

Pneumatic Dilatation and Surgical Myotomy for Achalasia

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ACHALASIA IS A RARE CHRONIC disorder of esophageal motor function, affecting approximately 1 person per 100 000 population per year¹ and causing substantial impairment in health-related quality of life.² Persons affected by achalasia typically report dysphagia, regurgitation, and chest pain. The principal functional abnormalities in achalasia are absence of esophageal body peristalsis and failure of the lower esophageal sphincter to relax normally on swallowing.³ Although the etiology is not known, the physiologic abnormality is thought to be degeneration of the esophageal myenteric plexus, predominantly affecting inhibitory ganglionic neurons.⁴

Achalasia is not curable, and the goal of therapy is palliation of symptoms by reducing the degree of esophageal obstruction at the level of the lower esophageal sphincter. Current therapeutic options include pharmacologic agents, endoscopic injection of botulinum toxin A into the lower esophageal sphincter, pneumatic dilatation of the lower esophageal sphincter, and surgical division of the smooth muscle of the lower esophageal sphincter (Heller myotomy).⁵

There is controversy about the optimal choice of initial management of achalasia. Long-term symptomatic improvement may be achieved with either pneumatic dilatation or surgical myotomy.^{5,6} Although pneumatic dilatation had been considered the first-line therapy for achalasia for many years,⁷ recent widespread use of laparoscopic surgery for achalasia has renewed in-

Context Pneumatic dilatation and surgical (Heller) myotomy are the 2 principal methods for treatment of achalasia. There are no population-based studies comparing outcomes of these 2 treatments in typical practice settings.

Objective To compare the outcomes of pneumatic dilatation and surgical myotomy for achalasia.

Design, Setting, and Participants Retrospective longitudinal study using linked administrative health data in Ontario. A total of 1461 persons aged 18 years or older received treatment for achalasia between July 1991 and December 2002, 1181 (80.8%) of whom had pneumatic dilatation and 280 (19.2%) of whom had surgical myotomy as the first procedure.

Main Outcome Measures Use of subsequent interventions for achalasia (pneumatic dilatation, surgical myotomy, or esophagectomy) following the first treatment during the study period, subsequent physician visits, and use of gastrointestinal medications among persons aged 65 years or older. We adjusted for confounding variables using regression models.

Results The cumulative risk of any subsequent intervention for achalasia after 1, 5, and 10 years, respectively, was 36.8%, 56.2%, and 63.5% for persons treated initially with pneumatic dilatation and was 16.4%, 30.3%, and 37.5% for persons treated initially with surgical myotomy (adjusted hazard ratio [HR], 2.37; 95% confidence interval [CI], 1.86-3.02; $P < .001$). Differences in risk were observed only when subsequent pneumatic dilatation was included as an adverse outcome; there was no statistical difference between the 2 groups with respect to the risk of subsequent surgical myotomy or esophagectomy. Compared with persons treated initially with surgical myotomy, those treated with pneumatic dilatation were not statistically different with respect to subsequent physician visits (adjusted rate ratio, 1.01; 95% CI, 1.00-1.03), or time to use of histamine-2 receptor blockers (adjusted HR, 1.19; 95% CI, 0.79-1.80), proton pump inhibitors (HR, 1.02; 95% CI, 0.70-1.49), and prokinetic medications (HR, 0.92; 95% CI, 0.60-1.41).

Conclusions Subsequent intervention after the initial treatment of achalasia is common. Although the risk of subsequent interventions among persons treated with surgical myotomy in typical practice settings is higher than previously thought, the risk of subsequent intervention is greater among persons treated with pneumatic dilatation than with surgical myotomy. This difference is attributable to the use of subsequent pneumatic dilatation rather than surgical procedures.

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terest in a greater role for surgical myotomy.⁸ In the only randomized trial comparing the outcomes of pneumatic dilatation and surgical myotomy, 95% of patients treated with surgical myotomy had a good long-term result compared with 65% of patients treated with pneumatic dilatation.⁹ Most reports of the outcomes of achalasia

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Table 1. Baseline Patient Characteristics According to Initial Treatment

Characteristics	Surgical Myotomy (n = 280)	Pneumatic Dilatation (n = 1181)	P Value
Age, mean (SD), y	48.8 (16.6)	52.5 (18.6)	.002
Sex, No. (%)			.86
Female	133 (47.5)	568 (48.1)	
Male	147 (52.5)	613 (51.9)	
Charlson comorbidity score, No. (%)			.90
0	263 (93.9)	1102 (93.3)	
1	15 (5.4)	68 (5.8)	
≥2	2 (0.7)	11 (0.9)	
Income quintile, No. (%)*			.84
5 (highest)	50 (17.9)	251 (21.3)	
4	48 (17.1)	196 (16.6)	
3	52 (18.6)	219 (18.5)	
2	63 (22.5)	249 (21.1)	
1 (lowest)	58 (20.7)	223 (18.9)	
Missing/not assigned	9 (3.2)	43 (3.6)	

*The value of income according to quintile varied between different neighborhoods.

treatment are produced by single centers and describe the effectiveness of only 1 treatment method.

