

Comparative study between laparoscopic Heller's cardiomyotomy and peroral endoscopic myotomy in treatment of esophageal achalasia

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Background

Achalasia is a motility disorder characterized by the lower esophageal sphincter's inability to relax in absence of peristalsis. It causes dysphagia, undigested food regurgitation, chest pain, weight loss, and respiratory symptoms such as nocturnal cough, recurrent aspiration, and pneumonia.

Patients and methods

This study included 46 patients who were admitted with symptoms of achalasia in Cairo University hospitals. Laparoscopic Heller's cardiomyotomy (LHM) was performed for 23 patients and peroral endoscopic myotomy (POEM) was done for other 23 patients. Clinical assessment using the Eckardt score was done for all patients preoperatively and 3 months postoperatively.

Results

The operative time ranged from 90 to 160 min in LHM patients (group 1) (mean, 125.7 min), whereas it ranged from 75 to 180 min in POEM patients (group 2) (mean, 123.8 min). BMI postoperatively ranged from 25.2 to 30.9 kg/m² (mean, 26.9 kg/m²) in group 1, whereas in group 2, it ranged from 16.02 to 43.36 kg/m² (mean, 26.8 kg/m²).

Conclusion

There was no significant difference between LHM and POEM in terms of their resolution or improvement of symptoms of achalasia in our research, but there was a significant difference regarding gastroesophageal reflux symptoms postoperatively between both groups, in which gastroesophageal reflux symptoms postoperatively occurred with POEM and did not occur with LHM.

Keywords:

achalasia, laparoscopic Heller, 's cardiomyotomy, lower esophageal sphincter, peroral endoscopic myotomy

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Introduction

Achalasia is the most well-known and well-understood primary motility disorder of the esophagus, with an annual incidence of 6 per 100 000 people [1]. Pathogenesis of achalasia is thought to be neurogenic degeneration caused by either idiopathic or infectious causes. This degeneration causes lower esophageal sphincter (LES) hypertension, failure of the sphincter to relax when swallowing, increase in intraluminal esophageal pressure, esophageal dilatation, and subsequent loss of progressive peristalsis in the esophageal body, resulting in dysphagia, regurgitation, chest pain, and weight loss [2].

Achalasia is diagnosed using a mixture of modalities, including gastroscopy, gastrografin esophagogram, esophageal manometry, and computed tomography [3]. Achalasia is traditionally treated with pneumatic balloon dilatation and botulinum toxin injection [4]. Even though botulinum toxin injection has been found to have excellent short-term results, its utility is limited

because of a short period of symptomatic relief, symptom recurrence, and problems of submucosal fibrosis [5].

Peroral endoscopic myotomy (POEM) was developed as a recent innovation in the surgical management of achalasia as a result of advances in minimally invasive and endoscopic treatments. Endoscopic submucosal dissection was used in this process to produce a method in which a submucosal tunnel is developed from the lower esophagus to the stomach, providing a plane on which myotomy can be done [6].

POEM may be an ideal endoscopic treatment for type achalasia as it allows not only myotomy of LES but also of the esophageal body, where hypertensive

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contractions frequently happen [7]. Advancement in symptoms and reduction in Eckardt stage were used to describe clinical response [8].

Therefore, this study was conducted to investigate if there are variations in efficacy and safety between POEM and laparoscopic Heller's cardiomyotomy for therapy of esophageal achalasia.

The main aim of this research was to compare outcomes between laparoscopic Heller's cardiomyotomy (LHM) and POEM regarding efficacy and safety in the therapy of achalasia.

The primary end points of the research were to perform clinical assessment of symptoms reflected by the Eckardt staging system preoperatively and 3 months postoperatively.

The secondary end points of the study were to assess BMI. 'We used BMI as one of the secondary end points of the study to be assessed as the increase in BMI is an important indicator for the success of the operation,' procedure duration, hospital stay, occurrence of adverse events (bleeding, perforation, leakage, recurrence, dysphagia, and reflux), and the cost of the operation.

