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The incidence of reintervention and reoperation following Heller myotomy across multiple indications

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Abstract

Introduction Achalasia is a debilitating primary esophageal motility disorder. Heller myotomy (HM) is a first-line therapy for the treatment of achalasia patients who have failed other modalities. Other indications for HM include diverticulum, diffuse esophageal spasm, and esophageal strictures. However, long-term outcomes of HM are unclear. This study aims to assess incidence of reintervention, either endoscopically or through minimally invasive or resectional procedures, in patients who underwent HM in New York State.

Methods The Statewide Planning and Research Cooperative System (SPARCS) administrative longitudinal database identified 1817 adult patients who underwent HM between 2000 and 2008 for achalasia, esophageal diverticulum, diffuse esophageal spasm, and esophageal strictures, based on ICD-9 and CPT codes. Through the use of unique identifiers, patients requiring reintervention were tracked up to 2016 (for at least 8 years follow-up). Primary outcome was incidence of subsequent procedures following HM. Secondary outcomes were time to reintervention and risk factors for reintervention.

Results Of the 1817 patients who underwent HM, 320 (17.6%) required subsequent intervention. Of the 320 patients, 234 (73.1%) underwent endoscopic reinterventions, 54 (16.9%) underwent minimally invasive procedures, and 32 (10%) underwent resectional procedures as their initial revisional intervention. Of the 234 patients who underwent endoscopic reintervention as their initial revisional procedure, only 40 (16.8%) required subsequent surgical procedures. Over a mean follow-up of 7.0 years, the mean time to a subsequent procedure was 4.3 ± 3.74 years. Reintervention rates after 10 years following HM for achalasia, diverticulum ,and other indication were 24.4%, 12.6%, and 37%, respectively.

Conclusion The majority of HM reinterventions were managed solely by endoscopic procedures (60.6%). Heller myotomy remains an excellent procedure to prevent surgical reintervention for achalasia and diverticulum.

Keywords Achalasia · Long-term reintervention rates · Heller myotomy · Esophageal diverticulum

Achalasia is a rare (incidence 1.6/100,000) esophageal motility disorder that is progressive and incurable [1]. Treatment focuses on symptom palliation and include pharmacological, endoscopic, and surgical interventions. Endoscopic options include botulinum toxin injection, pneumatic dilatation, and peroral endoscopic myotomy (POEM) [2]. Botulinum toxin injections have been shown to be effective, but the effect diminishes at 6 months [3]. POEM is a relatively newer

endoscopic treatment modality, and short-term outcomes have shown it to be very effective [4]. Clinical guidelines from the American College of Gastroenterology recommend pneumatic dilatation or Heller myotomy (HM) as first-line therapy in patients with low surgical risk [5]. One systematic review concluded that HM provided better symptomatic relief when compared to endoscopic modalities [6]. Symptomatic improvement has been shown in 89% of patients at 3-year follow-up, and 75% at 15-year follow-up [6, 7].

Despite the established efficacy of HM, data demonstrating the long-term efficacy and reintervention after HM are limited. At a single institution, 20% of 248 patients required subsequent interventions after HM at a median follow-up of 3 years [8]. One population-based study of employed Americans demonstrated that 9.5% of 871 patients required

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a reintervention in the first year after HM [9]. Furthermore, HM has been extended to treat other conditions including diffuse esophageal spasm, esophageal diverticulum, and esophageal stricture [10–14]. However, there is a paucity of multi-institutional, long-term data demonstrating the long-term efficacy of HM for non-achalasia disorders.

The purpose of this study is to evaluate the incidence of reintervention and reoperation after HM for different indications in New York State over a 15-year period. In addition, we sought to identify risk factors for reinterventions and reoperations.

Methods

The New York Statewide Planning and Research Cooperative System (SPARCS) administrative database was used to identify patients who underwent HM between January 1, 2000 and December 31, 2008. SPARCS is a longitudinal, all payer data reporting system that documents patient-level detail including demographics, diagnoses, and treatments for every hospital or surgery center encounter in the state of New York [15]. Each patient is assigned a unique identifier and can be followed across time and institution. Through the use of ICD-9 and CPT diagnostic and procedural codes, all patient undergoing HM for specific diagnostic codes were extracted. The extracted records were stratified by indication for procedure (achalasia, diverticulum and other) through primary diagnosis codes (530.0, 530.6, and 530.3, 530.5, 553.3). Patients were tracked for a minimum of 8 years (2000–2016) post procedure to assess for reintervention or reoperation. Reintervention and reoperation were categorized as endoscopic (pneumatic dilation, botox injections), minimally invasive (reoperative myotomy, fundoplication, hiatal hernia repair), and resectional (esophagogastrostomy, esophagoenterostomy, esophagocolostomy, esophagogastrectomy, esophagectomy). Exclusion criteria included: age < 8, missing identifiers, duplicated records, and patients who underwent HM with a primary diagnosis other than achalasia, diverticulum, esophageal dyskinesia/spasm, esophageal stenosis, and hiatal and paraesophageal hernia. The study was reviewed by the Institutional Review Board and deemed exempt. The need for written informed consent was exempt.