There are no published studies on the effectiveness of achalasia treatment in typical community practice. In the absence of population-based studies of the effectiveness of achalasia therapy, it is difficult to make treatment recommendations to patients. The aim of the present study was to describe the outcomes of pneumatic dilatation and surgical myotomy in typical practice using administrative health data in Ontario.

METHODS

Study Design

We conducted a retrospective cohort study using population-based administrative health data in Ontario. Patients were followed up for occurrence of outcomes of interest from the time of the initial procedure until December 31, 2002. The primary objective of the study was to compare pneumatic dilatation and surgical myotomy with respect to a variety of treatment outcomes, including short-term mortality, need for further interventions related to achalasia, and use of medications for gastroesophageal reflux disease.

Data Sources and Study Patients

We followed up persons with achalasia longitudinally by linkage of records

from several Ontario health databases, including the Canadian Institute for Health Information (CIHI) hospital separation database, the Ontario Health Insurance Plan (OHIP) physician claims database, the Registered Persons database (a vital statistics registry), and the Ontario Drug Benefit database, which covers pharmaceutical claims for persons aged 65 years or older. Because of changes in the unique personal identifier used to link records across Ontario health databases, we were unable to link individual records prior to April 1, 1991, and could not identify health services provided prior to this date.

We searched electronic hospital discharge records between July 1, 1991, and December 31, 2002, for all persons aged 18 years or older with a diagnosis of achalasia who were treated with pneumatic dilatation or surgical myotomy on an ambulatory or inpatient basis. We defined a person's first treatment during this period as the index event for all analyses, regardless of whether treatment for achalasia had been received previously. Between 1991 and 2001, the diagnosis of achalasia was defined by *International Classification of Diseases, 9th Revision* code 530.0. For 2002, the diagnosis of achalasia was identified by *International Statistical Classification of Diseases, 10th Revi-*

sion diagnosis code K22.0. Pneumatic dilatation was identified by OHIP fee codes Z525, Z523, and E698.

Surgical myotomy was identified by OHIP fee code S161. Since the OHIP codes did not identify with certainty whether the surgical myotomy was performed laparoscopically during the study period, we could not distinguish between open and laparoscopic surgical procedures. The addition of an antireflux procedure to a surgical myotomy was identified by OHIP fee code E758 or in the CIHI database by Canadian Classification of Procedures code 54.6 (1991-2001) and Canadian Classification of Interventions code 1.NA.72 (2002). Agreement between hospital discharge data and physician claims in Canada ranges from 77% to more than 98%.¹⁰

We excluded records of persons with achalasia who were younger than 18 years at the index procedure, lacked a valid unique personal identifier, resided outside of Ontario or in regions where physicians did not submit claims on a fee-for-service basis, did not have either a pneumatic dilatation or surgical myotomy during the study period, or who had any diagnosis of cancer.

Exposures

We collected information on age, sex, comorbidity, and income status. Comorbidity was measured using the Deyo adaptation of the Charlson comorbidity index.¹¹ Median annual income in neighborhood of residence was determined using 2001 census data, linked to postal forward sortation areas and categorized into community-specific quintiles within census regions.

Outcomes

The primary study outcome was defined a priori as the first occurrence of any (1) pneumatic dilatation, (2) surgical myotomy, or (3) esophageal resection following index treatment. Occurrence of esophagectomy was defined by OHIP fee codes S089 or S090. We also performed separate analyses for the occurrence of the first esophageal dilatation, myotomy, and esophagectomy.

We analyzed a number of secondary outcomes, including death within 30 days of initial treatment, long-term survival, and the number of physician visits following initial treatment, defined as the number of days on which a physician was seen, collected as a measure of health resource use. We also analyzed length of hospital stay following index therapy as a measure of procedure-related morbidity.

We measured use of upper gastrointestinal tract medications after treatment for persons aged 65 years or older at the time of initial treatment during the study period, for whom all prescription medications are provided by the Ontario Drug Benefit program. We measured the time from initial treatment to first prescription of histamine-2 receptor blockers (cimetidine, famotidine, nizatidine, and ranitidine), proton pump inhibitors (esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole), and prokinetic agents (cisapride, domperidone, and metoclopramide).

