

ORIGINAL RESEARCH

Outcomes of laparoscopic Heller myotomy without fundoplication on gastroesophageal reflux disease and dysphagia in type II Achalasia: A prospective study

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Date Received: April 2024

Date Accepted: May 2024

Online Publication: June 15, 2025

Abstract

Objective: Achalasia is an uncommon esophageal motility disorder that significantly impacts quality of life due to dysphagia, chest pain, and other related symptoms. Laparoscopic Heller myotomy (LHM) is a preferred treatment, although the necessity of adding fundoplication to prevent postoperative gastroesophageal reflux disease (GERD) remains debated.

Materials and Methods: This prospective cohort study from January 2023 to March 2024 at Imam Hossein Teaching and Therapeutic Center included 25 patients with type II achalasia. The study assessed the incidence and severity of GERD and dysphagia postoperatively at baseline, 3 months, and 6 months using the Achalasia Patient-Reported Outcomes Questionnaire (APRO), Brief Esophageal Dysphagia Questionnaire (BEDQ), and Gastro-Esophageal Reflux Disease Questionnaire (GERDQ).

Results: Post-surgery, dysphagia scores decreased significantly from 18.96 (SD = 4.02) to 12.11 (SD = 3.88) at 3 months ($p < 0.01$) and to 11.45 (SD = 3.67) at 6 months ($p = 0.64$). GERD scores also significantly reduced from 19.32 (SD = 4.18) to 9.14 (SD = 3.77) at 3 months ($p < 0.05$) and to 4.97 (SD = 2.45) at 6 months ($p = 0.001$).

Conclusion: LHM without fundoplication significantly reduces dysphagia in type II achalasia. Although effective in alleviating this primary symptom, it does not consistently prevent postoperative GERD, highlighting the need for individualized surgical planning.

Keywords: Achalasia, Laparoscopic Heller myotomy, Gastroesophageal reflux disease, Dysphagia, Fundoplication

Introduction

Achalasia is an uncommon esophageal motility disorder characterized by symptoms such as progressive dysphagia, esophageal insufficiency, chest pain, and weight loss, affecting approximately 1 to 3 individuals per 100,000 annually (1). It is definitively diagnosed through esophageal manometry, which reveals esophageal immobility and lower esophageal sphincter (LES) dysfunction (2). Treatment primarily aims to relieve the symptomatic esophageal outlet obstruction. Although pharmacological management is occasionally utilized for patients deemed at high surgical risk—typically those with significant comorbidities or advanced age—its long-term effectiveness remains suboptimal (3). While endoscopic dilation has been validated for safety and efficacy in controlled trials (4-5), laparoscopic Heller myotomy (LHM) is increasingly recognized as superior for most patients, offering effective symptom relief with fewer complications compared to conventional open surgeries (6). The surgical approach, specifically Heller myotomy, seeks to alleviate the distal esophageal obstruction via a laparoscopic method, now considered the gold standard due to its high success rate and reduced complications (7). However, the adjunctive use of fundoplication to prevent gastroesophageal reflux disease (GERD) post-myotomy is debated. Without fundoplication, GERD manifestations have been reported in 47% to 100% of cases, as the procedure eliminates the natural barrier against gastric acid reflux into the esophagus (8-9). Yet, concerns remain about inducing or worsening dysphagia in achalasia patients lacking esophageal peristalsis if fundoplication is performed (10-11). This study specifically evaluates the incidence of reflux and dysphagia in patients undergoing laparoscopic Heller myotomy without concurrent fundoplication, addressing a critical gap in understanding the direct consequences of omitting fundoplication in this cohort. By focusing on these specific postoperative outcomes, the research aims to clarify the role of fundoplication in optimizing surgical results in achalasia treatment.

Materials and Methods

This prospective cohort study was conducted from January 2023 to March 2024, focusing on the incidence of gastroesophageal reflux

disease (GERD) and dysphagia following laparoscopic Heller myotomy without fundoplication among patients diagnosed with type II achalasia. The study was carried out at the Imam Hossein Teaching and Therapeutic Center, with the initiation following ethical approval from the Medical Ethics Committee. Informed consent was obtained from all patients prior to their inclusion in the study.

