for age and found greater failure rates for patients younger than 40 years compared to older individuals (48% vs 78%, $P<.05$). One high-quality study found old age to be a predictor for clinical success,[17] while a large prospective longitudinal cohort study found younger age (<50 years) to be one of the strongest independent predictors for the need of repeat treatment.[13] This was also observed in the data from the European Achalasia Trial in which younger age was one of the predictors of need for redilation in the PD group.[7]

Male sex was found to be associated with poor outcome after PD for achalasia in a multivariate analysis.[18] This was also reported by 2 other prospective studies that described an increased risk for failed PD in younger male individuals.[19,20]

Patients with prior treatment

Evidence on the efficacy of PD in patients who have already received treatment with LHM or POEM is heterogeneous and inconsistent at this time.[21,22] In a retrospective study comparing success of PD in achalasia patients with or without prior LHM, patients with prior failed LHM experienced clinical improvement less frequently than patients without prior treatment (74% vs 52%, respectively) even though a larger balloon dilator was utilized on initial dilation in the previously treated group.[23] In a prospective study, Saleh and colleagues[24] demonstrated a modest success rate of 57% in symptom improvement with PD for recurrent symptoms after previous LHM. In a recent RCT comparing the efficacy of POEM versus PD for patients with persistent or recurrent symptoms after LHM (Eckardt score >3 and stasis $\geq$2 cm on timed barium), POEM demonstrated a greater response rate than PD (62.2% vs 26.7%, respectively).[25] When looking at patients who previously failed POEM therapy, PD appears ineffective. A study conducted by Van Hoeij and colleagues[26] showed that PD was successful in 0% to 20% of patients who had recurrent or persistent symptoms after POEM depending on the size of the balloon dilator utilized. This compared to 63% and 45% of those retreated with repeat POEM or LHM.

Intra-procedural Functional Lumen Imaging Probe

Functional lumen imaging probe (FLIP) measures luminal cross-sectional area (CSA) and distensibility at the EGJ and can complement the identification of EGJOO and achalasia. Intra-procedurally, FLIP measurements have been used to calibrate the extent and length of myotomy to increase the efficacy of treatment on EGJ opening.[27–30] FLIP measured EGJ distensibility index (EGJ-DI) has been found to correlate with myotomy increment and symptomatic outcomes after interventions for achalasia.[31–33] In a retrospective analysis at a high volume esophageal center, intraoperative use of FLIP during POEM for achalasia resulted in modifying the myotomy in over half of cases and was associated with improved clinical outcome.[34] Intraoperative EGJ CSA during POEM correlated with clinical response to therapy and post-

myotomy reflux esophagitis in a multicenter study.[35] Fewer studies have assessed the usefulness of FLIP during PD for achalasia. Wu and colleagues found that a change in EGJ-DI within a subject was highly predictive of immediate clinical response. An increment in EGJ-DI of 1.8 mm^2/mm Hg after a single PD predicts an immediate response with an accuracy of 87%.[36] In another study, however, Smeets and colleagues[37] found no difference in EGJ-DI after PD between patients with good and poor clinical outcome at 1 year follow-up.

EsoFLIP for Achalasia Treatment

Whereas air-filled balloons are used in PD, a therapeutic 30 mm hydraulic balloon dilator (esoFLIP) is available for treatment of achalasia using impedance planimetry technology, similar to that used in endoFLIP (Medtronic, Minneapolis, MN, United States). However, unlike endoFLIP that uses an infinitely compliant probe, esoFLIP utilizes a low-compliance balloon to facilitate esophageal dilation. Advantages of EosoFLIP balloon dilation include the ability to dilate over a range of diameters with a single balloon, up to 30 mm, in a controlled manner without need for fluoroscopy, and the availability of real-time lumen diameter measurement before, during, and after treatment.[38] Limitations include the slow filling rate of the balloon and the limited balloon size option. Observational studies have demonstrated clinical success rate of nearly 70% using EsoFLIP for achalasia and EGJOO.[39] However, optimal patient selection for esoFLIP dilation remains unclear and comparative studies with standard PD and other treatment methods are necessary before recommending widespread use of EsoFLIP for achalasia.

Complications

Achalasia is a chronic, benign, but incurable, condition. As previously mentioned, treatment of achalasia is focused on palliation of symptoms and prevention of complications. Complications may stem from the disease itself (eg, weight loss, aspiration) or from treatment. Treatment-related complications, along with efficacy, should be taken into consideration before deciding on a treatment modality for achalasia. In this section, we discuss procedure-related adverse events, including short-term and long-term complications.

