

Evaluation of short-term outcomes of laparoscopic Heller cardiomyotomy with Dor's fundoplication versus pneumatic dilatation for the treatment of achalasia

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Background

Achalasia is a rare esophageal motility disorder of unknown cause. However, the best treatment modality for achalasia is controversial. Treatment consists of disruption of the lower esophageal sphincter, classically either by endoscopic pneumatic dilation (PD) or laparoscopic Heller's myotomy combined with an anti-reflux procedure. The study aim was to compare laparoscopic Heller cardiomyotomy plus Dor's fundoplication (LHCM) with PD for the treatment of achalasia.

Patients and methods

In this interventional study, we included 50 adult patients diagnosed as having achalasia by performing either a barium study or by the absence of peristalsis and impaired relaxation of the lower esophageal sphincter on esophageal manometry. The patients were randomly classified into two groups according to the intervention performed: PD or LHCM. Follow-up evaluations were performed after 8 and 16 months.

Results

In total, 50 patients with achalasia and an Eckardt symptom score more than 3 were managed by two different interventions according to their groups. After 16 months of follow-up, the height of a barium-contrast column after 5 min was significantly lower in the LHCM group than in the PD group. There were no other statistically significant differences in the primary or secondary outcomes between the two groups.

Conclusion

After 16 months of follow-up, the rates of therapeutic success and number of complications were nearly similar between LHCM and PD. We conclude superiority of LHCM due to the better recorded height of barium swallow after 16 months of follow-up.

Keywords:

achalasia, esophagus, laparoscopic Heller myotomy, pneumatic dilatation

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Introduction

Esophageal achalasia is a rare primary esophageal motor disorder of unknown cause, characterized by insufficient relaxation of the lower esophageal sphincter (LES) and loss of esophageal peristalsis [1]. The disorder occurs with equal frequency in men and women, with an incidence of ~0.5–1.2 per 100 000 individuals, but recent data have indicated that it increases with age [2,3]. The main classic symptoms of achalasia are dysphagia for solids and liquids, regurgitation of undigested food or saliva, heartburn, and weight loss, which often lead to misdiagnosis of achalasia as a gastroesophageal reflux disease (GERD) [3,4]. Diagnosis of achalasia is challenging because of nonspecific symptoms with GERD and the low sensitivity of endoscopic studies [3,5].

Pneumatic dilatation (PD) and laparoscopic Heller's cardiomyotomy with Dor's fundoplication (LHCM)

are the common options in the management of esophageal achalasia [4]. These treatments reduce the pressure gradient across the LES and thus facilitate esophageal emptying by gravity and relief of dysphagia [4,6,7]. The treatment of choice for many years was repeated endoscopic PD, which leads to therapeutic success in 70–80% of patients [6]. The advent of minimally invasive surgery has given rise to substantial interest in this surgical technique, with LHCM combined with anti-reflux treatment, which has become the preferred treatment [8].

Randomized controlled trials that compared PD with LHCM have shown that the treatments were equally

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effective with no significant difference in the risk of complications between groups [5,6]. Another study showed that LHCM was more effective clinically and monometrically for patients with early-stage achalasia than PD, with no significant difference between the two procedures regarding complications [7]. A meta-analysis also suggested that laparoscopic Heller's myotomy may deliver greater response rates than those of PD less than or equal to 1 year after treatment [odds ratio (OR), 1.98 for 95% confidence interval] [9]. Currently, the choice of treatment depends largely on the physician's knowledge. Moreover, the outcome measures and treatment protocols in previous studies are different, making a comparison among various studies of the success rates of the treatment options problematic [10].

Aim

The main aim of this study was to compare the short-term outcomes of LHCM and PD for the treatment of achalasia.

