



# The Role of Fundoplication after Laparoscopic Heller Myotomy in Reducing Postoperative Symptoms in Patients with Achalasia: A Controlled Clinical Trial

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## Abstract

### Background:

Laparoscopic Heller myotomy (LHM) is considered the standard surgical approach in patients newly diagnosed with achalasia worldwide. However, proceeding to fundoplication after LHM remains controversial due to the observed postoperative symptoms, including dysphagia and regurgitation. This study was conducted to compare the postoperatively experienced regurgitation and dysphagia between those undergoing LHM with fundoplication and those with mere LHM.

### Methods:

This four-year controlled clinical trial was performed on adult patients with esophageal type two achalasia, referring to the Shariati Hospital, who gave their written informed consent to enroll. The diagnosis of achalasia was confirmed using manometric assessments. The control group underwent LHM with fundoplication, while the cases received LHM without fundoplication. The validated Achalasia Patients Questionnaire was used for assessing the experienced symptoms pre- and postoperatively. Also, esophagography was used to investigate the alterations of the symptoms pre- and postoperatively.

### Results:

A total of 48 patients were evaluated. 23 were assigned to the case group, while 25 were considered the controls (male to female ratio: 25 to 23). The mean age of the patients was 36.94 years, and the average disease duration was 6.22 years. Cases and controls were matched demographically. There was no statistically significant difference between the cases and controls regarding postoperative active or passive regurgitation or dysphagia to either solids or fluids. Also, the mean score of total clinical symptoms after the surgery was not significantly different between cases and controls. Lastly, esophagography revealed significant improvement regarding all the symptoms postoperatively ( $P=0.001$ ); however, no statistically significant difference existed in this regard between cases and controls.

### Conclusion:

Our results indicate no significant difference regarding the postoperative achalasia-related symptoms, namely regurgitation and dysphagia, between those patients undergoing LHM with and without fundoplication. However, further studies are required to thoroughly investigate the effects of various fundoplication techniques in relation to all achalasia-related symptoms to confirm these results.

### Keywords:

Achalasia, Regurgitation, Dysphagia, Fundoplication, Heller myotomy

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## Introduction

As a primary esophageal motility disorder,<sup>1</sup> achalasia affects esophageal peristalsis and musculature and eventually leads to progressive dysphagia due to the distortion of the lower esophageal sphincter.<sup>2</sup> Due to the progressive nature of the disease, shall it be left untreated, achalasia will lead to the dilation of the esophagus, which puts patients at high risk of aspiration pneumonia alongside other complications.<sup>3</sup> Therefore, acquiring appropriate treatment and monitoring strategies is essential for each newly diagnosed patient.<sup>4</sup>

Since the underlying neuronal loss causing the lost peristalsis is irreversible, eventually, most patients require surgical treatment.<sup>5</sup> Various approaches have been developed regarding the surgical treatment of achalasia and can be used case dependently considering the standardized guidelines.<sup>6</sup> Although options such as endoscopic injection of the botulinum toxin (BTX), endoscopic dilation, and perioral endoscopic myotomy are proved to be adequate to some extent,<sup>7</sup> laparoscopic Heller myotomy (LHM) is considered the standard of care by many experts.<sup>8,9</sup> Some studies have suggested LHM be a definitive treatment for achalasia. However, the related high complications rate raised controversies in this regard.<sup>10</sup> Some studies have suggested a high rate of postoperative reflux when merely conducting LHM.<sup>11</sup> Studies have recommended a remarkable reduction in postoperative reflux when adding fundoplication to LHM.<sup>12</sup> Since gastric esophageal reflux occurs in 10-30% of patients undergoing anterior fundoplication after Heller myotomy, some studies even suggest that total fundoplication might reduce these symptoms.<sup>13</sup>

Considering the abovementioned controversies, Herein, we aimed to compare the effects of combining fundoplication with LHM on reflux, dysphagia, and other related postoperative symptoms in patients with achalasia.

## Materials and Methods

Applying a controlled clinical trial design, a total of 48 patients were enrolled. Those patients older than 18 years referring to the Shariati hospital from 2017 to 2021 suffering from type two achalasia who gave their written informed consent to participate in the study were considered for inclusion.