Statistical Analysis

Baseline differences between groups were tested using the χ^2 test for categorical variables and analysis of variance for continuous variables. Differences between treatment groups with respect to dichotomous outcomes were compared using the χ^2 test. Nonparametric tests were used to compare the length of hospital stay following index treatment. Change in the relative use of the 2 procedures over time was tested using the Mantel-Haenszel extension test for trend.

The cumulative risk of experiencing adverse outcomes was estimated using Kaplan-Meier survival curves, and differences between groups were compared using the log-rank test. Cox proportional hazards models were used to estimate the time between the date of the index treatment and the date of the first adverse event, death, or December 31, 2002. Observation time was censored after the first adverse event. Multivariable models were used to adjust for potentially confounding variables.

Table 2. Cumulative Risk of Subsequent Interventions for Achalasia After 10 Years According to Initial Treatment

Subsequent Interventions	Cumulative Risk by Initial Treatment, %*		P Value†
	Surgical Myotomy	Pneumatic Dilatation	
Pneumatic dilatation, surgical myotomy, or esophagectomy	37.5	63.5	<.001
Pneumatic dilatation	33.6	60.5	<.001
Surgical myotomy	11.4	16.0	.10
Esophagectomy	6.8	2.1	.16

*The cumulative unadjusted risk of subsequent interventions was estimated using Kaplan-Meier methods.
†P values were calculated from the log-rank test.

The assumption of proportional hazards was checked by inspection of Kaplan-Meier curves and by log-log plots. Adjusted risks of adverse outcomes were obtained by fitting logistic regression models for pneumatic dilatation and surgical myotomy, adjusting for age, sex, and comorbidity, with each covariate centered at its mean value. Relative differences in physician visits were estimated using Poisson regression models, and the adjusted number of physician visits for each treatment group was estimated using multivariable linear regression models.

All statistical analyses were performed using SAS software, version 9.1 (SAS Institute Inc, Cary, NC). All P values were 2-tailed and considered to be statistically significant when less than .05. This study was approved by the research ethics boards of Sunnybrook and Women's College Hospital and the University of Toronto, Toronto, Ontario.

RESULTS

We identified 4401 persons with achalasia without a diagnosis of cancer between July 1, 1991, and December 31, 2002. Two hundred twenty persons (5.0%) were excluded from subsequent analyses because of residence outside of Ontario or in regions where fee-for-service claims were not routinely submitted and 114 (2.6%) were excluded because of age younger than 18 years at the index event. A total of 2606 persons (59.2%) did not have either a pneumatic dilatation or surgical myotomy procedure during the study period, most of whom had likely been

treated prior to July 1991. The final cohort therefore consisted of 1461 persons with achalasia, 1181 (80.8%) whose first procedure during the study period was a pneumatic dilatation and 280 (19.2%) whose first procedure was a surgical myotomy.

Baseline characteristics of patients according to their initial treatment are presented in TABLE 1. Persons in the pneumatic dilatation group were slightly older than those who received surgery as initial treatment (52.5 vs 48.8 years; $P = .002$). The distributions of sex, comorbidity, and income status in neighborhood of residence were similar between treatment groups.

The mean number of years of follow-up was 5.0 (median, 4.7 [range, 0.03-11.7] years). Among 1181 persons treated initially with pneumatic dilatation, 562 (47.6%) subsequently received 1 or more additional pneumatic dilatations, 148 (12.5%) had a surgical myotomy, and 13 (1.1%) had an esophagectomy. Of the 562 who had subsequent pneumatic dilatations during the study period, 407 (72.4%) had 1 or 2 subsequent pneumatic dilatations and 155 (27.6%) had 3 or more. Among 280 treated initially with surgical myotomy, 59 (21.1%) subsequently received 1 or more pneumatic dilatations, 24 (8.6%) had an additional surgical myotomy, and 6 (2.1%) had an esophagectomy. TABLE 2 summarizes the cumulative risk of subsequent interventions for achalasia after up to 10 years of follow-up, according to initial treatment during the study period.

Persons who received pneumatic dilatation as the initial treatment during the study period were more likely than those treated with surgical myotomy to require an additional pneumatic dilatation, surgical myotomy, or esophagectomy during follow-up ($P < .001$) (FIGURE). Among persons treated initially with surgical myotomy, 16.4% had another intervention after 1 year compared with 36.8% of persons treated initially with pneumatic dilatation. Five years after initial therapy, the risk of subsequent intervention was 30.3% and

56.2%, respectively, for persons treated with surgical myotomy and pneumatic dilatation. The 10-year cumulative risk of subsequent intervention for persons treated initially with surgical myotomy and pneumatic dilatation was 37.5% and 63.5%, respectively.