Participant Recruitment and Sampling

Patients were males and females aged 15 to 65 years, diagnosed with type II achalasia. They were selected through convenience sampling and referred to the medical center for treatment. Eligibility was confirmed through diagnostic tests, including barium swallow, esophageal manometry, and endoscopy. Exclusion criteria included prior thoracic or abdominal surgery, pregnancy, autoimmune diseases, uncontrolled diabetes, or any medical condition contraindicating general anesthesia or laparoscopic surgery. The sample size comprised 25 patients, calculated to achieve statistical power based on the formula derived from Elyasinia et al.'s studies [12].

Outcome Measures

Primary Outcomes: Assessed the incidence and severity of dysphagia at 3- and 6-months post-surgery. **Secondary Outcomes:** Included the severity of symptoms related to achalasia and GERD, measured using validated patient-reported outcome measures (PROMs):

Achalasia Patient-Reported Outcomes Questionnaire (APRO): This 11-item scale evaluates the severity of achalasia symptoms. Items are scored from 0 (no symptoms) to 5 (severe daily symptoms), assessing symptoms like dysphagia, chest pain, and regurgitation [13]. **Brief Esophageal Dysphagia Questionnaire (BEDQ):** A 10-item scale that quantifies swallowing difficulty over the past 30 days. It assesses the frequency and difficulty of swallowing different food textures. Scores range from 0 (no difficulty) to 40 (severe difficulty), with higher scores indicating worse dysphagia [14]. **Gastro-Esophageal Reflux Disease Questionnaire (GERDQ):** Measures the frequency and severity of GERD symptoms through a 6-item scale, scoring from 0 (no symptoms) to 5 (severe symptoms) [15].

Data Collection Timeline

Questionnaires were completed by patients before the surgery to establish baseline symptom severity, and again at 3- and 6-months

post-operation to monitor changes in symptoms and assess surgical outcomes. Endoscopic evaluations were conducted at these time points to provide objective measures of the anatomical and functional results of the surgery.

Postoperative Care

Following surgery, all patients were administered proton pump inhibitors for a period of three months to manage and mitigate potential gastroesophageal reflux symptoms. This postoperative care protocol aims to reduce the incidence of postoperative GERD, a common complication associated with this type of surgery.

Statistical Analysis

This study employed paired t-tests to analyze changes in symptoms of achalasia, as measured by the Achalasia Patient-Reported Outcomes Questionnaire (APRO), the Brief Esophageal Dysphagia Questionnaire (BEDQ), and the Gastro-Esophageal Reflux Disease Questionnaire (GERDQ), following laparoscopic Heller myotomy without fundoplication. Data normality was confirmed via Shapiro-Wilk tests, supporting the use of parametric tests for preoperative and postoperative comparisons at 3- and 6-month intervals. Effect sizes were calculated using Cohen's *d*, with values greater than 0.8 indicating large effects, about 0.5 indicating medium effects, and below 0.2 small effects. Significance was assessed at a two-tailed *p*-value of less than 0.05, and adjustments for multiple comparisons were made using Bonferroni correction to mitigate the risk of type I errors. Statistical analyses were performed using SPSS Version 26, ensuring rigorous data handling. In cases of missing data, an analysis was conducted to determine patterns of missingness, and incomplete datasets were excluded from the analysis to maintain the integrity and robustness of the results. This approach ensured that conclusions drawn from the study were based on complete and reliable data only. Detailed outcomes are summarized in Tables 2, 3, and 4, presenting the means, standard deviations, t-test results, *p*-values, and Cohen's *d*.

Results

Demographic and Clinical Characteristics of Patients. This study evaluated 25 patients

diagnosed with Type II Achalasia, comprising 15 males (60%) and 10 females (40%). The mean age of patients was 36.94 ± 5.50 years, with a mean Body Mass Index (BMI) of 24.3 ± 4.2 kg/m². These patients reported an average weight loss of 5.8 ± 7.5 kg over an average disease duration of 6.22 ± 1.20 years. Esophageal dilation, assessed by Barium swallow studies, showed that 50.9% (13/25) of the patients had Grade I dilation (<4 cm). Regarding medical therapies, 52% (13/25) were on proton pump inhibitors, 28% (7/25) used calcium channel blockers or nitrates, and 64% (16/25) took NSAIDs. Symptoms included dysphagia (100%), regurgitation (85.6%), chest pain (54.2%), cough (41.5%), and heartburn (26.3%). Additionally, esophagitis and hiatal hernia were observed in 12.7% (3/25) and 10.2% (3/25) of the patients, respectively. The average LES pressure, measured via manometry, was 37 ± 16.1 mm Hg. Table 1 provides a detailed breakdown of demographic and clinical characteristics by gender.

