The Long-term Efficacy of Pneumatic Dilatation and Heller Myotomy for the Treatment of Achalasia

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See CME exam on page 524.

Background & Aims: Studies comparing long-term success after pneumatic dilatation (PD) and laparoscopic Heller myotomy (HM) are lacking. This study compares long-term outcome of PD (single dilatation and graded approach) and laparoscopic HM and identifies risk factors for treatment failure. Methods: A cross-sectional follow-up evaluation of an achalasia cohort treated between 1994 and 2002 was followed-up for a mean of 3.1 years. There was a total of 106 patients treated by graded PD (1-3 dilatations with progressively larger balloons) and 73 patients treated by HM (20 had failed graded PD and crossed over to HM). A symptom assessment (structured telephone interview or clinic visit) was performed and patients were given freedom from alternative therapies to determine treatment outcome. Endoscopy, manometry, and timed barium esophagram were performed to determine the cause of treatment failure. Results: The success of single PD was defined as freedom from additional PDs: 62% at 6 months and 28% at 6 years (risk factors for failure: younger age, male sex, wider esophagus, and poor emptying on posttreatment timed barium esophagram). Freedom from subsequent PDs increased with each dilatation (graded PD). The success of graded PD and HM, defined as dysphagia/regurgitation less than 3 times/wk or freedom from alternative treatment, was similar: 90% vs 89% at 6 months and 44% vs 57% at 6 years (no risk factors for failure were identified). Causes of symptom recurrence were incompletely treated achalasia (96% after PD vs 64% after HM) and gastroesophageal reflux disease (4% after PD vs 36% after HM). Conclusions: No treatment cures achalasia. Short- and long-term success is similar for graded PD and laparoscopic HM. Therapeutic success decreases steadily over time. Achalasia patients need careful long-term follow-up evaluation.

A chalasia is characterized by destruction of the esophageal myenteric plexus.¹ The resulting esophageal aperistalsis and abnormal lower esophageal sphincter (LES) relaxation cannot be restored. Treatment is palliative and requires disrupting the LES to facilitate esophageal emptying.² As a result, chronic gastroesophageal reflux and its complications may occur.

The most effective treatments for achalasia are pneumatic dilatation (PD) and Heller myotomy (HM).³ Both have evolved over time. Newer noncompliant Rigiflex (Boston Scientific, Boston, MA) balloon dilators, which inflate to a designated diameter (30, 35, or 40 mm), have replaced older compliant, single-size balloons.⁴ Open myotomy via thoracotomy has been substituted by the laparoscopic approach, leading to shorter hospital stay, earlier recovery, and lower costs.⁵

Long-term follow-up evaluation with Rigiflex PD and laparoscopic HM usually is limited to less than 2 years, and there are no randomized trials. Although reviews of published series indicate similar success for both approaches,^{3,6} direct comparisons are not possible because the available clinical studies usually describe only a single technique.

Our purpose was to compare the outcomes of these 2 achalasia treatments. Specifically, we aimed (1) to evaluate the outcome of PD (both single dilatation and graded progression) and laparoscopic HM, (2) to identify risk factors for treatment failure, (3) to compare causes of failure, and (4) to describe adverse effects. Our ultimate goal was to refine the existing treatment algorithm for achalasia.¹

Patients and Methods

Study Population

Records of achalasia patients seen at the Cleveland Clinic Foundation between 1994 and 2002 by the senior

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Abbreviations used in this paper: GERD, gastroesophageal reflux disease; HM, Heller myotomy; LES, lower esophageal sphincter; PD, pneumatic dilatation; PPI, proton pump inhibitor; TBE, timed barium esophagram.

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gastroenterologist (J.E.R.) were identified through an ICD-9 code search. Two investigators (M.F.V. and J.E.R.) reviewed charts to determine eligibility and to extract information. The inclusion criteria were patient age 18 years or older with achalasia confirmed by manometry and timed barium esophagram (TBE), treated with Rigiflex PD and/or HM. The exclusion criteria were a prior esophageal surgery or insufficient chart data. The Institutional Review Board approved the study protocol on September 26, 2002.