Patients and methods

This study is a randomized clinical trial that included 46 patients who were admitted with symptoms of achalasia in Cairo University Hospitals. LHM was performed for 23 patients and POEM was done for other 23 patients. Clinical assessment using the Eckardt score was done for all patients preoperatively and 3 months postoperatively. This research was performed at the Department of General Surgery, Cairo University. Ethical Committee approval and written, informed consent were obtained from all participants.

Inclusion criteria

Patients were considered suitable for the current research if they met the following criteria: willing to consent to and follow the assessment and therapy plan, 18–65 years old of both sexes presenting with symptoms of achalasia requiring intervention after confirming the diagnosis by esophageal manometry study and upper gastrointestinal endoscopy.

Exclusion criteria

Exclusion criteria included patients having any bleeding disorders; patients with a severe

cardiopulmonary disease or another serious organic disease, making them high-risk surgical candidates; patients with any contraindication to radiation exposure (e.g. pregnancy); and patients with psychiatric disorders.

Informed written consent was obtained with an explanation of the possible complications that could occur in the perioperative period.

All patients were assessed using the Eckardt score, which is a simple measure to assess achalasia results, and it focuses on four symptoms: dysphagia, regurgitation, retrosternal pain, and weight loss. Four components are graded from 0 to 3. The score ranges from 0 to 12.

Eckardt symptom scoring and staging [15]

Score	Dysphagia	Retrosternal pain	Regurgitation	Weight loss
0	None	None	None	None
1	Occasional	Occasional	Occasional	< 5 kg
2	Daily	Daily	Daily	5 – 10 kg
3	Every meal	Every meal	Every meal	>10 kg
	Stage 0	Stage 1	Stage 2	Stage 3
Score total	0 – 1 (remission)	2 – 3 (remission)	4 – 6 (failure)	>6 (failure)