Patient demographics, indication for HM, comorbidities, and complications at the primary procedure were identified as potential risk factors for reintervention or reoperation. Indication for HM is defined as the primary diagnosis coded for the hospital record encounter for the index procedure. Frequency of reinterventions or reoperation was stratified by indication for HM. Primary outcome was incidence of subsequent esophageal procedures following HM. Secondary outcomes were time to reintervention and risk factors for reintervention.

Chi-square tests with exact P-values based on Monte Carlo simulation were utilized to examine the marginal association between categorical variables and patients' indication for HM (achalasia vs diverticulum vs other), as well as between types of reintervention/reoperation. Wilcoxon rank sum tests (for variables with 2 levels) and Kruskal–Wallis tests (for variables with > = 3 levels) were used to compare unadjusted marginal differences in follow-up time among different primary diagnosis groups, as well as the difference in time to reinterventions by reintervention types and patients' primary diagnosis. Cumulative incidences of reinterventions/reoperation (any type of reintervention, endoscopic procedure, minimally invasive procedure, resectional procedure) at a specific time point with death as a competing risk event were estimated using *cuminc()* function, *cmprsk* package in R. Univariate proportional sub-distribution hazards models (Fine-Gray models) were utilized to examine the marginal association between categorical variables and the incidence of reinterventions/reoperation. Indication for HM and other factors related to each outcome that were significant (p-value < 0.05) based on univariate analysis were further considered in multivariable Fine-Gray models. Forward selection was implemented based on p-values in the analysis of the risk for resectional procedure because of low number of patients with such outcomes[16]. In Fine-Gray models, a hazards ratio (HR) > 1 indicated higher risk to have reintervention, while an HR < 1 indicated lower risk. Statistical analysis was performed using SAS 9.4 (SAS Institute Inc., Cary, NC) and significance level was set at 0.05.

Results

A total of 1817 patients underwent HM between 2000 and 2008. Of these, the primary indication for HM was achalasia in 1549 (85.25%) patients, diverticulum in 213 (11.72%) patients, and others in 53 (3.03%) patients. Patient demographics, comorbidities, clinical information, and 30-day complications stratified by indication for HM are shown in Table 1. Patients who underwent HM for diverticulum had the highest median age than those who underwent HM for achalasia or other indications (73 vs 49 vs 64, $p < 0.0001$). Other significant differences amongst the three groups were insurance type, geographic region in NYS where the surgery was performed and average length of hospital stay. Patients who underwent HM for diverticulum or other conditions were more likely to have comorbidities as compared to achalasia (72.3% vs 61.81% vs 47.06%, $p < 0.001$). Furthermore, patients who underwent HM for diverticulum or other conditions were more likely to have complications as compared to achalasia (20.19% vs 23.64% vs 11.88%, $p < 0.0001$).

Table 1 Descriptive table of patients' baseline demographics, clinical information, comorbidities, and 30-day complications by indication for Heller myotomy