Patients and methods

Study design this study included 50 patients who were newly diagnosed with achalasia from June 2016 to June 2018 in three hospitals in two Middle Eastern countries. Written informed consent from all volunteers and approval of each institutional ethics committee were procured. The 50 patients were between the ages of 18 and 70 years and were enrolled on the basis of their diagnosis with achalasia either by esophageal manometry (showing absence of peristalsis and impaired relaxation of the LES with a nadir pressure of ≥ 10 mmHg) or by a barium study if their Eckardt symptom score was more than 3. The Eckardt score is the sum of regurgitation, dysphagia, weight loss, and chest pain (Table 1) and is higher with patients experiencing more severe symptoms, with 12 being the highest score.

The following data were obtained from each patient:

- (1) Personal history such as age, sex, weight, BMI, height, occupation, marital status, smoking, family history, and history of chronic diseases.
- (2) A physical examination and standard hematological and blood chemical workup were also performed for all patients.
- (3) Upper gastrointestinal endoscopy and esophageal manometry were performed along with barium swallow to evaluate the degree of esophageal stasis before treatment and during follow-up.

Table 1 Eckardt score: the final score is the sum of all four symptoms score ranging from 0 to 12

Symptoms	Scores			
	0	1	2	3
Dysphagia	None	Occasional	Daily	With every meal
Regurgitation	None	Occasional	Daily	With every meal
Chest pain	None	Occasional	Daily	Several times/day
Weight loss (kg)	0	<5	5–10	>10

Four patients out of 50 did not meet the exclusion criteria, including patients unfit for surgery, patients previously treated for achalasia, megaesophagus (diameter >7 cm), and pseudoachalasia. The patient selection flowchart is shown in Fig. 1.

Interventions

Pneumatic dilation

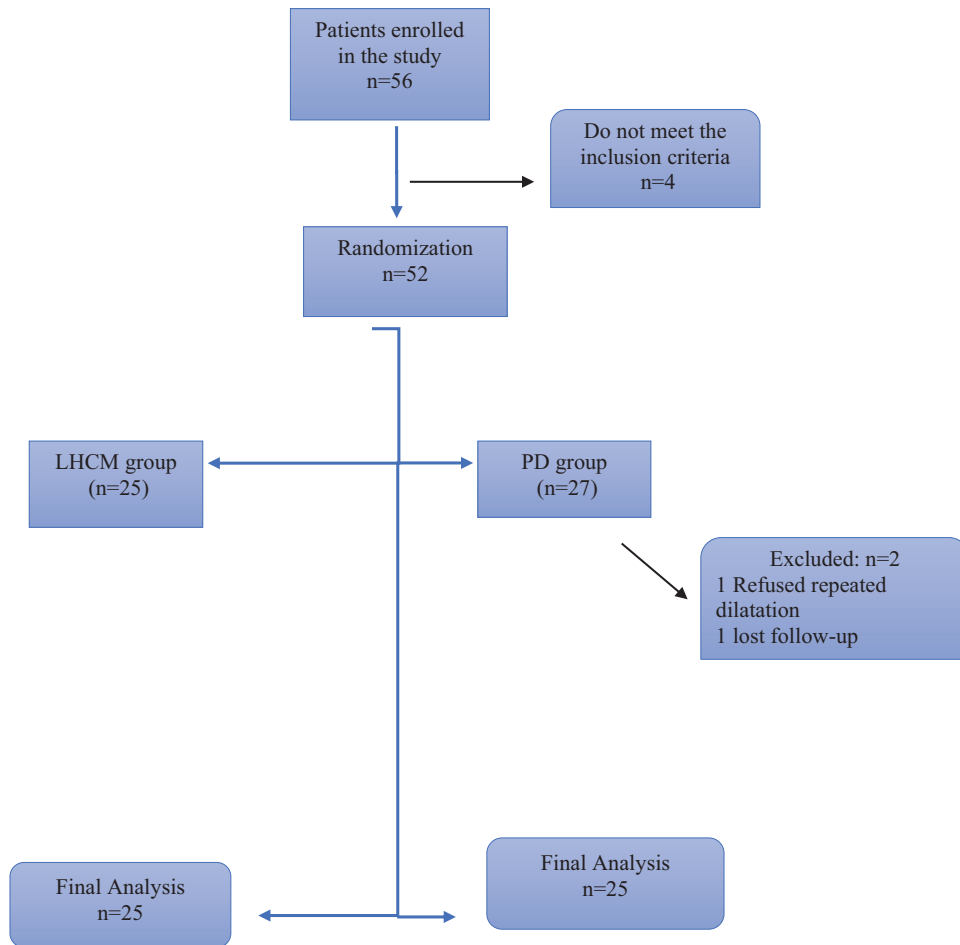
At the esophagogastric junction, a Rigiflex balloon was set and dilated for 1 min at a pressure of 5 PSI, followed by a pressure of 8 PSI for 1 min. All patients underwent two dilations: the first was performed with a 30-mm balloon, and the second was performed 1–3 weeks later with a 35-mm balloon. However, if the Eckardt score was more than 3, a third dilation was performed weeks later with a 40-mm balloon. If the Eckardt score was persistently more than 3, the treatment was considered to have failed.