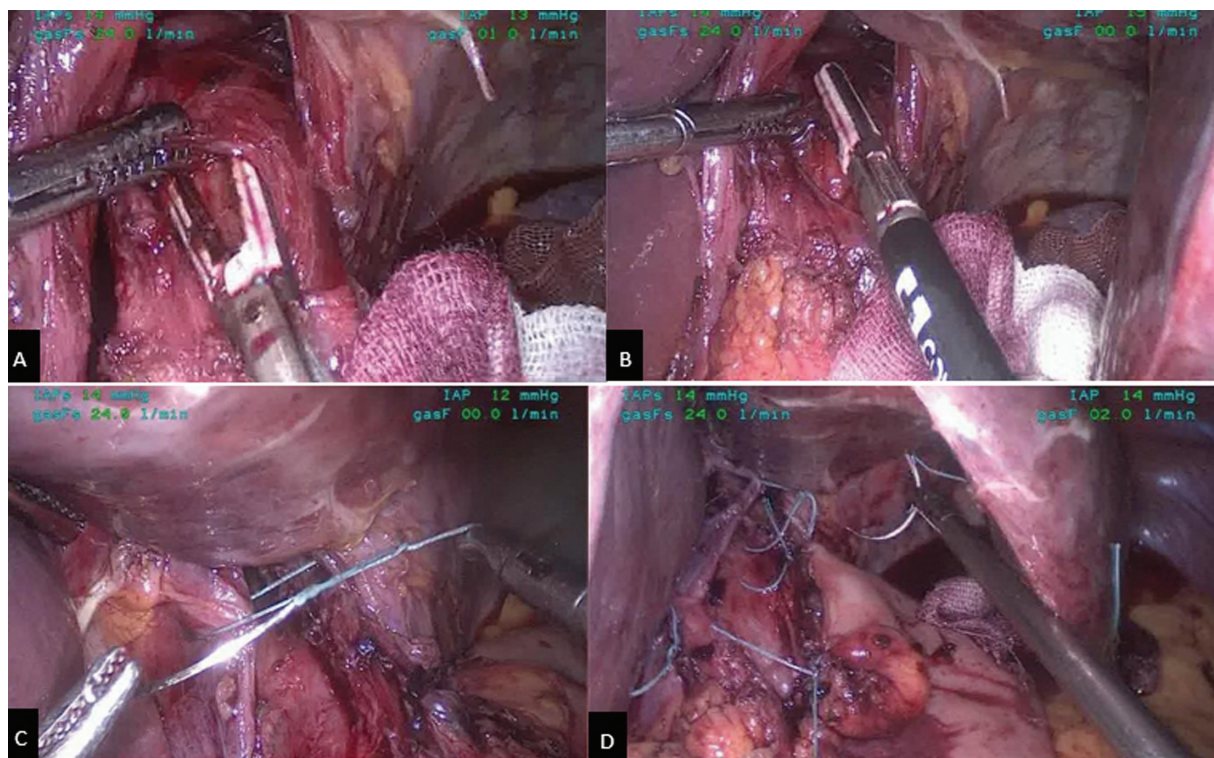
Surgical procedure

Laparoscopic Heller's cardiomyotomy

This procedure is considered the gold standard for treatment of achalasia (Fig. 1).

(a) Division of longitudinal muscle fibers of the esophagus was performed. 'Myotomy was carried out using a LigaSure. The myotomy was begun on the esophagus and carried out proximally to a distance of 5 cm from the gastroesophageal junction (GEJ) and distally 3 cm onto the cardia.' (b) Esophageal hiatus was reapproximated using ethibond. (c) An anterior (Dor) fundoplication was performed, and four 2-0 intracorporeal sutures were placed. On the left side, a suture was placed between the fundus, the apex of the left crus, and the superior (cephalad) cut edge of the muscularis to the left of the esophagus. A second suture was placed 2 cm inferior (caudad) to the first suture, approximating the left side of the fundus and the left side of the myotomy. The third suture is placed between the fundus and the superior (cephalad) cut edge of the muscularis to the right of the esophagus and the apex of the right crus. Finally, the fourth suture is placed between the right side of the fundus and the inferior (caudad) right side of the myotomy to complete an anterior partial fundoplication.

Figure 1



Steps from LHM procedure: (a) dissection of longitudinal muscle fibers from the mucosa. LHM, laparoscopic Heller's cardiomyotomy.

Peroral endoscopic myotomy

POEM was done in the operating room under rapid sequence General Anesthesia (GA) with endotracheal intubation, owing to the significant risk of aspiration for patients with achalasia.

The submucosal tunnel was started four cm proximal to the proximal portion of myotomy, and thus, 12 cm above the GEJ. The mucosa was lifted with the injection of saline with methylene blue on the anterior esophagus (12-o'clock position).

With the mucosa raised, a triangle tip endoscopic cautery knife was used to create a 2 cm longitudinal incision in the mucosa to allow for entry of the endoscope into the submucosal space.

The submucosal tunnel was carried out at least 3 cm onto the cardia of the stomach.

After the tunnel was created, the endoscope was drawn back to 6 cm above the GEJ as the starting location for the myotomy. This usually leaves 3–4 cm of overlap from where the tunnel and the myotomy starts. The triangle tip cautery knife was then used to divide the muscle, proceeding distally onto the gastric cardia.

Once the myotomy was completed, the scope was withdrawn from the tunnel. Careful inspection was

performed to confirm hemostasis and visualize any potential mucosal perforations.

The mucosal incision was then closed using endoscopic clips (Fig. 2).

Postoperative complications

Immediate postoperative complications were monitored during the hospital stay including the following: perforation; bleeding; pneumoperitoneum or pneumothorax, which is usually managed conservatively as CO₂ insufflation is used instead of air; a cardiopulmonary complication related to anesthesia; chest pain that can be controlled by analgesics; infection; and gastroesophageal reflux (GERD).

