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Achalasia Treatment, Outcomes, Utilization, and Costs: A Population-Based Study from the United States

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Abstract

Objective—Randomized trials show that pneumatic dilatation 30mm (PD) and laparoscopic myotomy (LM) provide equivalent symptom relief and disease-related quality of life for patients with achalasia. However, there remain questions about the safety, burden, and costs of treatment options.

Methods—We performed a retrospective cohort study of achalasia patients initially treated with PD or LM (2009–2014) using the Truven Health MarketScan® Research Databases. All patients had one year of follow-up after initial treatment. We compared safety, healthcare utilization, and total and out-of-pocket costs using generalized linear models.

Results—Among 1,061 patients, 82% were treated with LM. LM patients were younger (median age 49 vs. 52 years, $p<0.01$) but were similar in terms of sex ($p=0.80$) and prevalence of comorbid conditions ($p=0.11$). There were no significant differences in the one-year cumulative risk of esophageal perforation (LM 0.8% vs. PD 1.6%, $p=0.32$) or 30-day mortality (LM 0.3% vs. PD 0.5%, $p=0.71$). LM was associated with an 82% lower rate of re-intervention ($p<0.01$), 29% lower rate of subsequent diagnostic testing ($p<0.01$), and 53% lower rate of re-admission ($p<0.01$). Total and out-of-pocket costs were not significantly different ($p>0.05$).

Conclusions—In the United States, LM appears to be the preferred treatment for achalasia. Both LM and PD appear to be safe interventions. Along a short time-horizon, the costs of LM and PD were not different. Mirroring findings from randomized trials, LM is associated with fewer re-interventions, less diagnostic testing, and fewer hospitalizations.

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Introduction

Achalasia is a rare (incidence 1/100,000), disabling chronic condition characterized by aperistalsis of the esophagus and impaired relaxation of the lower esophageal sphincter (LES). Degeneration of ganglion cells in the myenteric plexus and abnormal nitric oxide levels lead to functional obstruction of the gastro-esophageal junction with accompanying symptoms of dysphagia, heartburn, chest pain, and weight loss.(1) These symptoms negatively impact health-related quality-of-life, work productivity, and functional status.(2) There is no cure for the disease,(1) but mechanical disruption of the LES by either endoscopic pneumatic dilatation 30mm (PD) or laparoscopic myotomy (LM) provides durable symptom relief.(3, 4) A recent multi-center randomized controlled trial (RCT) demonstrated that both PD and LM provide symptom relief in 90% of patients at two years, (5) while another showed that PD and LM provide equivalent improvement in achalasia-specific quality of life at five years.(6) Current practice guidelines from the American College of Gastroenterology (ACG) recommend either PD or LM as first-line therapy for patients with achalasia.(4) Assuming patients have access to provider teams that can safely and reliably offer both interventions, the choice between PD and LM should largely be based on patient preference.(4) However, patients rarely base treatment decisions on efficacy alone. Most patients want information about risks, the need for additional testing and/or interventions, and the amount of out-of-pocket expenses they will be responsible for. There is very little data about these “non-efficacy” outcome domains and as a result patients may not be making informed decisions about their care.

The goal of this study was to compare safety, health care utilization, and costs associated with PD and LM among a cohort of commercially-insured Americans with a new diagnosis of achalasia. We hypothesized that LM would be associated with lower rates of esophageal perforation and death, less frequent subsequent diagnostic testing and treatments, but similar costs (both out-of-pocket and total costs to the healthcare system) when compared to PD over a short (one year) time horizon.

Methods

This study adheres to reporting standards described by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.(7)

Study Design, Data Source, & Patients

We performed a retrospective cohort study of adult patients with a new diagnosis of achalasia (ICD-9 530.0) who were subsequently treated with PD or LM from January 1, 2009 to September 30, 2014 with at least one year of follow-up data using the MarketScan® Commercial Claims and Encounters Databases. For 2014, we only included patients treated prior to October 1 in order to prevent inconsistencies resulting from the introduction of ICD-10 codes on October 1, 2015. MarketScan® data captures information for inpatient and outpatient services for a subset of employed US adults and their dependents. Diagnoses and procedures are captured using International Classification of Diseases, 9th Revision (ICD-9), Current Procedural Terminology (CPT), and Healthcare Common Procedure Coding System (HCPCS) codes. All codes used in this study are included in the Appendix. This analysis of

de-identified data did not require review by the University of Washington Institutional Review Board.