The risk of additional interventions was lower among women than men (hazard ratio [HR], 0.85; 95% confidence interval [CI], 0.73-0.99), and higher among persons with greater burden of comorbid illness (HR per unit increase in the Charlson comorbidity

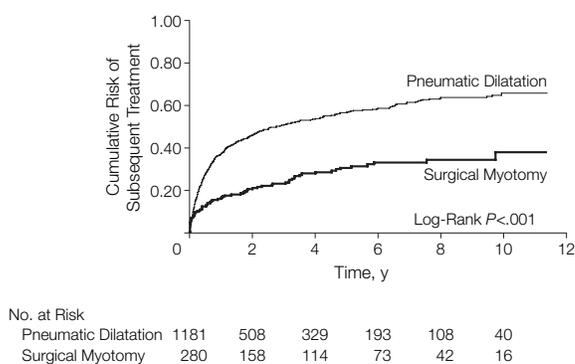
score, 1.33; 95% CI, 1.13-1.57). There was no relationship between the risk of subsequent treatment for achalasia and age or median neighborhood income. After adjustment for age, sex, comorbidity, and income status, persons treated initially with pneumatic dilatation were significantly more likely to receive additional interventions than those treated initially with surgical myotomy (HR, 2.37; 95% CI, 1.86-3.02; $P < .001$) (TABLE 3).

The adjusted probability of receiving subsequent interventions was 52.9% (95% CI, 50.1%-55.8%) for persons treated initially with pneumatic dilatation compared with 26.5% (95% CI, 21.6%-32.0%) for persons treated initially with surgical myotomy. In analyses estimating the relative risk of each type of reintervention separately according to initial treatment provided, initial pneumatic dilatation was associated with a nearly 3-fold risk of subsequent pneumatic dilatation compared with initial surgical myotomy. There were no statistically significant associations between initial treatment and subsequent need for surgical myotomy or esophagectomy (Table 3).

No deaths occurred within 30 days of a surgical myotomy, and 7 deaths (0.6%) occurred within 30 days of a pneumatic dilatation ($P = .20$). Twenty-five (8.9%) of 280 persons treated initially with surgical myotomy and 189 (16.0%) of 1181 persons treated initially with pneumatic dilatation died during the study period (adjusted HR for death among those treated with pneumatic dilatation compared with surgical myotomy, 1.22; 95% CI, 0.80-1.87). The median length of hospital stay following surgical myotomy was 4 days (mean, 5.7 [range, 1-34] days) and following pneumatic dilatation was 0 days (mean, 3.6 [range, 0-504.0] days; $P < .001$).

There was no difference in the adjusted mean rate of subsequent physician visits between persons treated initially with pneumatic dilatation (mean number of physician visits, 18.9; 95% CI, 18.7-19.0) compared with surgical myotomy (mean visits, 18.6; 95% CI, 18.4-18.9; rate ratio, 1.01; 95% CI, 1.00-1.03).

Figure. Time to Subsequent Treatment After Initial Treatment During the Study Period



Subsequent treatment was defined as the first pneumatic dilatation, surgical myotomy, or esophagectomy following initial treatment. Time to treatment failure was calculated from the date of the first treatment for achalasia during the study period. Observations were censored if treatment failure did not occur prior to death or December 31, 2002. Cumulative risk of treatment failure was estimated by Kaplan-Meier methods, and the curves were compared using the log-rank test.

Table 3. Adjusted Risk of Subsequent Interventions for Achalasia According to Initial Treatment

Interventions	Estimated Probability, % (95% CI)*	Hazard Ratio (95% CI)†
Subsequent pneumatic dilatation, surgical myotomy, or esophagectomy		
Initial surgical myotomy	26 (22-32)	2.37 (1.86-3.02)
Initial pneumatic dilatation	53 (50-56)	
Subsequent pneumatic dilatation		
Initial surgical myotomy	21 (17-26)	2.80 (2.14-3.66)
Initial pneumatic dilatation	48 (45-50)	
Subsequent surgical myotomy		
Initial surgical myotomy	7 (5-11)	1.51 (0.98-2.33)
Initial pneumatic dilatation	12 (10-14)	
Subsequent esophagectomy		
Initial surgical myotomy	2 (1-4)	0.49 (0.18-1.31)
Initial pneumatic dilatation	1 (0-2)	

Abbreviation: CI, confidence interval.

*The probability of subsequent interventions for achalasia was estimated using logistic regression models with adjustment for age, sex, and comorbidity using mean values for the covariates. Probabilities do not account for censored observations; therefore, values for the overall probability of subsequent treatment are lower than the cumulative probability of subsequent treatment.

†Hazard ratios represent the risk of subsequent interventions for persons treated initially with pneumatic dilatation compared with surgical myotomy and were estimated using Cox proportional hazards models with adjustment for age, sex, comorbidity, and income in neighborhood of residence.