Chart Review

The following were recorded in the chart: (1) baseline characteristics: frequency of dysphagia for solids and liquids and regurgitation on a 5-point scale (0 = never, $1 = \le 1$ time/mo, $2 = \le 1$ time/wk, $3 = \le 3$ times/wk, 4 = >3 times per week to daily, 5 = every meal), presence of chest pain, weight loss, heartburn (including proton pump inhibitor [PPI] use), diagnostic test results (TBE, manometry, and endoscopy), and prior PD or botulinum toxin (Botox; Allergen Inc., Irving, CA) injection outside the Cleveland Clinic Foundation, and (2) details of therapeutic procedures (Rigiflex PD, laparoscopic HM), including complications.

Diagnosis and Assessment of Achalasia

Timed barium esophagram. Fasting patients drank the maximum amount of low-density barium sulfate (E-Z-PAQUE, E-Z-EM, Westbury, NY) tolerated over 30–45 seconds without regurgitation or aspiration. Upright radiographs were taken 1 and 5 minutes after the last swallow. Distance (cm) from the esophagogastric junction to the top of a distinct barium column (height) and maximal esophageal width were measured.⁷ The radiographic diagnosis of achalasia was based on esophageal dilatation, impaired esophageal emptying, and esophagogastric junction tapering. Follow-up TBEs used the same volume as the original study.

Esophageal manometry. Pressure recordings of the esophageal body and LES were obtained with a water-perfused catheter. Achalasia was defined as abnormal LES relaxation and esophageal body aperistalsis on 10 wet swallows.²

Endoscopy. To exclude malignancy, upper endoscopy was performed in all patients at PD or before HM.

Treatment of Achalasia

The options of PD and HM were offered to all patients who were candidates for these therapies, and the decision on type of treatment was arrived at through a patient-physician discussion of risks and benefits. All procedures were performed by the senior gastroenterologist (J.E.R.) or the senior esophageal surgeon (T.W.R.).

Graded Rigiflex pneumatic dilatation. Upper endoscopy was performed under conscious sedation. A Rigiflex balloon passed over a guidewire that was centered across the gastroesophageal junction under fluoroscopy and distended to 7-12 psi (to obliterate the waist) for 60 seconds.⁴ The smallest balloon (30 mm) was used first. For failures, a 35-mm balloon was used after at least 4 weeks, followed by a 40-mm balloon

if necessary. In patients with prior dilatation, initial PD at the Cleveland Clinic Foundation was with a 35-mm balloon.

Laparoscopic Heller myotomy. A laparoscopic modified anterior HM extending 3 cm onto the stomach was the surgical procedure performed.⁸ The HM was laparoscopic in 88% of patients and open in 12% (before 1998). An antireflux procedure was performed in 33% of patients: 63% Toupet, 22% Dor, and 15% Belsey.

Cross-Sectional Follow-Up Evaluation

In summer/fall 2003, cross-sectional evaluations were performed by using a structured telephone interview to determine symptoms. Dysphagia and regurgitation frequencies were recorded using the 5-point scale, and heartburn requiring PPIs was noted. Patients were encouraged to return to the Cleveland Clinic Foundation for an interview and TBE, with additional testing and treatment based on symptoms and tests. For patients interviewed by both methods, the clinic visit was used for the initial evaluation data.

Analysis

End points. The success of single PD was defined as freedom from subsequent PDs. The success of graded PD and HM was defined as freedom from cross-over to alternative treatment, or dysphagia/regurgitation less than 3 times per week at last follow-up evaluation. This definition of symptomatic success was chosen as a reasonable clinical end point because these numbers represent the median of measures used in different studies.⁹

Additional end points were the number of PD perforations and heartburn requiring PPIs at the last follow-up evaluation.