Variable	Total ($N=1817$)	Achalasia ($N=1549$)	Diverticulum ($N=213$)	Other ($N=55$)	P-value*
Patients' demographic					
Age	52.00±28.00	49.00±25.00	73.00±20.00	64.00±25.00	<.0001
Gender (% Female)	881 (48.49%)	742 (47.90%)	109 (51.17%)	30 (54.55%)	0.4413
Race or ethnicity					
Asian, non-Hispanic	31 (1.71%)	28 (1.81%)	2 (0.94%)	1 (1.82%)	0.2089
Black, non-Hispanic	223 (12.27%)	198 (12.78%)	18 (8.45%)	7 (12.73%)	
Hispanic	157 (8.64%)	143 (9.23%)	11 (5.16%)	3 (5.45%)	
Other	247 (13.59%)	211 (13.62%)	28 (13.15%)	8 (14.55%)	
White, non-Hispanic	1159 (63.79%)	969 (62.56%)	154 (72.30%)	36 (65.45%)	
Region in NY					
West	230 (12.66%)	170 (10.97%)	44 (20.66%)	16 (29.09%)	<.0001
North and Mid	260 (14.31%)	212 (13.69%)	38 (17.84%)	10 (18.18%)	
Close to NYC	116 (6.38%)	91 (5.87%)	18 (8.45%)	7 (12.73%)	
NYC	941 (51.79%)	829 (53.52%)	92 (43.19%)	20 (36.36%)	
Long Island	270 (14.86%)	247 (15.95%)	21 (9.86%)	2 (3.64%)	
Insurance					
Commercial	1247 (68.63%)	1128 (72.82%)	92 (43.19%)	27 (49.09%)	<.0001
Medicaid	115 (6.33%)	104 (6.71%)	9 (4.23%)	2 (3.64%)	
Medicare	408 (22.45%)	274 (17.69%)	108 (50.70%)	26 (47.27%)	
Other or unknown	47 (2.59%)	43 (2.78%)	4 (1.88%)	0 (0.00%)	
Clinical information					
Length of stay	2.00±3.00	2.00±3.00	5.00±5.00	5.00±7.00	<.0001
Comorbidities					
Any comorbidity	917 (50.47%)	729 (47.06%)	154 (72.30%)	34 (61.82%)	<.0001
Congestive heart failure	19 (1.05%)	11 (0.71%)	8 (3.76%)	0 (0.00%)	0.0029
Valvular disease	76 (4.18%)	53 (3.42%)	22 (10.33%)	1 (1.82%)	0.0001
Chronic pulmonary disease	193 (10.62%)	142 (9.17%)	35 (16.43%)	16 (29.09%)	<.0001
Hypothyroidism	126 (6.93%)	99 (6.39%)	26 (12.21%)	1 (1.82%)	0.0037
Fluid and electrolyte disorder	119 (6.55%)	89 (5.75%)	22 (10.33%)	8 (14.55%)	0.0021
Depression	59 (3.25%)	46 (2.97%)	13 (6.10%)	0 (0.00%)	0.0224
Hypertension	501 (27.57%)	390 (25.18%)	92 (43.19%)	19 (34.55%)	<.0001
Complications					
Any complication	240 (13.21%)	184 (11.88%)	43 (20.19%)	13 (23.64%)	0.0002
Atelectasis	31 (1.71%)	19 (1.23%)	10 (4.69%)	2 (3.64%)	0.0035
Intestinal Complication	10 (0.55%)	6 (0.39%)	2 (0.94%)	2 (3.64%)	0.0136
Pneumonia	71 (3.91%)	47 (3.03%)	19 (8.92%)	5 (9.09%)	<.0001
Intestinal complication	33 (1.82%)	20 (1.29%)	12 (5.63%)	1 (1.82%)	0.0006
SIRS	3 (0.17%)	0 (0.00%)	2 (0.94%)	1 (1.82%)	0.0045

For continuous variable, median±IQR were reported

*For categorical variables, p-values were based on Chi-square test with exact p-value from Monte Carlo simulation; for continuous variable, p-value was based on Wilcoxon rank sum test

Among the 1817 HM patients, 320 (17.6%) required a subsequent intervention. Of those requiring a subsequent intervention, 279 (87.19%) were achalasia patients, 22 (6.87%) were diverticulum patients, and 19 (5.94%) were other patients.

In the achalasia reintervention cohort ($N=279$), 207 (74.2%) underwent endoscopic reintervention, 45 (16.1%) underwent minimally invasive procedures, and 27 (9.7%) underwent resectional procedures as their initial revisional intervention. Of the 207 patients who underwent endoscopic

reintervention as their initial revisional procedure, 170 (81.3%) were managed solely by endoscopic interventions and 37 (17.7%) required subsequent surgical (minimally invasive or resectional) procedures. In the diverticulum reintervention cohort ($N = 22$), 14 (63.6%) underwent endoscopic reintervention, 5 (22.7%) underwent minimally invasive procedures and 3 (13.6%) underwent resectional procedures as their initial revisional intervention. In the other indications reintervention cohort ($N = 19$), 13 (68.4%) underwent endoscopic reinterventions, 4 (21.1%) underwent minimally invasive procedures, and 2 (10.5%) underwent resectional procedures as their initial revisional intervention. This is shown in Table 2. Overall, 194 of the 320 patients (60.6%) who required reinterventions after HM, underwent endoscopic therapies alone.