Immediate complications

Rates of complications following PD have been reported in several studies. The most common immediate serious complication of PD is esophageal perforation, particularly when larger balloon sizes are used. In a recent systematic review and network meta-analysis by Facciorusso and colleagues[40], the risk of serious procedure-related adverse events with PD was 4.2% (95% confidence interval [CI] 1.8%–6.6%) overall, comparing to 1.4% (0%–3.2%) with POEM and 6.6% (1.4%–11.9%) with LHM. Esophageal perforation following PD was reported in 1.5% to 8% of cases among the included trials. Risk of perforation, and likely other complications, appears to vary depending on the operator as high-volume centers with esophageal motility expertise have reported perforation risks after PD as low as 0.37%.[41] Balloon size also affects the risk of complication with PD. Larger balloon size is associated with greater clinical efficacy after a single dilation but also greater risk of perforation.[4] Esophageal perforation following PD often requires urgent attention, ranging from conservative management with antibiotics, endoscopic clipping, and fasting to surgical repair, and (very rarely) esophagectomy in severe cases. Careful patient selection for treatment with PD and using a graded dilation strategy starting with the 30 mm balloon can help minimize procedure-related immediate serious complications.

Delayed complications

Gastroesophageal reflux disease. Gastroesophageal reflux disease (GERD) is a well-known complication following LES-directed interventions. In the systematic review and network meta-analysis by Facciorusso and colleagues[40] including only RCTs, the pooled rate of endoscopic evidence of esophagitis was 14.7% (95% CI 6.5%–13.1%) after PD, compared to 24.9% (16.4%–33.3%) after LHM and 45.4% (38.1%–52.9%) after POEM. However, the severity of esophagitis was typically mild, regardless of the treatment modality. Overall incidence of severe esophagitis after PD, LHM, and POEM was 1.5%, 3.7%, and 5.3%, respectively. Long-term follow-up of patients with achalasia in clinical remission showed that 5 years after treatment, patients who had undergone POEM were significantly more likely to be on PPI therapy for GERD comparing to those who had undergone PD (46% vs 13%).[9]

Blown-out myotomy. Treatment failure related to focal dilatation at the myotomy site of the esophagus occurring after POEM or LHM, termed blown-out myotomy (BOM) or pseudo-diverticulum, has recently been observed in a subset of patients with recurrent symptoms following myotomy. In a study that followed up on patients treated in an RCT comparing POEM to PD, none of the patients treated with PD developed BOM, whereas the incidence of BOM increased with time after POEM.[42] BOM was associated with greater Eckardt score in this population. Effective management of this long-term complication is currently unclear, and in rare cases of severe symptomatic BOM, an esophagectomy might be considered. The risk of BOM should, thus, be discussed with patients considering POEM or LHM and could be a reason to consider treatments that do not involve myotomy, such as PD.

Patient Selection

With the current enthusiasm over POEM, the new minimally invasive but effective treatment of all types of achalasia, the use of PD has waned in recent years. However, few studies have directly compared the long-term outcomes of POEM and PD, and the optimal endoscopic modality to treat achalasia remains uncertain. A meta-analysis conducted to compare the clinical outcomes of POEM to PD in the treatment of achalasia found greater treatment success with POEM comparing to PD in all types of achalasia, but especially in type III, for up to 36 months. However, risk of GERD was significantly greater with POEM comparing to PD (pooled odds ratio [OR] of 2.95 [P = .02] by symptoms and 6.98 [P = .001] by endoscopy).[43] Additionally, long-term complication of BOM has been seen with POEM but not with PD as mentioned earlier. Moreover, POEM often involves a brief inpatient admission for post-procedure monitoring, and the procedure is variably covered by insurance plans. Hence, PD remains a viable option for achalasia management.

Based on the recently published AGA clinical practice update, the decision on treatment modality should be based on shared decision-making, taking into account patient and disease characteristics, patient preferences, and local expertise.[44] Patient counseling on the pros and cons of each treatment option is important to establish realistic expectations of outcome. Emphasis should be made that PD is particularly effective in patients with Type I and II achalasia, while those with Type III achalasia should be advised to undergo POEM for a longer/tailored myotomy. Additional contraindications for PD may include severely dilated or tortuous (“sigmoid”) esophagus due to difficulty with centering of the PD balloon and visualizing the EGJ on fluoroscopy and increased risk of complications. The high likelihood of need for repeat dilation with larger balloon sizes should also be discussed with patients prior to making treatment decisions. **Table 1** and **Fig. 3** provide patient and procedure factors that should help steer

Table 1
Treatment decision considerations—procedure and patient factors with the number of "+" indicating factors favoring each respective therapeutic intervention

	PD	LHM	POEM
Definitive treatment	+	+++	+++
Invasiveness	+	+++	++
Recovery time	+	+++	++
Retreatment needs	+++	+	+
Outpatient treatment	+++	-	+
Achalasia type I	++	+++	+++
Achalasia type II	+++	+++	+++
Achalasia type III	+	++	+++
Dilated/tortuous esophagus	+	+++	+
Complication (imm)	+	++	+
Complications (chr)			
GERD	+	+	++
BOM	-	+	++
Need for specialized esophageal center	+	++	+++

Abbreviations: BOM, blown-out myotomy; chr, chronic; GERD, gastroesophageal reflux disease; imm, immediate; LHM, laparoscopic Heller myotomy with Dor fundoplication; PD, pneumatic dilation; POEM, per-oral endoscopic myotomy.

treatment decisions in achalasia. For example, a patient with type II achalasia without significant esophageal dilatation or tortuosity that values minimally invasive procedure with short recovery time and accepts the potential need for repeat intervention would be a good fit for PD. On the other hand, a type III achalasia patient with no particular risk factor for GERD should be counseled and referred for POEM, if available.