Characteristics	Total (n=25)	Male (n=15)	Female (n=10)
Age (years), mean $\pm$ SD	36.94 $\pm$ 5.50	38.00 $\pm$ 4.50	35.40 $\pm$ 6.00
BMI (kg/m ²), mean $\pm$ SD	24.3 $\pm$ 4.2	24.0 $\pm$ 4.0	24.7 $\pm$ 4.4
Weight loss (kg), mean $\pm$ SD	5.8 $\pm$ 7.5	6.0 $\pm$ 7.7	5.5 $\pm$ 7.3
Duration of Disease (years), mean $\pm$ SD	6.22 $\pm$ 1.20	6.50 $\pm$ 1.00	5.90 $\pm$ 1.40
Esophageal Dilatation			
- Grade I (<4 cm), %	50.9% (13)	53.3% (8)	50.0% (5)
Grade II (4–6 cm), %	36.4% (9)	33.3% (5)	40.0% (4)
Grade III (>6 cm), %	12.7% (3)	13.3% (2)	10.0% (1)
Previous Medical Therapies, %			
Proton-pump inhibitors	52% (13)	53% (8)	50% (5)
Calcium-channel blockers or nitrates	28% (7)	33% (5)	20% (2)
NSAIDs	64% (16)	67% (10)	60% (6)
Symptoms, %			
Dysphagia	100% (25)	100% (15)	100% (10)
Regurgitation	85.6% (21)	87% (13)	80% (8)
Chest Pain	54.2% (13)	60% (9)	40% (4)
Cough	41.5% (10)	46.7% (7)	30% (3)
Heartburn	26.3% (7)	33.3% (5)	20% (2)
Endoscopic Findings, %			
Esophagitis	12.7% (3)	13.3% (2)	10.0% (1)
Hiatal hernia	10.2% (3)	13.3% (2)	10.0% (1)
Manometry (LES pressure, mm Hg, mean $\pm$ SD)	37 $\pm$ 16.1	36 $\pm$ 15.2	38 $\pm$ 17.0

Table 1: Demographic and Clinical Characteristics of Patients.

BMI: Body Mass Index, NSAIDs: Non-Steroidal Anti-Inflammatory Drug, LES: Lower Esophageal Sphincter.

Note 1: Esophageal dilation grades are based on the maximum diameter measured during the Barium swallow study.

The Achalasia Patient-Reported Outcomes (APRO) questionnaire was used to assess preoperative and postoperative symptom scores for dysphagia, reflux, and chest pain. Dysphagia scores significantly decreased from a pre-surgery mean of 18.96 (SD = 4.02) to

12.11 (SD = 3.88) three months post-surgery ($t = 4.52$, $p < 0.01$, Cohen's $d = 1.62$). At six months, the score marginally declined to 11.45 (SD = 3.67), though this reduction was not statistically significant ($t = 0.47$, $p = 0.640$, Cohen's $d = 0.19$). Reflux scores dropped significantly from 19.32 (SD = 4.18) pre-surgery to 9.14 (SD = 3.77) at three months ($t = 7.81$, $p < 0.05$, Cohen's $d = 2.53$) and further to 4.97 (SD = 2.45) by six months ($t = 3.42$, $p = 0.001$, Cohen's $d = 1.24$). Chest pain scores also decreased significantly from 10.12 (SD = 2.10) pre-surgery to 4.58 (SD = 1.80) at three months ($t = 9.38$, $p < 0.05$, Cohen's $d = 2.88$) and to 3.92 (SD = 1.67) at six months ($t = 2.20$, $p = 0.034$, Cohen's $d = 0.65$). Each symptom's statistical details across all time points are summarized in Table 2.