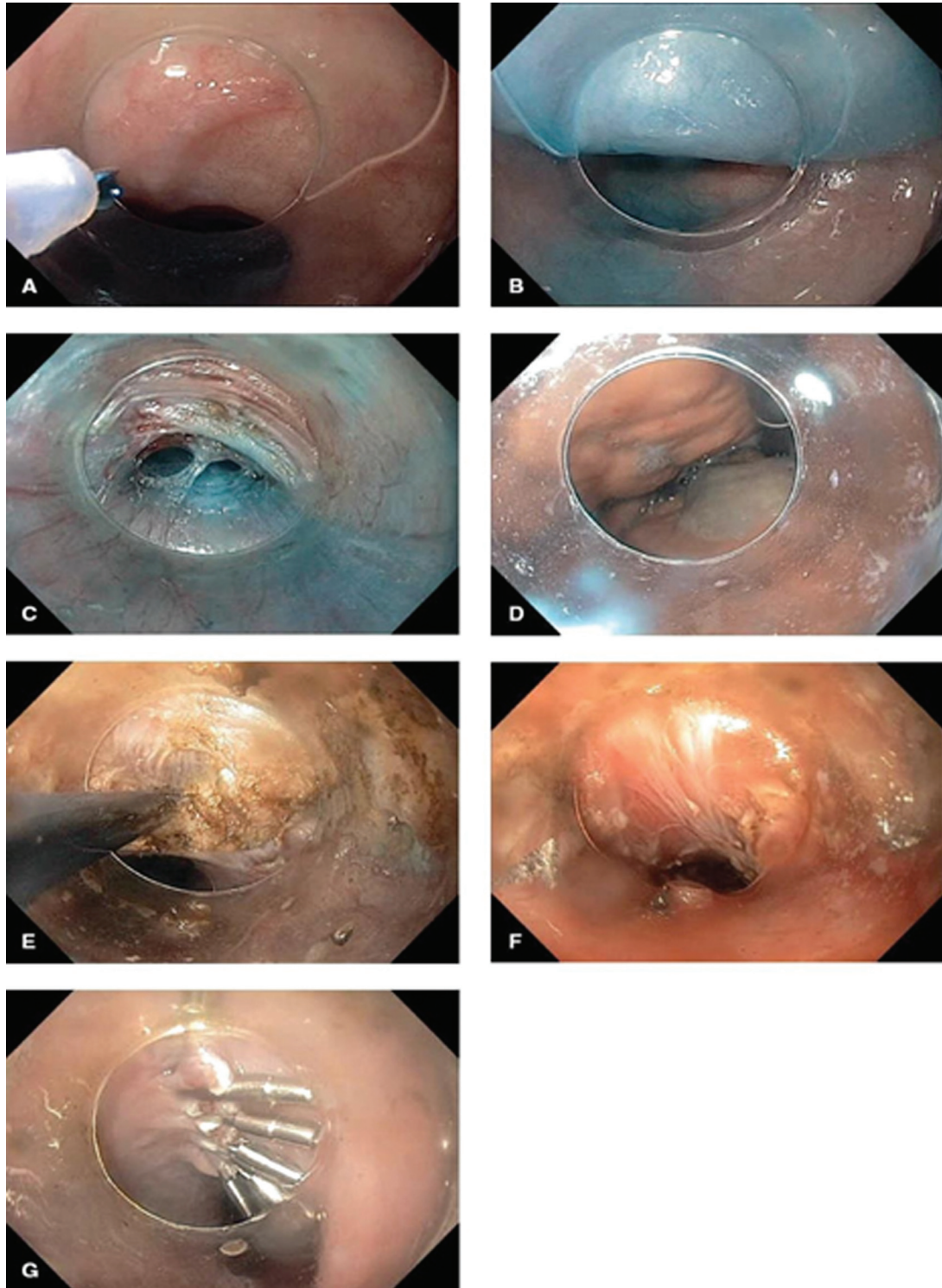
Problems were assessed according to the Clavien–Dindo classification of postoperative complications.