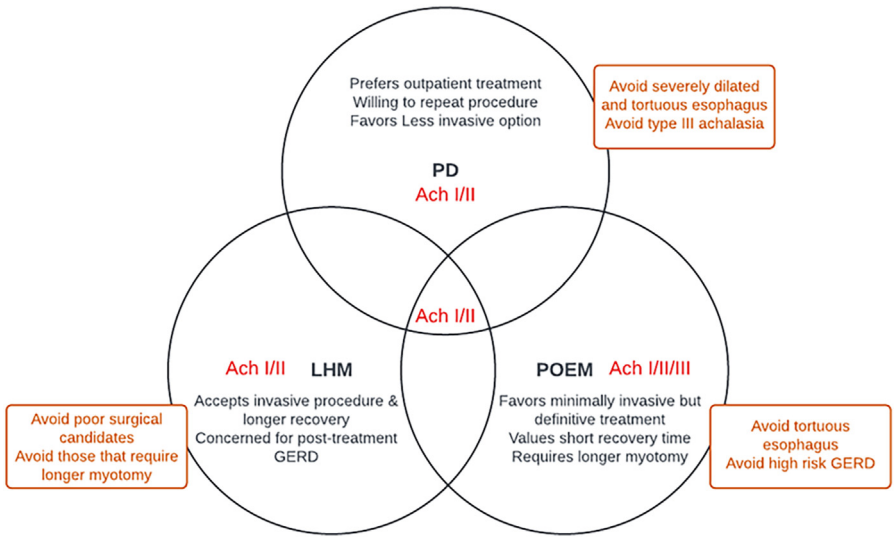

Fig. 3. Treatment decision considerations based on achalasia subtype, invasive nature of treatment, treatment recovery time, esophageal dilation/configuration, and risk of gastroesophageal reflux disease. Ach, achalasia; LHM, laparoscopic Heller myotomy with Dor fundoplication; PD, pneumatic dilation; POEM, per-oral endoscopic myotomy.

FUTURE DIRECTIONS

Although the use of PD for achalasia would appear to have reached a steady state in recent decades as compared to other more novel treatments, its place as a first-line, minimally invasive, outpatient treatment option with little recovery time is well supported by the literature. Several clinical questions remain to direct future studies to optimize the use of PD in EGJ outflow disorders. First, a standardized dilation protocol does not currently exist and studies comparing outcomes with a graded dilation protocol using 30 mm initial dilation versus the use of larger balloon in select subjects (ie, young male individuals), as well as studies to establish an optimal interval between repeat dilations should be performed. The potential utility of FLIP during PD to assess predilation and post-dilation EGJ distensibility and diameter should be further assessed. An endoscopic scoring system for achalasia based on luminal Contents, Anatomy, Resistance, and Stasis (CARS score) was recently developed and has been shown to perform well in predicting achalasia diagnosis.[45] Use of CARS score to assess treatment response should be investigated as it could help identify those refractory to initial dilation and expedite retreatment during a single endoscopy in patients with achalasia previously treated with PD. Long-term comparative studies between PD and surgical myotomies should be done to compare enduring efficacy and side effects among treatment modalities. Finally, studies to assess use of PD for other non-achalasia conditions such as conclusive EGJOO with preserved esophageal peristalsis or as salvage therapy for postsurgical myotomy failure patients may expand the utility of PD.

SUMMARY

The role of PD has been in question in recent years with the increasingly positive efficacy data on POEM as a minimally invasive treatment of achalasia. However, the benefits of PD, including the quick procedure in an outpatient setting with minimal post-procedure recovery time, lower risk of post-procedure complications such as GERD or BOM, lower cost, and (sometimes) better accessibility by patients, should not be overlooked. While the data suggest better response of type III achalasia to POEM, PD should remain a first-line treatment option in achalasia types I and II, particularly in patients without severely dilated or tortuous esophagus, for which preservation of their anatomy may be key to achieving better long-term outcomes.

CLINICS CARE POINTS

- The pros and cons of pneumatic dilation, along with those for laparoscopic Heller myotomy and per-oral endoscopic myotomy, should be discussed with patients with treatment-naive achalasia.
- Patients with type III achalasia and those with severely dilated and tortuous esophagus should consider a treatment option other than pneumatic dilation.
- Current evidence suggests a limited role of pneumatic dilation in patients with previously-treated achalasia with recurrent symptoms.

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