Eligible adult patients aged 18–64 were required to have one year of continuous enrollment in MarketScan® prior to the first claim for achalasia. Patients older than 64 were not included as they may have Medicare supplemental insurance and thus their healthcare costs would not be accurately reflected in MarketScan®. We excluded patients who had been treated with either PD or myotomy via any approach in the one year prior to diagnosis. We excluded patients who were treated prior to 2009 because the specific CPT code for LM was not generated until 2008. Following initial treatment with PD or LM, patients were excluded if they had less than one year of continuous enrollment, unless disenrollment was due to death.

From 2007–2014, we found 3,245 patients between the ages of 18–64 with a diagnosis of achalasia who subsequently were treated with PD or LM. Of these, 1,157 were excluded because they had less than one year of continuous enrollment prior to their diagnosis; 879 were excluded because they had less than one year of follow-up after initial therapy; 58 were excluded because of age <18 years; 10 patients had a record of an intervention (PD or LM) prior to their diagnosis; 44 were excluded because they were treated in 2008; and 36 were excluded because they were missing information on one or more covariates.

Potentially confounding variables included age, sex, Elixhauser comorbidity score,⁽⁸⁾ insurance type, region, prior evaluations (esophagogastroduodenoscopy [EGD], esophagogram, pH testing, or manometry), prior treatment (botulinum toxin injection or dilation <30mm), and year of treatment. We re-categorized insurance type based on the burden of out-of-pocket costs associated with each plan. This method has been described and implemented in previous studies using MarketScan® data.⁽⁹⁾

Initial Treatment Type

The first claim for PD or LM on or after the date of diagnosis determined the patient's treatment group. For example, a patient who was initially treated with PD but subsequently underwent LM within the following year would still be classified in the PD cohort.

Outcomes

Safety—Perforation was defined as a claim containing an ICD-9 code for perforation that occurred during an “unplanned” hospitalization. An unplanned hospitalization was defined as any hospitalization that occurred within seven days of any (initial or recurrent) PD; hospitalization following any LM whose length exceeded five days; or any re-admission to the hospital within seven days following discharge for LM. Death was measured by MarketScan® and includes any death occurring in the inpatient setting within 30 days of any PD or LM.

Subsequent diagnostic testing and treatment—We measured subsequent interventions (myotomy via any incisional approach, dilation of any size, botulinum toxin injection, and esophagectomy), subsequent diagnostic testing (EGD, esophagogram, pH test, or manometry), and hospitalizations in the one year following initial therapy.

Costs—The cost analysis was from both the payer and patient perspective. Out-of-pocket expenses include all co-payments, co-insurance, and deductibles paid by the patient at the time of initial treatment and in the subsequent one year. All costs were standardized to 2015 dollars using the consumer price index.(10)

Analysis

Patient characteristics were summarized using frequency distributions for categorical variables, and medians for continuous variables. For costs, we reported both median and mean costs as the variable was non-normally distributed. We performed significance testing using the Pearson chi-square statistic for categorical variables and the nonparametric equality of medians test or Student's t-test for continuous variables. A p-value of <0.05 was considered statistically significant. Multivariable regression with generalized linear models and robust standard errors was used to determine the association between initial treatment type, healthcare utilization, and costs. We adjusted for age, sex, Elixhauser score, insurance type, region, calendar year, prior diagnostic testing, and prior intervention with botulinum toxin or dilation <30mm. We modeled each healthcare utilization outcome measure as a continuous variable, specifying a negative binomial distribution with a log link.(11) For costs, we specified a gamma distribution with a log link.(12) Adjusted mean cost differences were then estimated using the delta –method with the 'margins' command in STATA.(13)

Analyses were conducted using STATA software, version 13 (Stata Corp).

Results

Among 1,061 patients (median age 49 years, range 18–63, 49% female) the majority of patients (n=871, 82%) underwent initial treatment with LM. These patients were younger (median age 49 versus 52 years, $p<0.01$) and more frequently underwent diagnostic testing prior to treatment (97% versus 90%, $p<0.01$) compared to patients who underwent initial treatment with PD. Specifically, patients undergoing initial treatment with LM more frequently underwent diagnostic testing with manometry (80% versus 66%, $p<0.01$). There was significant regional variation in treatment patterns ($p<0.01$): patients residing in the Western region had the highest rates of treatment with LM (90%) whereas patients residing in the Northeastern region had the lowest rates of treatment with LM (77%). Patients with a low burden of out-of-pocket expenses more frequently underwent initial treatment with LM (90%) compared to those with some burden or high burden ($p=0.02$). There was significant temporal variation in treatment patterns: patients treated in 2014 had the highest rates of treatment with LM (89%) whereas patients treated in 2010 had the lowest rate of treatment with LM (75%). We found no significant differences between treatments with regard to patient sex, Elixhauser comorbidity score, or whether a patient had previously undergone treatment with botulinum toxin injections or a dilation <30mm. (Table 1)