The following assessments were obligatory for final

inclusion in the study: Confirming the diagnosis of achalasia with manometric assessments indicating the presence of simultaneous contractions along the esophagus with no relaxation in the lower esophageal sphincter, and performing standard esophagography for all patients in an approved center after completing the validated version of the "Achalasia Patients Questionnaire." The questionnaire evaluated active and passive regurgitation, chest pain, the severity of dysphagia, dysphagia to solids, and dysphagia to fluids. The two primary outcomes were the measurement of gastroesophageal reflux and dysphagia in the case group compared with the controls. Receiving a score of 4 or less out of 18 points regarding the total clinical symptoms or reducing the fluid column height in the esophagogram paraclinically by 80% was considered an improvement. Patients were evaluated while not undergoing pH-affecting drug treatment.

Those who have received any prior surgical treatment for achalasia were excluded. The other indications of the exclusion were: pregnancy, having accompanying esophageal malignancy or having undergone pneumatic balloon dilation therapy over three times. Lastly, those with any types of achalasia other than type two were excluded.

Eventually, 23 patients were assigned to the case group, and 25 were categorized as the controls. The case group underwent LHM without fundoplication, while the control group underwent LHM accompanied by fundoplication. The prevalence of postoperative symptoms regarding dysphagia, regurgitation, chest pain, and overall clinical symptoms were calculated according to the Achalasia Patients Questionnaire in each group, and statistical analysis was conducted using the Mann-Whitney U test. Lastly, esophagography was conducted pre- and postoperatively in 0, 3, and 5 minutes and the results were statistically compared between cases and controls. SPSS software version 25 was used for statistical analysis.

## Results

A total of 48 patients were studied. 23 patients were assigned to the case group, and 25 were categorized as the controls. The mean age was 36.94, with the male to female ratio of 25 to 23. The mean duration of the disease was 6.22 years. Cases and controls

were matched demographically, and no statistically significant difference was present regarding the demographic features. There was no statistically significant difference between the two groups regarding treatment satisfaction. Table 1 illustrates the demographic features of the cases compared with the controls. Also, the prevalence of postoperative complications among patients is summarized in Table 2.

Overall, 31 patients had dysphagia to solids, and 11 patients had liquids dysphagia postoperatively. The prevalence of postoperative dysphagia was not significantly different between cases and controls, nor was the severity of general dysphagia. 19 patients had active regurgitation after the surgery, while 20 patients had passive regurgitation. This difference was not statistically significant, either. 15 patients experienced chest pain postoperatively. There was no statistically significant difference between the two groups in this regard, either. The frequency and analysis results regarding the postoperative dysphagia and regurgitation, as the primary evaluated outcomes, are summarized in Tables 3 and 4.

The mean score of total clinical symptoms after the surgery was 5.22 in cases compared with 4.36 in the controls (total=4.77). This difference was not statistically significant ( $P=0.488$ ).

The results of the esophagogram pre- and postoperatively showed a significant improvement considering the overall experienced symptoms. However, the total score was not significantly different between those undergoing Heller myotomy with and without fundoplication. Table 5 illustrates these results. Lastly, the results regarding the effects of the surgery evaluated by esophagography are summarized in Table 6.

## Discussion

Herein, we aimed to compare the postoperative achalasia-related symptoms in patients undergoing

LHM between those undergoing LHM with fundoplication and those with mere LHM.

LHM is considered the standard surgical approach for those patients with newly diagnosed achalasia who are experiencing related complications, including reflux and dysphagia, by many experts.<sup>14</sup> However, symptoms persist postoperatively in some cases. It has been suggested that persistent symptoms postoperatively can be related to receiving other forms of treatment, dilation, BTX injection, and fundoplication.<sup>15</sup> Therefore, in this study, we focused on evaluating the effects of fundoplication on postoperative dysphagia and reflux after LHM in those patients who had not received any type of treatment prior to the study.

Regarding the postoperative dysphagia to solids and fluids, no significant difference was found in our study between those undergoing LHM with fundoplication and those without it. This finding is congruent with former results, indicating that LHM will improve the dysphagia symptoms in patients with achalasia, regardless of being accompanied by fundoplication or not.<sup>16</sup> There is a relative agreement in this regard in the current literature; however, controversies exist concerning the effects of the type of fundoplication, namely partial anterior, partial posterior, or total, on the results.<sup>17</sup> Further studies are required to scrutinize the current hypotheses in this regard.