Four hundred eighteen persons (28.6%) were aged 65 years or older at the time of the initial intervention and were included in analyses of antireflux and prokinetic medication use after initial treatment. Most filled at least 1 prescription for antireflux or prokinetic medications during follow-up. There was no statistical difference between treatment groups with respect to the time to first use of histamine-2 receptor blockers, proton pump inhibitors, or prokinetic medications (TABLE 4). We studied use of antireflux medications in the group of patients who had surgical myotomy to determine whether use of an antireflux procedure at the time of surgical myotomy affected the risk of subsequent use of medications related to gastroesophageal reflux. Fourteen (46.7%) of 30 patients who had a fundoplication at the time of the initial surgical myotomy subsequently used antireflux medications in the follow-up period compared with 13 (41.9%) of 31 who did not have a fundoplication ($P = .71$).

A pneumatic dilatation occurring after an earlier treatment episode may be done in the context of a "graded" approach, using a progressively larger balloon size to improve symptoms that persist following dilatation with a smaller balloon. These dilatations may be considered additional planned treatments rather than failure of initial therapy and usually occur within a short time after initial treatment. Among persons treated initially with pneumatic dilatation, 7.0% had a subsequent dilatation within 1 month and 16.5% had a subsequent dilatation within 3 months.

In the final 2 years of the study, surgical myotomy was used as initial treatment in more than 25% of cases, whereas in the years before 2001, it was used in 14% to 19% of cases. The test for linear trend was not statistically significant ($P = .15$).

COMMENT

There are a variety of treatment options for achalasia. However, response to medications is poor,^{5,12} and

Table 4. Relative Risk of Use of Antireflux and Prokinetic Medications After Treatment for Achalasia

Medications	Hazard Ratio (95% Confidence Interval)*	
	Unadjusted	Adjusted†
Histamine-2 receptor blockers‡	1.16 (0.77-1.74)	1.19 (0.79-1.80)
Proton pump inhibitors§	1.03 (0.71-1.50)	1.02 (0.70-1.49)
Prokinetic agents	0.98 (0.64-1.49)	0.92 (0.60-1.41)

*Hazard ratios represent the risk of first use of a medication class among persons treated initially with pneumatic dilatation compared with surgical myotomy and were estimated using Cox proportional hazards models.

†Adjusted for age, sex, comorbidity, and income in neighborhood of residence.

‡Histamine-2 receptor blockers include cimetidine, famotidine, nizatidine, and ranitidine.

§Proton pump inhibitors include esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole.

||Prokinetic agents include cisapride, domperidone, and metoclopramide.

the effect of intrasphincteric botulinum toxin injection is transient¹³ and substantially worse than both surgery¹⁴ and pneumatic dilatation.¹⁴⁻¹⁷ Therefore, in patients with achalasia who are in good general health, the principal therapeutic decision is between pneumatic dilatation and surgical myotomy.

In this population-based study of persons with achalasia in Ontario, we found that many patients require subsequent interventions after either pneumatic dilatation or surgical myotomy. However, less than 40% of patients treated initially with surgical myotomy received subsequent interventions compared with more than 60% of patients treated initially with pneumatic dilatation. Although most of our findings are consistent with the body of literature regarding the effectiveness of pneumatic dilatation and surgical myotomy for achalasia,¹⁷⁻²² the risk of subsequent interventions following surgical myotomy was much higher than the current literature suggests. Our study had several unique advantages compared with other reports of the outcomes of achalasia therapy. We were able to conduct a longitudinal analysis of a large number of patients with a rare disease. Our large sample of population-based data allows a more precise estimate of the long-term likelihood of retreatment than do previously published studies and provides estimates of the outcomes of different treatments by clinicians in typical care settings.

In deciding whether to treat a patient with pneumatic dilatation vs surgical myotomy, there are a variety of

considerations, including the risks of the 2 procedures, their relative effectiveness in improving the symptoms of achalasia, and the risk of treatment consequences such as gastroesophageal reflux. Pneumatic dilatation is performed under conscious sedation and does not require a general anesthetic, and a single treatment may suffice. However, there is a risk of esophageal perforation of 1% to 5%, requiring emergency surgery in more than 50% of cases in which perforation does occur.^{23,24} Although clinical improvement in symptoms occurs in 80% to 90% of patients, long-term follow-up studies suggest that symptoms requiring additional treatment recur in more than 60% of patients.¹⁸ Surgical (Heller) myotomy²⁵ results in clinical improvement in 88% to 97% of patients.^{13,26-28} Laparoscopic surgery for achalasia²⁹ can now be successfully accomplished in virtually all patients, with a short hospital stay and a convalescence period of 1 to 2 weeks,^{30,31} and does not appear to be less effective than conventional surgery when performed by experienced surgeons.^{32,33}