Unadjusted Analysis

Among those who underwent initial treatment with LM, seven patients (0.8%) had an esophageal perforation, although none of these patients had an additional claim for surgical repair, stent, or pleural decortication. Three patients (1.6%) in the PD group had an

esophageal perforation. Two of these patients had a claim for a surgical intervention (esophageal repair and pleural decortication), and the third did not have any claim for surgical or endoscopic intervention. Perforation rates were not significantly different between PD and LM ($p=0.32$). Thirty-day death rates were also not significantly different across treatments (0.5% versus 0.3%, $p=0.75$). Given of the very low number of esophageal perforations and deaths, we did not perform a multivariate adjustment.

Compared to those who underwent PD, LM patients had lower rates of subsequent diagnostic testing (73% versus 85%, $p<0.01$), re-intervention (9.5% versus 48%, $p<0.01$), and hospitalizations (10% versus 23%, $p<0.01$) in the year after initial treatment. Patients treated with LM had higher initial mean total costs (\$29,257 versus \$5,683, $p<0.01$) and out-of-pocket costs (\$970 versus \$452, $p<0.01$). Despite this, at one year there was no difference in mean total costs (\$30,110 versus \$23,610, $p=0.66$) or out-of-pocket costs (\$1,061 versus \$1,274, $p=0.18$). (Table 2)

Multivariable Adjusted Analysis

In the adjusted analyses, the findings were similar: initial treatment with LM was associated with an 82% lower incidence of re-intervention ($p<0.01$), a 29% lower incidence of subsequent diagnostic testing ($p<0.01$), and a 53% lower incidence of hospitalization ($p<0.01$). Adjusted mean differences in total one year costs (\$6,733, $p=0.06$) and one-year out-of-pocket costs (\$135, $p=0.29$) were not significantly different between LM and PD (Table 3).

Discussion

We conducted the largest study of achalasia care and outcomes among patients within the US. Four out of five patients were treated with LM. LM was associated with less subsequent diagnostic testing, fewer re-interventions, and fewer hospitalizations. Differences in esophageal perforation and death rates but were not statistically significant. One year after treatment, total costs and out-of-pocket costs were not significantly different between patients initially treated with LM or PD.

Our findings corroborate expert surgical opinion—LM is the predominant therapy for achalasia in the US.⁽¹⁴⁾ This finding is in stark contrast to a prior population-based study from Canada evaluating patients treated in the 1990s. In that study, ~80% of patients were treated with PD whereas in our study ~80% of patients were treated with LM.⁽¹⁵⁾ Reasons for these differences in care may include evolving practice patterns, differing treatment preferences based on country of residence, and the fact that LM became more widely available over time.⁽¹⁴⁾ Regardless of the reasons for differences in care across nations and time, it is important to note that in the US patients with achalasia are initially evaluated by gastroenterologists rather than surgeons. Because gastroenterologists are the “gate keepers”, it is possible that care patterns observed in our study indicate that American gastroenterologists believe that achalasia is better treated with LM rather than PD.

In considering two treatment options, an important consideration is whether there is a difference in safety. We hypothesized that LM would be associated with a lower incidence of

both esophageal perforation and death in the one year following initial therapy. Underpinning this hypothesis is the evidence from randomized studies demonstrating higher rates of re-intervention after initial treatment with PD.(5, 6) Safety must be assessed in terms of cumulative risk because each intervention, both initial and subsequent, carries an independent risk of perforation and/or death. Esophageal perforation is a life-threatening complication that can occur after PD or LM. However, a perforation that occurs during LM is almost always recognized and repaired at the time of surgery adding only a few minutes of time to the operation and has little, if any, impact on the patient's subsequent clinical course. (5, 16, 17) Perforation resulting from PD is more likely to present in a delayed fashion with much higher rates of morbidity and mortality.(4) In our study, no patient in the LM cohort who had an esophageal perforation required an additional surgical intervention, whereas the majority of patients with a perforation after PD required a separate operative intervention to repair the defect.