Over a mean follow-up of 7.0 years (range 0 to 16.9 years), the average time to any reintervention or reoperation was longest in the achalasia group compared to diverticulum and others (4.5 years vs 2.9 years vs 3.3 years, $p = 0.0284$). No statistical difference amongst the 3 indications was seen when looking at time to each subgroup of procedure as shown in Table 3.

The cumulative incidence curves for any subsequent procedures among all HM patients stratified by procedure type and indication for HM are shown in Figs. 1 and 2. The reintervention or reoperation rates for achalasia patients at 1 years, 5 years, 10 years, and 15 years are 5.7%, 13.6%, 24.4%, and 31.4%.

Supplemental Table A describes the risk factors associated with having any type of subsequent procedure after adjusting for possible confounding factors. Indication for

Table 2 Number of HM Patients with subsequent procedures by indication for Heller myotomy

| Indication for HM	# Requiring subsequent procedure(s)	Subsequent procedure type (1st)			# of patients solely managed endoscopically	# of patients requiring resectional procedures
		Endoscopic reintervention	Minimally invasive procedures	Resectional procedures		
Achalasia ($n = 1549$)	279 (18.0%)	207 (13.3%)	45 (2.9%)	27 (1.7%)	170 (11.0%)	48 (3.1%)
Esophageal diverticulum ($n = 213$)	22 (10.3%)	14 (6.6%)	5 (2.3%)	3 (1.4%)	11 (5.2%)	4 (1.9%)
Others ($n = 55$)	19 (34.5%)	13 (23.6%)	4 (7.5%)	2 (3.8%)	13 (23.6%)	2 (3.6%)

Table 3 Time interval (days) to subsequent intervention after Heller myotomy

Reintervention	Indication for Heller myotomy	N	Mean	SD	Min	Median	IQR	Max	P-value[*]
Any type of reintervention	Any	320	1573.9	1368.2	1	1222	2234.5	6061	
	Achalasia	279	1639.8	1372.2	1	1351	2245	6061	0.0284
	Diverticulum	22	1053.5	1300.3	2	425	1782	4397	
	Other	19	1208.5	1257.2	3	656	2069	4010	
Minimally invasive procedures	Any	76	1728.6	1553.0	2	1130.5	2478	6061	
	Achalasia	64	1831.8	1580.3	2	1295.5	2490.5	6061	0.2966
	Diverticulum	8	895.3	1052.3	195	453.5	759	3296	
	Other	4	1745.0	1785.1	203	1490	2989	3797	
Resectional procedures	Any	54	1729.6	1553.2	1	1329	2785	4867	
	Achalasia	48	1823.3	1527.2	1	1524.5	2755.5	4867	0.2421
	Diverticulum	4	1268.0	2091.9	95	290	2307	4397	
	Other	2	405.0	568.5	3	405	804	807	
Endoscopic procedures	Any	259	1687.2	1343.0	2	1473	2158	5875	
	Achalasia	225	1742.5	1350.7	14	1611	2180	5875	0.1278
	Diverticulum	18	1510.3	1376.8	2	1435.5	2298	4397	
	Other	16	1108.4	1090.6	3	740.5	1164.5	4010	