Considering the postoperative active or passive regurgitation as well, no significant difference existed between cases and controls. However, other works emphasized the significant role of adding a fundoplication, either partial anterior, partial posterior,

**Table 2.** The frequency of postoperative symptoms

Complication	Number of cases
Solids dysphagia	31
Fluids dysphagia	11
Active regurgitation	19
Passive regurgitation	20
Chest pain	15

**Table 1.** Demographic features of the cases and controls

Group	Mean age (years)	Mean disease duration (years)	Male to female ratio	Postoperative satisfaction rate
Cases	34.48	6.00	12/11	17/23
Controls	39.20	6.44	13/12	18/25
Total	36.94	6.22	25/23	35/48

**Table 3.** The statistical analysis results regarding the postoperative dysphagia in cases compared with controls

Dysphagia	Score	Frequency	Prevalence in cases versus controls				P value
			Cases		Controls		
			Score	Frequency	Score	Frequency	
Solids	0	17					0.268
	1	13	0	11	0	6	
	2	7	1	4	1	9	
	3	11	2	3	2	4	
	Total	48	3	5	3	6	
Fluids	0	34					0.432
	1	7	0	15	0	19	
	2	5	1	4	1	3	
	3	2	2	3	2	2	
	Total	48	3	1	3	1	
Overall	0	17					0.662
	1	10	0	7	0	10	
	2	18	1	7	1	3	
	3	3	2	10	2	8	
	Total	48	3	1	3	2	

**Table 4.** The statistical analysis results regarding the postoperative regurgitation in cases compared with controls

Regurgitation	Score	Frequency	Prevalence in cases and controls				P value
			Cases		Controls		
			Score	Frequency	Score	Frequency	
Active	0	29					0.060
	1	8	0	11	0	18	
	2	11	1	4	1	4	
	3	0	2	8	2	3	
	Total	48	3	0	3	0	
Passive	0	28					0.141
	1	7	0	11	0	17	
	2	9	1	4	1	3	
	3	4	2	5	2	4	
	Total	48	3	3	3	1	

**Table 5.** The statistical results of the esophagography pre- and postoperatively

Status	Min	Mean±SD	Comparative results (Mean±SD)			P value
			Min	Cases	Controls	
Preoperative	1	14.88±5.08	1	15.04±5.36	14.72±4.92	0.829
	3	12.07±4.58	3	12.32±4.56	11.84±4.67	0.717
	5	10.67±4.33	5	10.87±4.31	10.48±4.44	0.759
Postoperative	1	5.94±7.58	1	6.04±7.88	5.84±7.45	0.927
	3	4.29±6.52	3	4.04±6.33	4.52±6.80	0.803
	5	3.23±5.45	5	2.87±4.96	3.56±5.94	0.664

**Table 6.** The results regarding the effects of the surgery on esophagography

Min	Mean±SD	Mean±SD	P value
1	14.88±5.08	5.94±7.58	0.001
3	12.07±4.58	4.29±6.52	0.001
5	10.67±4.33	3.23±5.45	0.001

or total, in reducing the gastroesophageal reflux symptoms postoperatively.<sup>18</sup> Although a relative agreement exists regarding the necessity of adding one type of fundoplication to reduce postoperative gastroesophageal reflux, controversies exist regarding the best type of fundoplication, and studies suggest that selection can be made depending on the surgeon's choice.<sup>19</sup> Future works are essential to thoroughly address this issue.

### Conclusion

Our results indicate no significant difference between conducting LHM with or without fundoplication in the patients' reflux, active or passive regurgitation, dysphagia to solids and fluids, and chest pain postoperatively. Also, although esophagography revealed significant improvement of the achalasia-related symptoms after LHM, the difference in these improvements between cases and controls was insignificant. Still, further studies are required to thoroughly evaluate whether conducting a certain type of fundoplication in LHM would indeed significantly alter the experienced achalasia-related postoperative symptoms.

### Conflict of Interest

The authors declare no conflict of interest related to this work.

### Ethical Approval

Present study approved by ethical committee of Tehran university of medical sciences.

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