In the course of the follow-up period, patients with reappearance of symptoms received further dilation with a 35-mm balloon and, if required (i.e. if the Eckardt score remained >3), a 40-mm balloon. After the second series of dilations, a concluding series of dilations were permitted only if the symptoms reoccurred after 2 years. In addition, if the patient showed recurring symptoms within 2 years after the second dilation series, the treatment was considered to have failed.

Laparoscopic Heller cardiomyotomy with Dor fundoplication

The first step of the procedure was to mobilize the distal esophagus by exposing the diaphragmatic crura and dividing the phrenoesophageal ligament. Myotomy involved the division of all layers of the lower 4–6 cm of the esophagus above the gastroesophageal junction down to the mucosa as well as division of at least 2 cm over the stomach. Then, an anterior Dor fundoplication of 180° was performed. During the follow-up period, if the patients exhibited symptoms of Eckardt score more

Figure 1



Flowchart of the study sample, from 56 patients enrolled in the study, 52 patients were fit into the inclusion and exclusion criteria and 50 patients completed the study (25 in each group).

than 3 after surgery, the treatment was considered to have failed.

Outcomes

- (1) The principle end result of the study was to keep the Eckardt score less than or equal to 3 during the follow-up period, which stretched to more than or equal to 18 months for all participating patients. Therefore, esophageal manometry to assess the lower esophageal pressure along with barium swallow was performed at every follow-up attempt.
- (2) To evaluate quality of life, the European Organization for Research and Treatment of Cancer disease-specific questionnaire module for assessing quality of life in patients with esophageal cancer (QLQ-OES24) and the Short-Form Health Survey (SF-36) were used. The SF-36 mental and physical summary scores assess quality of life by scoring the general aspects of health from 0 to 100, with higher scores indicating

better results of good health [11]. In contrast, the QLQ-OES24 investigates multiple parameters of esophageal function, with lower scores indicating better results [12].

Results

After exclusions, a total of 50 patients with achalasia and Eckardt symptom scores more than 3 underwent one of the two different procedures. The mean ages of the patients who underwent the LHCM and PD procedures were 45.86 ± 15.25 and 80 ± 12.35 years, respectively. The number of females in the LHCM and PD groups were 14 (56%) and 15 (60%), respectively. Furthermore, the mean BMI values were $25.35 \pm 1.11 \text{ kg/m}^2$ in the LHCM group and $25.79 \pm 0.91 \text{ kg/m}^2$ in the PD group. The mean symptom durations were 46.12 ± 27.18 months in the LHCM group and 52.84 ± 30.45 months in the PD group. Differences in occupation, comorbidity, and smoking habits were not significant (Table 2).