Symptom	Time Frame	Mean (SD)	t-test Comparison	p-value	Cohen's d
Dysphagia	Pre-surgery	18.96 (4.02)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.01 0.640	1.62 0.19
	3 Months	12.11 (3.88)			
	6 Months	11.45 (3.67)			
Reflux	Pre-surgery	19.32 (4.18)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.05 0.001	2.53 1.24
	3 Months	9.14 (3.77)			
	6 Months	4.97 (2.45)			
Chest Pain	Pre-surgery	10.12 (2.10)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.05 0.034	2.88 0.65
	3 Months	4.58 (1.80)			
	6 Months	3.92 (1.67)			

Table 2: Detailed Statistical Analysis of APRO Symptoms Before and After Surgery

The GERDQ (Gastroesophageal Reflux Disease Questionnaire) assessed mean preoperative and postoperative scores, revealing significant improvements across multiple symptoms. Heartburn scores decreased from a pre-treatment mean of 3.0 (SD = 1.0) to 1.5 (SD = 0.5) three months post-treatment, achieving statistical significance ($p < 0.05$, Cohen's $d = 2.22$). Regurgitation scores also dropped notably from 3.0 (SD = 1.0) to 1.4 (SD = 0.4), with a p-value of < 0.045 and a Cohen's d of 2.48. Sleep disturbances significantly decreased from 2.5 (SD = 0.8) to 1.0 (SD = 0.3) post-treatment ($p < 0.05$, Cohen's $d = 1.60$). The need for additional medication was significantly reduced from 2.8 (SD = 0.7) to 0.9 (SD = 0.2) ($p < 0.01$, Cohen's $d = 2.67$). Detailed statistical results are summarized in Table 3.

Symptom	Time Frame	Mean (SD)	t-test Comparison	p-value	Cohen's d
Heartburn	Pre-treatment	3.0 (1.0)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.05 0.150	2.22 0.50
	3 Months	1.5 (0.5)			
	6 Months	1.2 (0.4)			
Regurgitation	Pre-treatment	3.0 (1.0)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.015 0.200	2.48 0.48
	3 Months	1.4 (0.4)			
	6 Months	1.1 (0.3)			
Sleep Disturbances	Pre-treatment	2.5 (0.8)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.05 0.100	1.60 0.47
	3 Months	1.0 (0.3)			
	6 Months	0.8 (0.2)			
Additional Medication	Pre-treatment	2.8 (0.7)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.01 1.000	2.67 0.00
	3 Months	0.9 (0.2)			
	6 Months	0.9 (0.2)			
Epigastric Pain	Pre-treatment	2.0 (0.6)	Pre vs. 3 Months 3 Months vs. 6 Months	0.200 0.500	0.53 0.28
	3 Months	1.5 (0.5)			
	6 Months	1.3 (0.4)			
Nausea	Pre-treatment	1.5 (0.5)	Pre vs. 3 Months 3 Months vs. 6 Months	0.100 0.700	0.67 0.17
	3 Months	0.9 (0.3)			
	6 Months	0.8 (0.2)			

Table 3: Detailed Statistical Analysis of GERDQ Symptoms Before and After Surgery

The BEDQ (Brief Esophageal Dysphagia Questionnaire) revealed significant

improvements in dysphagia symptoms from pre-treatment to 3 months post-treatment. Notable improvements included trouble eating solid foods ($p < 0.01$, Cohen's $d = 2.2$), soft foods ($p < 0.003$, Cohen's $d = 1.6$), and swallowing liquids ($p < 0.001$, Cohen's $d = 2.5$). Additionally, there was a significant decrease in coughing or choking while swallowing ($p = 0.005$, Cohen's $d = 1.8$). In contrast, pain while swallowing did not show statistically significant improvement ($p = 0.650$). From 3 to 6 months, symptoms generally stabilized, with no significant changes observed. These results are detailed comprehensively in Table 4.

Symptom	Time Frame	Mean (SD)	t-test Comparison	p-value	Cohen's d
Trouble Eating Solid Food	Pre-treatment	3.0 (1.0)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.01 0.210	2.2 0.5
	3 Months	1.0 (0.3)			
	6 Months	0.5 (0.2)			
Trouble Eating Soft Foods	Pre-treatment	2.0 (0.7)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.003 0.650	1.6 0.0
	3 Months	0.0 (0.0)			
	6 Months	0.0 (0.0)			
Trouble Swallowing Liquids	Pre-treatment	4.0 (1.2)	Pre vs. 3 Months 3 Months vs. 6 Months	< 0.001 0.450	2.5 0.4
	3 Months	2.0 (0.6)			
	6 Months	1.0 (0.3)			
Pain While Swallowing	Pre-treatment	3.0 (0.9)	Pre vs. 3 Months 3 Months vs. 6 Months	0.650 0.320	1.9 0.3
	3 Months	2.0 (0.6)			
	6 Months	1.0 (0.3)			
Coughing or Choking While Swallowing	Pre-treatment	3.0 (0.9)	Pre vs. 3 Months 3 Months vs. 6 Months	0.005 0.870	1.8 0.2
	3 Months	1.0 (0.3)			
	6 Months	0.0 (0.0)			