*P-values were based on Wilcoxon rank sum test (for variables with 2 levels) and Kruskal–Wallis test (for variables with $> = 3$ levels)
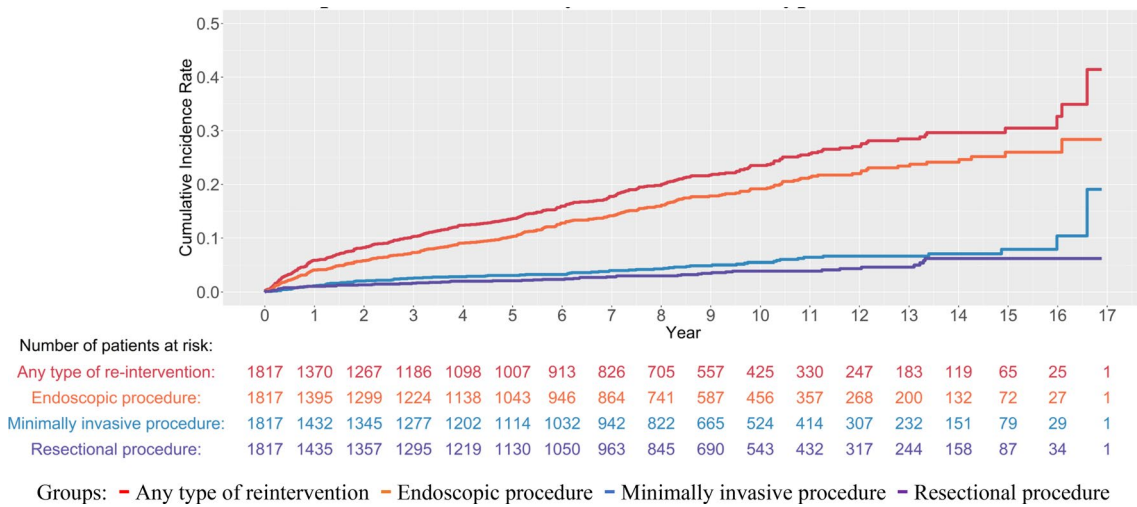
Fig. 1 Cumulative incidence of different reinterventions among Heller myotomy patients stratified by reintervention type. Groups: Any type of reintervention, Endoscopic procedure, Minimally invasive procedure, Resectional procedure
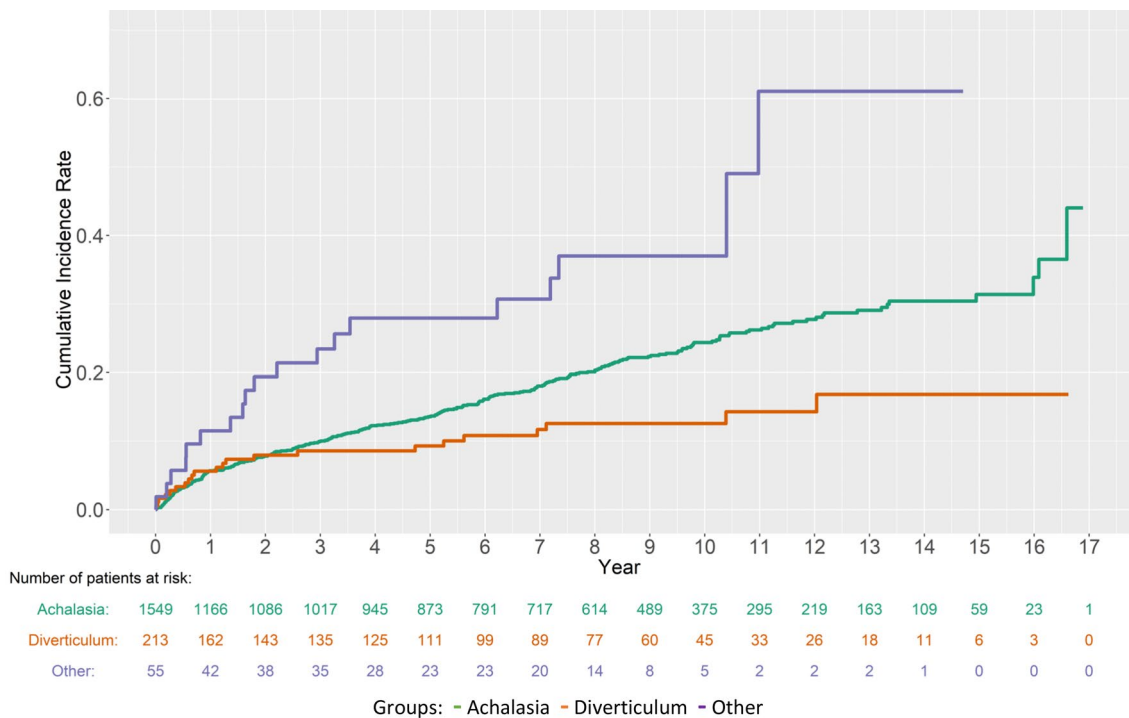
Fig. 2 Cumulative incidence curves for any reintervention by indication for Heller myotomy. Groups: Achalasia, Diverticulum, Other

HM was significantly related to subsequent reintervention ($p = 0.0005$). Patient with diagnosis other than achalasia and diverticulum were more likely to have any subsequent procedure (HR 20.12 95% CI 1.223–3.308), while patients with diverticulum were less likely to have any subsequent procedure (HR 0.538 95% CI 0.343–0.845). There was no statistical significant relationship between hospital volume of Heller myotomy (low volume = ≤ 6 cases, high

volume = > 6 cases annually) and need for subsequent procedure. Patients with comorbidities such as renal failure (HR 2.573 95% CI 1.076–6.156, $p = 0.0337$) and depression (HR 1.739 95% CI 1.044–2.897, $p = 0.0336$) and complications such as abscess formation (HR 25.562 95% CI 3.054–213.962, $p = 0.0028$) and enteritis (HR 5.803 95% CI 4.829–6.974, $p = < 0.001$) were more likely to have subsequent procedures. See Supplemental Table B for risk

factors associated with subsequent endoscopic, minimally invasive, and resectional procedures. (Supplemental Table B).