Table 2 Demographic data of the two groups

Laparoscopic Heller cardiomyotomy with Dor fundoplication (N=25)		Pneumatic dilatation (N=25)	P value
Age	45.16±10.371	47.80±12.352	0.417
Sex [n (%)]			
Male	11 (44.0)	10 (40.0)	
Female	14 (56.0)	15 (60.0)	1.000
Occupations [n (%)]			
Not working	14 (56.0)	13 (52.0)	
Working	11 (44.0)	12 (48.0)	1.000
Comorbidity [n (%)]			
Hypertension	3 (12.0)	4 (16.0)	1.000
Diabetes mellitus	5 (20.0)	6 (24.0)	1.000
Dyslipidemia	2 (8.0)	2 (8.0)	–
Cardiovascular	2 (8.0)	1 (4.0)	1.000
Smoking [n (%)]			
Smoker	6 (24.0)	5 (20.0)	1.000
Ex-smoker	2 (8.0)	1 (4.0)	
Height (cm)	170.16±9.035	167.88±7.886	0.347
Weight (kg)	73.76±9.554	72.88±7.574	0.720
BMI (kg/m ²)	25.35±1.114	25.79±0.914	0.132
Follow-up (months)	10.08±3.201	10.52±2.974	0.532
Dysphagia before treatment	24.31±11.260	25.60±12.857	0.712
Symptoms duration (months)	46.12±27.187	52.84±30.449	0.415

Table 3 Primary and secondary outcomes at 8 and 16 months of follow-up according to treatment

	LHM (N=25)	Baseline PD (N=25)	P value	After 8 months		After 16 months		P value	
				LHM (N=25)	PD (N=25)	P value	LHM (N=25)		PD (N=25)
Eckardt score	8.04±2.5	7.08±1.89	0.141	1.56±1.08	2.04±1.74	0.433	1.04±1.060	1.72 ±1.275	0.053
Lower esophageal sphincter (mmHg)	30.36±1.4	34.20±1.9	0.051	10.20±1.3	14.00±1.6	0.001*	10.40±1.25	11.60 ±1.89	0.240
	11	79		54	83		8	3	
Height of barium-contrast column after 5 min (cm)	13.48±3.4	14.72±3.0	0.396	4.00±2.34	2.96±2.13	0.109	3.88±2.522	5.48 ±2.917	<0.001*
Quality of life									
QLQ-OES24	39.60±2.0	36.32±1.4	0.101	13.00±1.5	14.32±1.7	0.120	12.08±1.47	13.68 ±1.62	0.102
	00	35		81	25		0	6	
Short-Form Health Survey (SF-36)									
Physical component summary	47.72±1.3	48.08±1.4		54.76±0.7	51.92±1.1		53.04±1.51	51.92 ±1.28	
	70	12	0.341	79	87	0.110	3	8	0.051
Mental component summary	41.60±1.4	43.92±1.8		49.44±1.4	49.28±1.5		49.96±1.33	48.52 ±1.66	
	14	01	0.451	74	42	0.735	8	1	0.105

PD, pneumatic dilatation; QLQ-OES24, European Organization for Research and Treatment of cancer disease-specific questionnaire module for assessing quality of life in patients with esophageal cancer. *Statistically significant P value (P<0.05).

The main outcomes of the current research are illustrated in detail in Table 3, which shows a baseline higher value of Eckardt score above 7 for both groups. After appropriate interventions, the Eckardt score showed a dramatical decrease in 8 months at 1.5 for the LHM group while it was 2.04 for the PD group. A remarkable decrease was noticed

in Eckardt score of the LHM group at 1.04 after 18 months of follow-up, while it showed only slight decrease in PD at the same follow-up time with a P value of 0.053. However, it does not reach statistical significance, but it indicated a better response to the LHM than PD in the participants of the study. Statistically significant values were recorded in the

height of barium-contrast column at the endpoints of follow-up in favor of LHM over PD (3.88 vs. 5.48, respectively). In addition, assessment of the LES pressure expressed a low value throughout the follow-up time in LHM with the largest measuring 4 mm/Hg difference after 4 months of follow-up (10.2 vs. 14 mm/Hg; $P=0.001$).