For treatment failures seen at The Cleveland Clinic, additional testing determined the cause. Upper gastrointestinal endoscopy and pH monitoring diagnosed esophagitis, peptic stricture, and abnormal acid exposure. Manometry (lower esophageal sphincter pressure, >15 mm Hg) and TBE (25% increase from prior test) diagnosed incompletely treated achalasia.

Statistics. A multiphase nonproportional hazard model was used to analyze time to failure,¹⁰ allowing characterization of complex failure rates by simple additive components.

Variables used for multivariable analysis are listed in Table 1. Variable selection was in 2 steps: (1) bootstrap aggregation (bagging¹¹) using 500 replications to determine the frequency of candidate variables (including transformations of continuous variables to best comply with model assumptions), with non-informative imputation of missing data, and (2) forward stepwise selection to fit a multivariable model to the dataset. Comparison of the latter results with those of bagging assessed the consistency of variable selection.

To compare treatments, a separate hazard model was estimated for all 179 observations, and a treatment variable was tested in each hazard phase. Because this was a nonrandomized comparison patient to selection bias, we accounted for known differences between groups by developing a propensity score

	Early phase		Late phase			
	Single PD	Graded PD	НМ	Single PD	Graded PD	HM
Age	•					
Sex	•					
Symptom duration						
Baseline dysphagia						
Baseline regurgitation				٠		
Baseline chest pain						
Baseline heartburn						
Baseline weight loss						
Prior pneumatic						
dilatation						
Prior botulinum toxin						
injection						
Baseline esophageal	•			٠		
width at 1 minute						
Baseline esophageal						
width at 5 minutes						
Baseline esophageal				•		•
height at 1 minute						
Baseline esophageal						
height at 5 minutes						
Baseline LES pressure						
Baseline esophageal						
Vigorous achalasia ^a						
Change in	•					
posttreatment TBE						

Table 1. Factors Associated With Increased Ris	isk for Failure on the Hazard Model
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NOTE. Checked boxes indicate an increased risk for failure. Empty boxes indicate a factor that was not found to be associated with increased risk for failure.

^aVigorous achalasia defined as esophageal body contractions >37 mm Hg.

based on nonparsimonious logistic regression analysis of patient characteristics and findings. From this model, the propensity for being treated by HM vs PD was calculated for each patient, and the resulting propensity score was used to adjust estimates of group differences.^{12,13} In this comparison, 20 patients appeared in both groups (cross-over). Therefore, so that follow-up time was not duplicated, patients undergoing PD and subsequent HM were censored at HM and then re-entered at a new time zero, the time of HM. This is a customary cross-over analysis strategy, sometimes known as a *modulated renewal process.*¹⁴ At the time of cross-over to HM, patients were classified as a PD failure.

To determine the value of follow-up TBE, the percentage change from baseline to first follow-up evaluation (within 2 months of treatment) was evaluated as a predictor of success using linear regression.

Results were computed with SAS 8.2 software (SAS Institute, Cary, NC), using a significance level of .05.

Results

Patient Population

A total of 169 achalasia patients without prior esophageal surgery were identified; 10 patients had insufficient chart data. Nineteen of 159 patients had undergone unsuccessful nonsurgical therapy before treatment at the Cleveland Clinic Foundation. Seven patients had PD (all single balloon), 9 received Botox, and 3 had both.

Initial treatment of the 159 patients was PD in 106 and HM in 53. Twenty patients failing PD crossed over to surgery and were included initially in the PD group and subsequently in the HM group (cross-over analysis), bringing the total number of HM patients to 73.

Both groups were similar, except for older age in the PD group (mean, 52 vs 47 y, P = .02). The average follow-up period for the 159 patients was 3.1 years (range, .1–8.4 y), with a median of 2.6 years (25th and 75th percentiles, .8 and 4.9 y). During cross-sectional follow-up evaluation, more than 70% of the cohort was followed-up (Table 2).