In our study, we considered a subsequent pneumatic dilatation to represent an adverse outcome regardless of whether the initial treatment was pneumatic dilatation or surgery. Others have examined the outcomes of "graded" pneumatic dilatation, wherein only crossover to surgery, persistence of severe symptoms,³⁴ or more than 3 dilatations during follow-up are considered failure of pneumatic dilatation. In our study, we sought to provide a description of the expected outcomes of

a typical instance of treatment by either pneumatic dilatation or surgical myotomy and were unable to determine the specific indication for treatment. Less than 14% of those treated initially by pneumatic dilatation had more than 3 dilatations during the study period, suggesting that dilatation “fails” in very few patients when a graduated approach of up to 3 dilatations is not considered to represent failure. However, only a small proportion of subsequent dilatations occurred within 3 months of the initial dilatation, suggesting that late recurrence of symptoms rather than planned early reintervention is responsible for most pneumatic dilatations occurring during follow-up.

We were interested in measuring the risk of chronic gastroesophageal reflux after treatment of achalasia by surgical myotomy or pneumatic dilatation. Gastroesophageal reflux may occur after both pneumatic dilatation³⁵ and surgical myotomy^{31,36} and has historically been a major long-term problem after treatment of achalasia, necessitating esophagectomy in patients who developed severe gastroesophageal reflux in the era before widespread use of proton pump inhibitors and histamine-2 receptor blockers.³⁷ We did not identify any differences in the use of antireflux or prokinetic medications between patients treated by pneumatic dilatation or surgical myotomy. Use of medications is not likely a reliable measure of gastroesophageal reflux since many patients take medications in the absence of documented acid reflux and others with reflux are asymptomatic and do not take antireflux medications.

We did not find a difference in the pattern of antireflux medication use between patients who had an antireflux procedure as part of a surgical myotomy and patients who did not. However, there were few persons who were aged 65 years or older at the time of surgery, in whom we could study postoperative medication use. A recent clinical trial demonstrating a 90% reduction in the risk of gastroesophageal reflux after a surgical myotomy with the ad-

dition of an antireflux procedure³⁸ has reduced the degree of controversy about its routine use in achalasia surgery.³⁹

We did not find a difference in subsequent health resource use, as measured by the number of physician visits, between pneumatic dilatation and surgical myotomy. We were unable to measure specific complications of the procedures. *International Classification of Diseases* codes for complications (E-codes) are insensitive for the detection of procedure-related complications, and we were unable to develop a valid algorithm for ascertainment of esophageal perforation using diagnosis and procedure codes. As expected, we found that the median length of stay was much shorter for pneumatic dilatation than for surgical myotomy.

While the broader use of laparoscopic surgery has increased the rate of some surgical procedures, we did not identify a large increase in the rate of surgical myotomy over the study period, except for a modest increase in the use of surgical myotomy during the final 2 years of the study. Therefore, secular changes in the use of surgical myotomy during the study period are unlikely to have affected our results.

Our study has several limitations. First, it is possible that the observed differences in outcomes of pneumatic dilatation and surgical myotomy in our observational study were due in part to selection bias. Although those treated with pneumatic dilatation were older, on average, than those treated with surgery, age was not an independent determinant of use of subsequent procedures. We used regression models to adjust for measured confounders. The majority of patients in our study were treated initially with pneumatic dilatation, reflecting a bias toward use of dilatation in Ontario during the period we studied. It is not clear in which direction this selection bias would influence the results, since it is not known which treatment would be offered preferentially to patients with a worse expected outcome.

Our use of administrative health data did not allow us to measure symp-

toms, function, or quality of life, arguably the most important outcomes for achalasia treatment. It is possible that patients who did not receive subsequent treatment still had severe disability. Clinical information in administrative health databases varies in quality. However, a diagnosis code for achalasia is probably highly specific, especially when linked to a procedure such as pneumatic dilatation or myotomy. We do not believe that many cases of achalasia were missed, since we would expect to see a similar number of new cases of achalasia as was found in our study, given the incidence of the disease and the population of Ontario (12 million). To improve the accuracy of outcome ascertainment, we relied primarily on the occurrence of procedures, which are coded more accurately than diagnoses in the administrative data sets we used.¹⁰

Because we were unable to link records reliably prior to 1991, we were not able to develop an incident cohort of patients with achalasia who had not been previously treated. However, developing an incident cohort for this disease using administrative health data is problematic. The “look-back” window for prior treatments should be very long, since persons may receive subsequent interventions many years after a previous intervention. Ensuring that no treatments were provided in the previous 1 or 2 years would not identify with certainty patients who had not previously undergone surgery or pneumatic dilatation for achalasia. To the extent that treatment outcomes are better for subsequent pneumatic dilatations than for first pneumatic dilatations,³⁴ our results probably overestimate the effectiveness of a first episode of pneumatic dilatation in terms of the need for subsequent treatment. By studying persons who had an intervention during a specified time interval, our study design was biased in favor of including patients with greater intensity of treatment, which might result in an overestimate of the risk of subsequent treatment.