Evaluation of the quality of life (Table 3) by the recoded questionnaires revealed a similarly detected scores between the two groups except for the physical component part in 18 months follow-up with a greater score detected in the LHM group. However, the P value did not reach the statistical limit ($P=0.051$), it means that the patients demonstrated a good response to LHM in their physical activities after they have undergone the surgical intervention.

A comparison of the successful treatments, as shown by Kaplan–Meier survival curves, for PD with LHCM is shown in Fig. 2. The area under the curve showed a greater dimension and spacing toward the curve of LHM between 1 year to one-and-a-half year with a higher success rate. However, the difference is not a huge one and the P value for the Kaplan–Meier survival curves is 0.70, it means that a higher success rate is recorded in most of the cases who underwent LHM.

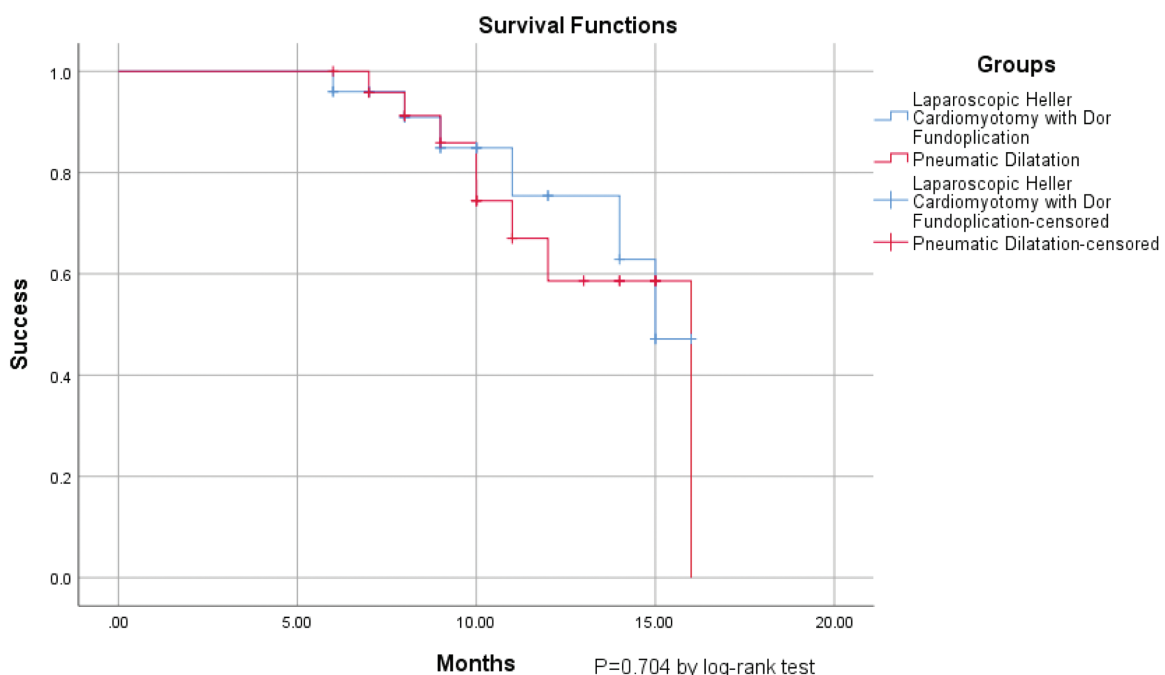
Complications of achalasia treatment are outlined in Table 4. The mucosal tear rate was 4% in the LHCM

group, and the number of esophageal perforation complications was 4% in the PD group. The bleeding rate was minimal and detected in only two patients in the LHM group and four others in the PD group. They are all managed conservatively. There were no recorded mortality in our series of cases. In addition, no single radiological or endoscopic recurrence was detected in the LHM arm, while 16% (four patients) required repeated PD due to failure in response. The recurrence symptom rates were 16% in the LHCM group and 24% in the PD group.