Effectiveness of Single Pneumatic Dilatation

Freedom from a second PD was 62% at 6 months and 50%, 38%, and 28% at 2, 4, and 6 years, respec-

	PD	НМ	Р
Number of patients	106	73	NS
Mean age, y	52	47	.02
% men	52	52	NS
Mean follow-up	38	32	NS
evaluation, mo (range)	(1–105)	(1–102)	
% cross- sectional follow-up evaluation in 2003	74	71	NS
Median dysphagia score ^a	5	5	NS
Median regurgitation score ^a	4	5	NS
Mean LESP, mm Hg	41	36	.05
Mean barium height 5 min, cm	16	15	NS

Table 2. Patient Characteristics

NS, not significant; LESP, lower esophageal sphincter pressure.

^aFrequency of dysphagia for both solids and liquids and regurgitation was scored using a 5-point scale: 0 = never, 1 = once per month or less, 2 = once per week or less, 3 = 3 times per week or less, 4 = >3 times per week to daily, 5 = every meal.

tively (Figure 1). Two hazard phases for risk for second PD were identified, an early phase (29 patients required additional dilatation within 6 months) and a late phase (another 20 patients required additional PD during prolonged follow-up evaluation). Four variables were associated with increased early risk for second PD: younger age, male sex, wider esophagus at 1 minute on baseline TBE, and no improvement in barium height at 5 minutes 1 month after treatment (Table 3). Women had better outcome with single dilatation. For both sexes,

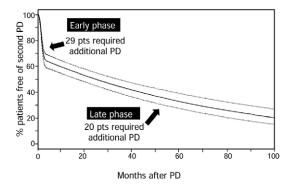


Figure 1. Two hazard phases for risk for second PD were identified, an early phase (patients requiring additional dilatation within 6 months) and a late phase (patients requiring additional PD during prolonged follow-up evaluation).

Table 3. Factors Associated	With Risk for Failure
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Treatment	Factors	Р
Early phase		
Single PD	Younger	.02
-	Younger man	.03
	Wider baseline esophagus	.02
	Less change in 5-min barium height after treatment	.02
Graded PD	No predictors	
HM	No predictors	
Late phase		
Single PD	Less baseline regurgitation	<.01
	Wider baseline esophagus	<.01
	Shorter barium column at baseline	<.01
Graded PD	No predictors	
HM	Taller barium column at baseline	<.01

NOTE. Factors that were not predictive of failure are listed in Table 1.

but particularly for men, there was an age-related response, with greater success as age increased (Figure 2). The effect of age and posttreatment change in barium height on the outcome of single PD is shown in Figure 3; a greater decrease in barium height after single PD was associated with a more successful outcome. Three factors were associated with late risk for second PD: lower baseline regurgitation score, wider esophagus at 1 minute on baseline TBE, and shorter column of barium at 1 minute on baseline TBE (Table 3). Perforation after single PD occurred in 2 of 106 patients (1.9%).

Effectiveness of Graded Pneumatic Dilatation

Of the 106 patients treated with single PD, 49 required a second dilatation and 6 required a third dilatation. Outcome improved when a larger balloon was used (Figure 4). The success of graded PD (good symp-

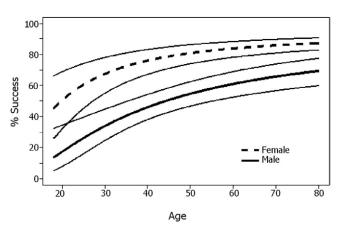


Figure 2. Effect of age and sex on the early phase (within 6 months) outcome of single PD. The 95% confidence intervals are shown for each curve. Younger patients, especially men, have a higher likelihood of early failure after single (30 mm) PD. --, women; --, men.