Finally, we were not able to distinguish reliably between open and lap-

aroscopic procedures for surgical myotomy. However, open and laparoscopic surgeries for achalasia are equivalent with respect to treatment outcomes when performed by surgeons who are skilled in these procedures.³²

In conclusion, subsequent interventions for the treatment of achalasia are common among persons treated with either pneumatic dilatation or surgical myotomy, although the risk of subsequent interventions is substantially lower among those treated with surgical myotomy. Persons with achalasia should be aware of the long-term effectiveness of pneumatic dilatation and surgical myotomy in average practice settings. Considerations affecting the treatment choice should include

patients' attitudes toward surgical procedures and the desire to avoid subsequent interventions. A randomized clinical trial comparing pneumatic dilatation and surgical myotomy with respect to achalasia symptoms, esophageal function, and health-related quality of life is necessary to determine whether one procedure is superior to the other.

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Study concept and design: Lopushinsky, Urbach.

Analysis and interpretation of data: Lopushinsky, Urbach.

Drafting of the manuscript: Lopushinsky, Urbach.

Critical revision of the manuscript for important intellectual content: Lopushinsky, Urbach.

Statistical analysis: Lopushinsky, Urbach.

Obtained funding: Lopushinsky, Urbach.

Administrative, technical, or material support: Urbach. **Study supervision:** Urbach.