Table 4: Detailed Statistical Analysis of BEDQ Symptoms Before and After Surgery

Discussion

This study investigated the incidence and severity of GERD and dysphagia following laparoscopic Heller myotomy without fundoplication in patients diagnosed with type II achalasia. Unlike Elyasinia et al. (2022) [12], who observed significant symptom relief with the addition of fundoplication, our findings suggest that Heller myotomy alone effectively reduces dysphagia symptoms but may be less effective in managing GERD symptoms postoperatively. This observation aligns partially with Santoro et al. (2022) [16], whose meta-analysis suggested that fundoplication does not significantly alter postoperative reflux symptoms, though they emphasized the need for additional research into long-term outcomes. This suggests that while the benefits of fundoplication might not be immediately apparent post-surgery, they may play a crucial role in long-term symptom management.

Contrary to the findings of Kummerow Broman et al. (2018) [17], which favored the addition of Dor fundoplication for reducing postoperative symptoms, our study indicates that the absence

of fundoplication does not adversely affect immediate postoperative outcomes related to dysphagia. However, considering the research from Richards et al. (2004) [18] and Rebecchi et al. (2008) [19], there appears to be some support for using fundoplication as a strategy to potentially reduce the risk of developing postoperative GERD.

LHM is regarded as the standard surgical approach for patients newly diagnosed with achalasia who are experiencing complications, including reflux and dysphagia [20]. However, symptoms may persist postoperatively in some cases. It has been suggested that persistent postoperative symptoms can be related to prior treatments such as dilation, BTX injection, and fundoplication [21]. In terms of postoperative dysphagia to solids and fluids, our study found no significant difference between patients undergoing LHM with or without fundoplication, aligning with prior results that LHM improves dysphagia symptoms in patients with achalasia, regardless of accompanying fundoplication [22]. The literature currently reflects a general agreement on this outcome, though there are ongoing debates about the effects of different types of fundoplication—partial anterior, partial posterior, or total—on the results [23].

This study has several limitations that warrant mention. The sample size was relatively small, limiting the generalizability of the findings. Additionally, the lack of a control group with fundoplication prevents a direct comparison that might fully elucidate the benefits or drawbacks of excluding fundoplication from the surgical procedure. Moreover, the follow-up period may not be sufficient to capture long-term outcomes, particularly concerning the development of GERD, which can evolve over a longer time frame. Future studies should focus on long-term follow-up to better understand the implications of omitting fundoplication and to determine the best strategies for minimizing postoperative complications such as GERD, which remains a significant concern in the management of achalasia post-Heller myotomy. The divergence in these findings emphasizes the variability in patient responses and underscores the importance of individualized treatment planning. It also highlights the need for ongoing evaluation of

surgical outcomes to optimize the approach for achalasia treatment.

The findings reveal that while laparoscopic Heller myotomy without fundoplication effectively reduces dysphagia symptoms, it may be less effective in managing GERD postoperatively. These results highlight the procedure's ability to address the primary symptoms of achalasia but also underscore the potential need for additional strategies to prevent GERD, a common postoperative complication. The study emphasizes the importance of individualized treatment planning, taking into account each patient's clinical profile and risk factors for postoperative complications such as GERD. Although immediate outcomes for dysphagia show improvement, the long-term risk of GERD poses a significant concern that warrants further investigation. Future research should focus on long-term follow-up to assess the full implications of omitting fundoplication and refine strategies for managing postoperative GERD.

Acknowledgments

We thank the staff and patients at the Imam Hossein Teaching and Therapeutic Center for their cooperation and involvement in this study. Special thanks to the medical and surgical teams whose dedication made this research possible. We also appreciate the support from the Medical Ethics Committee for their guidance and oversight throughout the study duration.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest

The authors declare no conflict of interest

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