Although we did not find statistically significant differences in rates of esophageal perforation or death, we were underpowered to detect significant differences in outcomes given the event rates, despite being the largest US study to date. With 80% power, a properly powered study would require 2,798 patients who underwent PD and 20,511 patients who underwent LM to determine that the two-fold higher perforation rates associated with PD were not due to chance. Our findings underscore the need for a multi-center registry of patients with achalasia to better evaluate rare procedure-related adverse events. Evidence of safety differences could potentially lead to changes in the current ACG guidelines and strongly influence patient preferences.

Patients who were initially treated with PD had significantly higher rates of re-intervention, subsequent diagnostic testing, and hospitalization. These findings support the findings of Lopushinsky, et al, who reported similar findings with regards to re-intervention. (15) Similarly, in the largest RCT to date, all patients randomized to PD underwent at least two dilations as part of their initial treatment, which in and of itself indicates that they required more interventions over time in order to reach the same level of symptom relief. The authors of that study acknowledged that if re-intervention is used as an indicator of treatment success, PD would be considered less effective than LM.(5) This statement highlights the controversy that exists within the field of achalasia, namely regarding how we define treatment success. Some argue in favor of multiple dilations to achieve symptom relief, stating that “the road to Heller’s myotomy should be paved with good distentions”(18) while others state that despite the equivalent short-term efficacy, over a longer time horizon surgical myotomy is superior and thus “paving the way” to an inevitable operation is inappropriate.(14) Fortunately, everyone agrees that patients should be given all possible information regarding potential treatment outcomes. Our study of community based practice confirms what has been observed in clinical trials—LM is associated with less subsequent testing and treatment, which is less of a burden for most patients. Accordingly, patients should be counseled about differences in the burden of care following LM and PD.

Another consideration is the difference in cost (both from the payer and patient perspective) associated with the two interventions. As with safety outcomes, a treatment associated with multiple interventions over time would be expected to have a higher overall cost, which may

be important to both patients and payers. We hypothesized that over a one year time horizon costs would be similar between LM and PD because the high upfront costs of surgery would equal the costs of re-interventions in the first year after initial therapy. While our results did not support this, there was a trend towards significance in total cost difference between LM and PD ($p=0.06$). Over a longer time horizon, we expect that the continual need for re-intervention, re-admission, and diagnostic testing in the PD group would likely lead to higher costs and potentially more complications.

As with any study, there are limitations to our approach. First, despite having strict inclusion criteria we may have inadvertently included some patients who had been treated with PD or LM more than one year prior to their “initial diagnosis” and that in reality we were capturing patients who were undergoing re-interventions. If this were the case, we would have included patients with more severe disease which may be associated with worse outcomes. A second is that the relatively short follow-up period prevents us from making inferences beyond one year. We were dependent upon patients having continuous enrollment to be included in our study, and requiring a longer time horizon for continuous enrollment would further reduce our cohort size and power. The population in this study may not be generalizable to the broader population of achalasia patient. Because MarketScan® draws from a subset of employed, insured adults it often includes a younger and healthier population than the general public. However, the incidence of achalasia is highest in individuals aged 30–60,(19) and most Americans are employed.

A final consideration is that we were unable to account for selection bias that may also impact patient outcomes. Guidelines from professional organizations state that patients being considered for either treatment must be surgical candidates given the risk of esophageal perforation requiring operative intervention in PD. Recommended drivers of treatment choice are age, sex, patient preference, and provider expertise.(4) Younger age and male sex predict a higher risk of treatment failure with PD.(20, 21) We adjusted for these variables in our analysis. However, we could not measure provider expertise, which is presumably associated with treatment outcomes. We also could not measure other predictors of poor treatment response including the interval between symptom onset and treatment; baseline LES pressure; or the height of the column or esophageal diameter on a barium study.(21, 22) Because we cannot measure how these variables were distributed across treatment groups, we cannot predict the direction of any potential bias that these variables may introduce.