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REFERENCES

- Podas T, Eaden J, Mayberry M, Mayberry J. Achalasia: a critical review of epidemiological studies. *Am J Gastroenterol*. 1998;93:2345-2347.
- Ben Meir A, Urbach DR, Khajanchee YS, Hansen PD, Swanson LL. Quality of life before and after laparoscopic Heller myotomy for achalasia. *Am J Surg*. 2001;181:471-474.
- Achkar E. Achalasia. *Gastroenterologist*. 1995;3:273-288.
- Mearin F, Mourelle M, Guarner F, Papo M, Balboa A. Patients with achalasia lack nitric oxide synthase in the gastro-oesophageal junction. *Eur J Clin Invest*. 1993;23:724-728.
- Spieß AE, Kahrilas PJ, Spieß AE, Kahrilas PJ. Treating achalasia: from whalebone to laparoscope. *JAMA*. 1998;280:638-642.
- Abid S, Champion G, Richter JE, McElvein R, Slaughter RL, Koehler RE. Treatment of achalasia: the best of both worlds. *Am J Gastroenterol*. 1994;89:979-985.
- Richter JE. Surgery or pneumatic dilatation for achalasia: a head-to-head comparison: now are all the questions answered? *Gastroenterology*. 1991;97:1340-1341.
- Patient Care Committee Society for Surgery of the Alimentary Tract. Esophageal achalasia: SSAT patient care guidelines. *J Gastrointest Surg*. 2004;8:367-368.
- Csendes A, Braghetto I, Henríquez A, et al. Late results of a prospective randomised study comparing forceful dilatation and oesophagomyotomy in patients with achalasia. *Gut*. 1989;30:299-304.
- Williams J, Young W. A summary of studies on the quality of health care administrative databases in Canada. In: *Patterns of Health Care in Ontario*. 2nd ed. Ottawa, Ontario: Canadian Medical Association; 1996.
- Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. *J Clin Epidemiol*. 1992;45:613-619.
- Traube M, Hongo M, Magyar L, McCallum RW. Effects of nifedipine in achalasia and in patients with high-amplitude peristaltic esophageal contractions. *JAMA*. 1984;252:1733-1736.
- Zaninotto G, Annesse V, Costantini M, et al. Randomized controlled trial of botulinum toxin versus laparoscopic Heller myotomy for esophageal achalasia. *Ann Surg*. 2004;239:364-370.
- Bansal R, Nostrant TT, Scheiman JM, et al. Intrasphincteric botulinum toxin versus pneumatic balloon dilation for treatment of primary achalasia. *J Clin Gastroenterol*. 2003;36:209-214.
- Vaezi MF, Richter JE, Wilcox CM, et al. Botulinum toxin versus pneumatic dilatation in the treatment of achalasia: a randomised trial. *Gut*. 1999;44:231-239.
- Ghoshal UC, Chaudhuri S, Pal BB, Dhar K, Ray G, Banerjee PK. Randomized controlled trial of intrasphincteric botulinum toxin A injection versus balloon dilatation in treatment of achalasia cardia. *Dis Esophagus*. 2001;14:227-231.
- Mikaeli J, Fazel A, Montazeri G, Yaghoobi M, Malekzadeh R. Randomized controlled trial comparing botulinum toxin injection to pneumatic dilatation for the treatment of achalasia. *Aliment Pharmacol Ther*. 2001;15:1389-1396.
- Karamanolis G, Sgouros S, Karatzias G, et al. Long-term outcome of pneumatic dilation in the treatment of achalasia. *Am J Gastroenterol*. 2005;100:270-274.
- Eckardt VF, Gockel I, Bernhard G. Pneumatic dilatation for achalasia: late results of a prospective follow up investigation. *Gut*. 2004;53:629-633.
- Mineo TC, Ambrogio V, Mineo TC, Ambrogio V. Long-term results and quality of life after surgery for oesophageal achalasia: one surgeon's experience. *Eur J Cardiothorac Surg*. 2004;25:1089-1096.
- Vela MF, Richter JE, Wachsberger D, Connor J, Rice TW. Complexities of managing achalasia at a tertiary referral center: use of pneumatic dilatation, Heller myotomy, and botulinum toxin injection. *Am J Gastroenterol*. 2004;99:1029-1036.
- Bonatti H, Hinder RA, Klocker J, et al. Long-term results of laparoscopic Heller myotomy with partial fundoplication for the treatment of achalasia. *Am J Surg*. 2005;190:874-878.
- Panaccione R, Gregor JC, Reynolds RP, et al. Intrasphincteric botulinum toxin versus pneumatic dilatation for achalasia: a cost minimization analysis. *Gastrointest Endosc*. 1999;50:492-498.
- Katz P. Two effective treatment options—let the patient decide. *Am J Gastroenterol*. 1994;89:969-970.
- Payne WS. Heller's contribution to the surgical treatment of achalasia of the esophagus. *Ann Thorac Surg*. 1989;48:876-881.
- Frantzides CT, Moore RE, Carlson MA, et al. Minimally invasive surgery for achalasia: a 10-year experience. *J Gastrointest Surg*. 2004;8:18-23.
- Rosemurgy A, Villadolid D, Thometz D, et al. Laparoscopic Heller myotomy provides durable relief from achalasia and salvages failures after botox or dilation. *Ann Surg*. 2005;241:725-733.
- Fernandez AF, Martinez MA, Ruiz J, et al. Six years of experience in laparoscopic surgery of esophageal achalasia. *Surg Endosc*. 2003;17:153-156.
- Shimi S, Nathanson LK, Cuschieri A. Laparoscopic cardiomyotomy for achalasia. *J R Coll Surg Edinb*. 1991;36:152-154.
- Ramacciato G, Mercantini P, Amodio PM, et al. The laparoscopic approach with antireflux surgery is superior to the thoracoscopic approach for the treatment of esophageal achalasia: experience of a single surgical unit. *Surg Endosc*. 2002;16:1431-1437.
- Swanson LL, Penning J. Laparoscopic esophagomyotomy for achalasia. *Surg Endosc*. 1995;9:286-290.
- Bloomston M, Serafini F, Boyce HW, et al. The "learning curve" in videoscopic Heller myotomy. *JSL*. 2002;6:41-47.
- Patti MG, Fisicella PM, Perretta S, et al. Impact of minimally invasive surgery on the treatment of esophageal achalasia: a decade of change. *J Am Coll Surg*. 2003;196:698-703.
- Vela MF, Richter JE, Khandwala F, et al. The long-term efficacy of pneumatic dilatation and Heller myotomy for the treatment of achalasia. *Clin Gastroenterol Hepatol*. 2006;4:580-587.
- Shoenut JP, Duerksen D, Yaffe CS, Shoenut JP, Duerksen D, Yaffe CS. A prospective assessment of gastroesophageal reflux before and after treatment of achalasia patients: pneumatic dilation versus transthoracic limited myotomy. *Am J Gastroenterol*. 1997;92:1109-1112.
- Jara FM, Toledo-Pereyra LH, Lewis JW, et al. Long-term results of esophagomyotomy for achalasia of esophagus. *Arch Surg*. 1979;114:935-936.
- Malthaner EA, Tood TR, Miller L, et al. Long-term results in surgically managed esophageal achalasia. *Ann Thorac Surg*. 1994;58:1343-1346.
- Richards WO, Torquati A, Holzman MD, et al. Heller myotomy versus Heller myotomy with Dor fundoplication for achalasia: a prospective randomized double-blind clinical trial. *Ann Surg*. 2004;240:405-412.
- Lyass S, Thoman D, Steiner JP, Phillips E. Current status of an antireflux procedure in laparoscopic Heller myotomy. *Surg Endosc*. 2003;17:554-558.