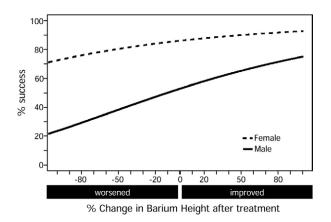


Figure 3. Predictive value of change in barium height after treatment on early phase outcome of single PD. A lack of improvement in posttherapeutic barium height at 5 minutes was associated with early risk for needing a second PD. - -, women; —, men.

tom control or freedom from treatment cross-over) was 90% at 6 months and 82%, 64%, and 44%, at 2, 4, and 6 years, respectively (Figure 5A). For graded PD, there was an early hazard phase (9 patients failing within 6 months) and a late phase (24 failures on prolonged follow-up evaluation). Risk factors for early or late graded PD failure were not identified. Perforation occurred after 1 of these 55 additional dilatations (1.8%). The overall occurrence of perforation after graded PD was 3 of 106 patients (2.8%) or 3 of 161 dilatations (1.9%).

Effectiveness of Laparoscopic Heller Myotomy

Of 73 patients treated with HM, good symptom control or freedom from treatment cross-over was 89% at 6 months and 86%, 78%, and 57% at 2, 4, and 6 years, respectively (Figure 5A). There was an early hazard phase (8 patients failing within 6 months) and a late phase (9

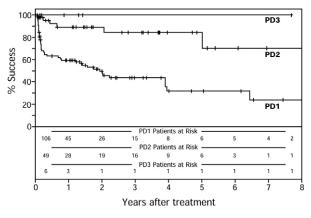


Figure 4. Survival curves for successful outcome after performing 1, 2, and 3 PD. Hash marks show censoring of patients. PD1, single PD. Freedom from subsequent PD (success) was better with 2 PDs (PD2), and best with 3 PDs (PD3).

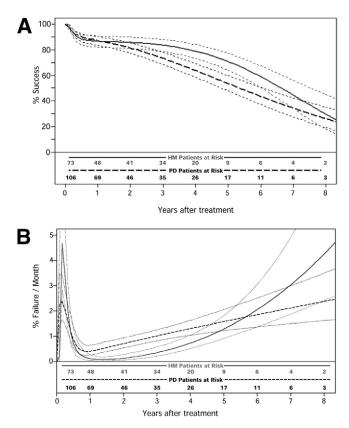


Figure 5. (*A*) Long-term success of graded PD and laparoscopic HM. The 95% confidence intervals are shown for each curve. The outcomes of PD and HM were similar in both the early and late phases. (*B*) Hazard curves for failure of graded PD and laparoscopic HM. The 95% confidence intervals are shown for each curve.

failures on prolonged follow-up evaluation). The risk factors for early failure of HM were not identified. A higher column of barium at 1 minute on baseline TBE was associated with an increased risk for late HM failure.

Pneumatic Dilatation Versus Laparoscopic Heller Myotomy

There was no difference in outcomes of PD compared with HM for both early (P = .83) and late (P = .13) hazard phases (Figure 5A). The success of both treatments showed ongoing decreases over time. HM patients showed a plateau in hazard for approximately 3 years before symptoms relapsed. In contrast, PD patients relapsed at a fairly constant rate over time (Figure 5B). Heartburn requiring PPIs was more common after HM than PD (56% vs 26%, P < .01). Although fundoplication reduced heartburn requiring PPIs, it still was frequent (39% vs 65% without fundoplication, P = .04).

Reason for Failure of Therapy

Diagnostic tests (endoscopy, pH testing, and manometry) were available to identify the reason for symptom recurrence in 23 of 33 (70%) patients failing graded PD and 14 of 17 (82%) patients failing HM. The remaining symptomatic patients did not return to The Cleveland Clinic for follow-up evaluation. PD failure was caused by incompletely treated achalasia in 22 of 23 (96%) patients and gastroesophageal reflux disease (GERD) in 1 (4%). In contrast, HM failure was caused by achalasia in 9 of 14 (64%) patients and GERD in 5 (36%).