In the first population-based study of US adults with achalasia, LM appears to be the preferred initial treatment. Mirroring results from RCT's, we found that initial treatment with LM was associated with a lower rate of re-intervention, subsequent diagnostic testing, and readmission when compared to PD. Both treatments appear to be safe interventions. Despite the higher up-front costs of LM, one year total and out-of-pocket costs were not significantly different. Future research efforts should focus on establishment of a multi-center clinical registry to ascertain outcomes among a broader population of patients with achalasia. Such a registry could track clinical and patient-centered outcomes over time to further inform treatment guidelines and further aid patient decision making.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline Characteristics of Patients Treated with Pneumatic Dilatation 30mm Compared to Those Treated with Laparoscopic Myotomy

Variable	Pneumatic dilatation, N=190	Laparoscopic myotomy, N=871	p Value
Age, y, median [range]	52 [18–63]	49 [18–63]	<0.01
Sex, f, n (%)	91 (48)	425 (49)	0.8
Elixhauser Score, n (%)			0.55
0	51 (27)	219 (25)	
1	47 (25)	255 (29)	
2	43 (23)	169 (19)	
3+	49 (26)	228 (26)	
Insurance plan type, n/row total n (%)			0.02
Low burden	15/144 (10)	129/144 (90)	
Some burden	160/818 (20)	658/818 (80)	
High burden	15/99 (15)	84/99 (85)	
Region, n/row total n (%)			<0.01
Northeast	51/221 (23)	170/221 (77)	
North Central	46/237 (19)	191/237 (81)	
South	73/410 (18)	337/410 (82)	
West	20/193 (10)	173/193 (90)	
Year, n/row total n (%)			0.04
2009	22/148 (15)	126/148 (85)	
2010	50/203 (25)	153/203 (75)	
2011	32/193 (17)	161/193 (83)	
2012	41/207 (20)	166/207 (80)	
2013	31/186 (17)	155/186 (83)	
2014	14/124 (11)	110/124 (89)	
Prior diagnostic evaluation, n (%)			
Any	170 (90)	844 (97)	<0.01
EGD	51 (27)	303 (35)	0.04
UGI	148 (78)	756 (87)	<0.01
pH test	38 (20)	209 (24)	0.24
Manometry	125 (66)	698 (80)	<0.01
Prior treatment, n (%)			
Any	63 (33)	249 (29)	0.21
Botulinum toxin injection	20 (11)	85 (10)	0.75
Pneumatic dilatation < 30mm	48 (25)	185 (21)	0.23

EGD, esophagogastroduodenoscopy; UGI, upper gastrointestinal

Table 2

Unadjusted Safety, Healthcare Utilization, and Cost Outcomes Associated with Pneumatic Dilation 30mm Compared to Those Treated with Laparoscopic Myotomy

Variable	One-Year Outcomes		
	Pneumatic dilation, N=190	Laparoscopic myotomy, N=871	p Value
Safety, n (%)			
Esophageal perforation	3 (1.6)	7 (0.8)	0.32
30-day in-hospital death	1 (0.5)	3 (0.3)	0.71
Utilization, n (%)			
Any re-intervention	92 (48)	83 (9.5)	<0.01
Botulinum toxin injection	9 (4.7)	8 (0.9)	<0.01
Pneumatic dilation <30mm	56 (30)	50 (5.7)	<0.01
Pneumatic dilation 30mm	35 (18)	5 (0.6)	<0.01
Surgical myotomy *	19 (10)	29 (3.3)	<0.01
Esophagectomy	1 (0.5)	2 (0.2)	0.49
Subsequent diagnostic testing, n (%) †	162 (85)	624 (73)	<0.01
Readmission, n (%)	44 (23)	87 (10)	<0.01
Mean costs, \$			
Total	23,610	30,110	0.66
Out-of-pocket	1,575	1,684	0.18
Median costs, \$			
Total	9,608	22,946	<0.01
Out-of-pocket	1,061	1,274	0.18

* Re-intervention includes botulinum toxin injection, pneumatic dilatation of any size, myotomy via any approach, and esophagectomy.

† Subsequent diagnostic test includes esophagogastroduodenoscopy, pH testing, manometry, or esophagogram.

Table 3

Adjusted Outcomes Comparing Patients Who Underwent Initial Treatment with Laparoscopic Myotomy Compared to Pneumatic Dilatation

Variable	Data
Re-intervention incidence rate ratio, (95% CI)	0.18 (0.13–0.25)
Subsequent diagnostic testing incidence rate ratio, (95% CI)	0.71 (0.62–0.80)
Hospitalization incidence rate ratio, (95% CI)	0.47 (0.32–0.68)
Total cost difference, \$, mean (95% CI)	6,733 (–307 to 13,774)
Out-of-pocket cost difference, \$, mean (95% CI)	135 (–113 to 384)

Adjusted for age, sex, Elixhauser comorbidity score, insurance type, region, year, prior diagnostic treatment, and prior intervention with PD<30mm or botulinum toxin injectio.