Discussion

Although HM has long been established as the procedure of choice for treatment of severe achalasia [17], the long-term rates of reintervention and reoperation have been unclear. Previous studies suggest that such rates range from 4.9% to 29.4% [8, 9, 18–20]. However, these studies are specific to achalasia patients over a shorter follow-up period with a smaller cohort. To our knowledge, this is the largest study in identifying rates and risk factors for HM reintervention/reoperation across different interventions. Importantly, because of the population-based approach, the potential for loss to follow-up is limited.

The present study suggests that the 10 year rates of reintervention/reoperation are highest when HM is performed for other indications compared to achalasia and diverticulum (37% vs 24.3% vs 12.6%, respectively). The other indications include esophageal spasms, esophageal strictures, paraesophageal hernia, and hiatal hernia. HM has been used to treat esophagogastric junction outflow obstruction and diffuse esophageal spasms (DES) after failure of medical therapy [10, 21, 22]. Leconte et al. reported failure to improve DES symptoms in 25% of patients following myotomy in a small study with 3 year follow-up.[23]. Myotomy may not be successful in the treatment of DES as it is hypothesized to decrease the intensity of the contractions but not the frequency [21]. Treatment of esophageal stricture with myotomy has only been successful and demonstrated in small case series [13, 14]. All 3 patients in one study [13] and 2 patients in a second study [14] demonstrated success with myotomy with a median follow-up of 10 years and 5 years, respectively.

The results of this study show a lower reintervention or reoperation rate over 15 years for diverticulum patients compared to achalasia patients (16.8% vs 31.4%). However, the baseline demographics and comorbidities are markedly different between the two patient populations. Patients who underwent HM for diverticulum are older (median age 73 vs 49) and more likely to have comorbidities (congestive heart failure, valvular disease, pulmonary disease, hypertension) compared to the achalasia group. Age and comorbidities are independent prognostic factors for postoperative complications and increased risk of mortality following elective surgery [24, 25]. Surgical management of patients is heavily influenced by patient's age and frailty score [26]. In this study, physicians may have advised against subsequent procedures in diverticulum patients. However, the results of our study are consistent with a previous study in which

esophageal diverticulum is a favorable patient characteristic for laparoscopic HM [27].

In prior studies that investigated the timing to reinterventions, patients had the highest risk in the first 12 months after HM [8, 28–31]. One study of 248 patients who underwent HM for achalasia showed reinterventions occurred in 12% and 28% of the patients at 1 year and 5 years, respectively [8]. A vast majority (82%) of their reinterventions were endoscopic. Our study demonstrated lower rates of reintervention at 5.7% and 13.6% at 1 year and 5 years, respectively. The majority of our reinterventions were endoscopic, which is consistent with prior studies [8, 32].

Other studies have identified longer duration of symptoms, male patients and low lower esophageal sphincter pressures preoperatively as risk factors for HM failure [33–35]. We identified comorbidities in renal failure and depression and complications of abscess and enteritis as independent risk factors for any type of reintervention/reoperation. These risk factors can help with patient expectations and optimize postoperative surveillance. Further research is needed to validate these risk factors.

There are several limitations of this study. First, this is a retrospective study using an administrative database. Since this data are extracted from a single state, our findings cannot be generalizable to other geographic areas. Patients who received subsequent procedures at other states are not included in the current analysis. Clinical information is not provided and thus patient history, symptom severity and prior treatments cannot be analyzed. In addition, we are unable to identify technical factors contributing to the need for reintervention. There is the potential of miscoding diagnosis and procedure codes. Furthermore, there are currently no ICD-9, ICD-10 or CPT codes for POEM. We were unable to include POEM as an reintervention, although the number of PEOM procedures performed prior to 2016 is likely limited. We calculated success of HM based on freedom from reintervention or reoperation, rather than symptoms.

Conclusion

HM is an effective treatment for achalasia and esophageal diverticulum with long-term success rates of 68.6% and 83.2% at 15 years. The majority of reinterventions after HM were managed endoscopically (60.6%). Given the rate of reinterventions, it is imperative to set patient's expectations when planning for HM and to maintain long-term surveillance postoperatively.

Compliance with ethical standards

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