Discussion

This study comprised a large series of achalasia patients treated with Rigiflex PD and laparoscopic HM and compared the long-term outcome of these therapies. Our results allow refinement of the algorithm for achalasia treatment and emphasize the need for long-term follow-up evaluation because any treatment of achalasia is palliative.

Analyzing the effect of a single PD allows tailoring of the graded PD strategy. Sex and age are important factors (Figure 2). Success appears to be more likely in women than men across all ages. Younger patients, especially men, have a higher likelihood of early failure with a 30-mm PD balloon. Therefore, it may be reasonable to perform the initial PD with a 35-mm balloon for men less than age 50. However, this recommendation needs to be tested formally with an appropriately designed randomized trial.

The effects of age and sex on outcome of PD are consistent with available literature. Several studies with previous-generation balloons suggested that younger patients had less success.^{15–17} For example, Eckardt et al¹⁵ followed-up 54 patients for a mean of 13.6 years and found that young patients (≤ 40 y) responded poorly to a single PD with the Browne-McHardy (Westlake, OH) balloon (35 mm). Sex was not a predictor, possibly because of the larger balloon used, in contrast to our graded dilatation approach. Goshal et al¹⁸ recently reported that men had a higher propensity to fail PD. In another study describing predictors of Rigiflex PD outcome, Farhoomand et al¹⁹ reported that young men (<45 y) had less improvement with a 30-mm balloon than older men or women in general. They did not detect a high failure rate among young women (<35 y), possibly because of a smaller sample size (26 women compared with 51 in our series). Reasons for failure among men and young people are not known, although differences in LES muscle characteristics have been postulated.^{19,20}

TBE, a simple, reproducible, and easy-to-obtain esophageal emptying measure, has predictive value be-

fore and after PD²¹ or HM.²² In our study, a wider esophagus (implying advanced disease) and lack of improvement in posttherapeutic barium height at 5 minutes (indicative of unsuccessful LES disruption) were associated with early risk for needing a second PD. A reduction in barium height after treatment may be a particularly important predictor in men (Figure 3). Latephase risk for second PD was associated with a wider, shorter column on baseline esophagram and less regurgitation, both markers of more advanced disease.²²

Although factors guiding balloon size choice for initial PD were found, our model could not predict successful outcome for graded PD. Therefore, age and sex influences can be overcome if the LES is disrupted adequately by graded PD. This is confirmed further by our therapeutic success, which was better with 2 PDs and best with 3 (Figure 4). Only 6 patients underwent a third PD. As laparoscopic HM became more popular in the late 1990s, we encouraged surgery (especially in men) after early failure of 2 PDs. In contrast, Eckardt et al¹⁵ found no long-term benefit of a second PD, leading them to advocate surgery after a single PD failed. However, their strategy was one of repeated dilatation with the same 35-mm balloon, rather than graded PD. The most statistically significant factor associated with a favorable long-term outcome in the series by Eckardt et al¹⁵ was posttreatment LES pressure less than 10 mm Hg.

There is limited information on long-term outcome of laparoscopic HM. The pooled successful symptom response was 88% in 924 patients undergoing laparoscopic HM in 21 uncontrolled trials (mean follow-up period, 19 mo).³ More recently, Frantzides et al²³ reported favorable long-term outcome in 92% of 53 patients followed-up for a median of 3 years after laparoscopic HM with floppy Nissen. However, their high success may have been owing to considering dysphagia several times per week or reflux requiring medication as a good outcome. Unfortunately, there is no standardized definition of therapeutic success in achalasia, making comparisons difficult. Definitions of success vary from strict (symptoms once per week or less)²⁴ to liberal (50% decrease in symptoms or freedom from repeat treatment).²⁵

We found no risk factors for early HM failure. Late HM failure was associated with a higher barium column on baseline esophagram, a finding that is difficult to explain. Few HM series have identified predictors of success. A recent report of 73 patients followed-up for a mean of 24 months after laparoscopic HM found that a higher preoperative LES pressure predicted long-term resolution of dysphagia.²⁶ Chapman et al²⁷ found that intraoperative manometry to document residual high

LES pressure, followed by myotomy revision, improved outcome.