Discussion

Heller cardiomyotomy and endoscopic PD are the two main treatments for achalasia, which disrupt the circular muscle of the LES to prevent spasticity in the cardia. Peroral endoscopic myotomy is a new endoscopic technique that is gaining popularity in treating achalasia and other GI disorders, but it lacks reproducibility and long-term results assessing its efficacy; moreover, it needs training expertise and specialized centers that are not widely available. It is difficult to assess the superiority of one method over another because of the low disease prevalence. A few studies have compared both techniques in the management of achalasia and found similar efficacy and varying complications. The European Achalasia Trial group showed that the therapeutic success rate for

Figure 2



Kaplan–Meier curves of the survival functions of achalasia patients who either underwent LHCM or PD ($P=0.704$). LHCM, laparoscopic Heller cardiomyotomy plus Dor's fundoplication; PD, pneumatic dilatation.

Table 4 Comparison of preoperative and postoperative complications between the two groups

	LHCM (N=25) [n (%)]	Pneumatic dilatation (N=25) [n (%)]	P value
Preoperative			
Mucosal tear	1 (4.0)	0	1.000
Esophageal perforation	0	2 (8.0)	0.490
Bleeding	2 (8.0)	4 (16.0)	0.667
Venous thrombosis	1 (4.0)	0	1.000
Postoperative follow-up			
Recurrent symptoms	4 (24.0)	6 (32.0)	0.754

LHCM, laparoscopic Heller's cardiomyotomy with Dor's fundoplication.

LHM was similar to that of PD after 2 years of follow-up [6]. Some physicians consider PD to be the first-line management option because it can be performed on an outpatient basis with fewer complications, and LHCM is considered to be the second-line option after PD failure [13,14]. Hence, the main objective of this study was to use a comparative study design to evaluate the two state-of-the-art treatments, PD and LHCM.

We conducted this study on a sample of 50 patients diagnosed with achalasia and who had an Eckardt symptom score more than 3. The patients were randomly assigned to group A, which was treated by LHCM and group B, which was treated by endoscopic PD. The patients' age, sex, and BMI were comparable between the two groups with no statistically significant differences shown. The symptom durations in groups A and B were 46.12 ± 27.187 and 52.84 ± 30.449 months, respectively, and there were no significant differences in occupation, comorbidity, and smoking habits between the groups. Our results are consistent with those of Boeckxstaens *et al.* [15], who conducted a study on 201 patients with idiopathic achalasia.

The current study showed a significant difference in the height of the barium-contrast column after 5 min at 16 months between the two groups, with lower height among patients in the LHCM group. Vela *et al.* [16] demonstrated that the postprocedure reduction in the height of the barium column at 5 min is considered to be a predictor of success, especially in men, and lack of improvement carries a risk for repeating the surgical procedure in contrast to a study by Moonen *et al.* [6] that found no significant differences in the height of the barium-contrast column after 5 min at 1, 2, and 5 years between the LHCM group and PD group. Another study reported by Boeckxstaens *et al.* [15] showed no significant differences in the height of the barium-contrast column after 5 min at 1 and 2 years between the two groups. However, for the other parameters of the primary and secondary outcomes at 8 and 16 months of follow-up, our study has shown no significant difference in Eckardt scores

between the studied groups. In contrast to our findings, the study of Boeckxstaens *et al.* [15] found that the success rates after 1 and 2 years of follow-up were 93 and 90%, respectively, for LHCM and were 90 and 86%, respectively, for PD, when the cutoff point in the study was a decrease in the Eckardt scale scores to less than or equal to 3 as the criterion for successful treatment.

Regarding quality of life, the current study showed no significant differences in the physical or mental component after 8 and 16 months of follow-up between the PD and LHM groups, which agrees with the findings of a study reported by Moonen *et al.* [6] that showed no significant difference in the quality of life after 1, 2, and 5 years of follow-up between the two groups. Another study reported by Boeckxstaens *et al.* [15] using the same SF-36 survey showed no significant difference in quality of life after 1 and 2 years of follow-up between the two groups. A study reported by Persson *et al.* [7] using the Psychological General Well-being questionnaire showed that the total Psychological General Well-being score was significantly higher in the LHM group than in the PD group after 3 years. The difference was evident in all domains, particularly for anxiety and self-control, but after 5 years, the difference was diminished.