Prior Botox treatment or PD did not affect PD or HM outcome. Although prior Botox treatment has been blamed for increased difficulty and mucosal perforation during myotomy,²⁸ a recent study of 73 HMs found that preoperative PD or Botox treatment did not correlate with fibrosis in esophageal muscle biopsy examination or therapeutic outcome.²⁹

Our data suggest that PD and HM have similar outcome in both the early and late phases. Despite enthusiasm for one technique over another, we found an ongoing decrease over time in freedom from failure after both. The predicted outcomes virtually were identical in the early phase (Figure 5A). Failure after PD increased at a fairly constant rate (Figure 5B) and nearly always was caused by recurrent obstruction at the incompletely disrupted LES. Although 26% of patients were on PPIs on last follow-up evaluation, complicated GERD was rare (4%). In contrast, failure after HM showed a different pattern of deterioration. From 10 to 30 months, there was a plateau after which failures increased at a rate greater than for PD (Figure 5B). Although incomplete myotomies occurred, many patients developed a new disease, GERD requiring PPIs in 56% and severe dysphagia/regurgitation frequently requiring bougie dilatation in 36% of failures. Although fundoplication reduced this complication, it still was frequent (39%). The literature examining the effect of an antireflux procedure is controversial. A study with follow-up evaluation limited to 6 months showed that fundoplication achieved a significant reduction in distal esophageal acid exposure on pH monitoring.³⁰ However, a recent meta-analysis found no significant difference in postmyotomy pH studies in patients with or without fundoplication.³¹ Furthermore, studies with longer follow-up periods have shown no effect of fundoplication on the amount of heartburn 24 months after myotomy,³² and no reduction in the use of PPIs 33 months after surgery.²⁶ We have shown, however, an important effect of fundoplication on establishing a physiologic balance between adequacy of myotomy and consequent regurgitation.33

The time delay in HM failure may reflect, in part, the time to development of reflux complications. These sobering results remind us that achalasia treatments are palliative and symptoms frequently recur over time. Thus, we suggest follow-up evaluation every 1–2 years to assess symptoms, with additional evaluation and treatment when necessary.

We believe the long-term data from our report can be useful to physicians and patients in the decision-making process when considering PD and HM because they provide reasonable expectations for durability of the treatments and the possibility of needing additional and different therapies along the way. Although the success of both therapies decreases with time, we have reported previously that the best chance of success may lie, at least for some patients, in the use of a combination of treatments (including botulinum toxin injection, PD, HM, and esophagectomy). In our experience, this approach leads to a success rate of 93% for symptom improvement,³⁴ but these patients were followed-up for less than 1 year on average and the results may be different with prolonged follow-up evaluation.

Limitations of our study should be noted. Follow-up evaluation was prospective, but our cohort of patients was based on retrospective chart review. Treatments were not assigned randomly, but were chosen based on a patient–physician discussion of risk, benefits, and patient preferences. To overcome treatment selection bias, methods for nonrandomized comparisons were used (propensity score).^{12,13} However, we acknowledge that unmeasured factors may contribute to the observed failure rates. In addition, the number of patients at risk for treatment failure is small beyond 5 years. However, our data show a decrease in success for both treatments over time. Continued follow-up evaluation may elucidate this issue further.

In summary, short- and long-term outcomes are similar for graded PD and laparoscopic HM; thus, these therapies should be considered equivalent. Neither treatment cures the disease, and symptom relapse is common because of either incomplete myotomy or GERD. Therefore, achalasia patients need careful long-term follow-up evaluation.

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