The present study showed a significant difference in the LES pressure of 10.20 ± 1.3 and 14.00 ± 1.6 in the LHCM and PD groups, respectively, after 8 months of follow-up between the groups, which is consistent with the results of a study reported by Boeckxstaens *et al.* [15] that showed a significant difference after 1 year of follow-up between the two groups, with a higher LES pressure in the PD than in the LHCM group. Another study reported by Moonen *et al.* [6] showed a significant difference in the LES pressure after 1 year of follow-up between the two groups, with a higher pressure in the PD group than in the LHCM group. In contrast to a study reported by Borges *et al.* [17] that showed no significant

difference in the decrease in the LES pressure less than 50% after 3 months of follow-up between the two groups, with 60.7% for the PD group and 85.7% for the LHCM group.

Effectiveness, durability of response, and procedure-related complications affect the choice of treatment. Among the entire surgical community, mucosal tears that immediately healed during surgery occur in 4% of patients. Esophageal perforation complications in PD were noted in 4% of patients, a rate that is comparable to that previously reported by Boeckxstaens *et al.* [15]. Esophageal perforation appeared in four (4%) of the 95 patients in the PD group, which is comparable to that reported by Hamdy *et al.* [9]. Esophageal perforation occurred in one (4%) of the 50 patients, mucosal tears occurred in 12% in the LHCM group, and abnormal gastric acid toxicity occurred in 15% of the PD patients and 23% of the LHCM patients. On the other hand, symptom improvement for PD and LHCM patients who experienced gastroesophageal reflux events was higher but transient in the PD group than in the LHM group, which may be explained by a combination of the Dor fundoplication technique with Heller myotomy to minimize postoperative acid reflux in the LHCM group. Twenty-six percent of the patients included in the study by Vela *et al.* [16] were on proton-pump inhibitors at the last follow-up evaluation, and complicated GERD was rare (4%); however, an anti-reflux procedure was performed in only 33% of those patients. In a study by Hamdy *et al.* [9], 16 and 28% of patients developed reflux symptoms after PD and laparoscopic Heller myotomy, respectively. The current study showed no significant difference in the recurrence of symptoms after 1 month between the two groups, which were 16 and 24% in the LHCM and PD groups, respectively. These findings were comparable to those reported by Hamdy *et al.* who found that the rates of recurrent symptoms after 1 year were 26.3 and 8.3% in the PD and LHCM groups, respectively [9].

The Kaplan–Meier curve analyses in the present study showed no significant difference in the treatment success rates between the two groups, although the numerical results were higher for the LHM group than for the PD group at 7, 10, and 15 months. Those findings agree with those of a study reported by Moonen *et al.* [6] which showed no significant differences in the success rates of 94% for LHM and 90% for PD after 1 year, 89% (LHCM) and 86% (PD) after 2 years, and 84% (LHM) and 82% (PD) after 5 years of follow-up between the two groups. In contrast, another study reported by Persson *et al.* [7] showed significant differences in the success rates of 96, 96, 92,

and 88% for LHCM and of 79, 68, 64, and 61% for PD after 1, 3, 5, and 6.5 years of follow-up, respectively, between the groups.

There were some study limitations that should be considered when interpreting the results. We performed our study in multiple centers, and the results could have been affected by the degree of operator experience. Other limitations included the small sample sizes of the studied groups and the lack of postprocedure motility studies.

Conclusion

This study showed that the therapeutic success rates of LHCM at different follow-up time points expressed some superiority only in the heights of barium-contrast column and LES pressure in addition to other variables that were in favor of the surgical side. However, these findings do not reach a level of recommendation or guidance of one approach over the other. A long-term follow-up of randomized controlled trials is highly recommended to allocate the best technique for the treatment of achalasia.

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Conflicts of interest

There are no conflicts of interest.

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