The Clavien–Dindo classification

The therapy used to correct a specific complication is the basis of this classification to rank a complication in an objective and reproducible manner.

It consists of seven grades (I, II, IIIa, IIIb, IVa, IVb, and V). The introduction of the subclasses a and b

Figure 2



Steps of POEM procedure: endoscopic view. (a) Injection needle for saline lift. (b) Mucosa lifted after saline injection. (c) Submucosal dissection. (d) Blue dye visualized in gastric cardia with retroflexion. (e) Circular muscle myotomy. (f) Myotomy completion with splaying of longitudinal muscle fibers. (g) Mucosal closure with clips. POEM, peroral endoscopic myotomy

allows a contraction of the classification into five grades (I, II, III, IV, and V) depending on the size of the population observed or the focus of a study.

Complications that have the potential for long-lasting disability after patient's discharge (e.g.

paralysis of a voice cord after thyroid surgery) are highlighted in the present classification by a suffix ('d' for disability). This suffix indicates that a follow-up is required to comprehensively evaluate the outcome and related long-term quality of life.

Grades	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are drugs such as antiemetics, antipyretics, analgesics, diuretics, and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic, or radiological intervention
IIIa	Intervention not under general anesthesia
IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU-management
IVa	Single organ dysfunction (including dialysis)
IVb	Multiorgan dysfunction
Grade V	Death of a patient

IC, intermediate care [16].

*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.

Three months postoperatively

Patients were contacted by phone and asked about clinical assessment using the Eckardt score.

Results

This study included 46 patients ($n=46$) who were admitted with symptoms of achalasia. Group 1 included 23 patients who underwent LHM, whereas group 2 included the other 23 patients who underwent POEM. Clinical assessment using the Eckardt score was done for all patients preoperatively and 3 months postoperatively. In this study, we compared LHM and POEM.

Group 1 included cases with an age range from 18 to 60 years (mean, 36.48 years), with a men: women ratio of 9 : 14 (39.1% : 60.9%), whereas group 2 patients' age ranged old from 18 to 63 years (mean, 35.8 years), with male : female ratio of 16 : 7 (69.6% : 30.4%). Overall, three (12.9%) patients with hypertension, type 2 diabetes mellitus, and liver cirrhosis were reported in group 1, whereas seven (30.1%) studied cases in group 2 had type 2 diabetes mellitus and ischemic heart disease, hypertension, chronic kidney disease and hypertension, hypothyroidism, hyperthyroidism, 3-A syndrome (achalasia, alacrimia, and Addison's disease), and chronic obstructive pulmonary disease (Table 1). The time of illness ranged from 4 months to 9 years (median, 2 years) in group 1, whereas in group 2, it ranged from 5 months to 16 years (median, 2 years).

BMI ranged from 22 to 28.2 kg/m² in group 1 and from 21.5 to 37 kg/m² in group 2.

LES pressure ranged from 23 to 56 mmHg (mean, 38.2 mmHg) in the group 1 studied cases, whereas in the group 2 studied cases, it ranged from 18 to 76 mmHg (mean, 38.3 mmHg). In the meanwhile, the integrated relaxation pressure ranged from 20.1 to 41.6 mmHg (mean, 30 mmHg) in group 1 patients and ranged from 11.5 to 49.4 mmHg (mean, 26 mmHg) in group 2 patients. There were six (26.1%) patients with type I achalasia, nine (47.8%) patients with type II achalasia, and six (26.1%) studied cases of type III achalasia in group 1, whereas in group 2, eight (34.7%) patients had type I achalasia, 12 (52.2%) patients had type II achalasia, and three (13.1%) patients had type III achalasia. In group 1, five patients had previous intervention (all were endoscopic balloon dilation), whereas in group 2, 10 patients had previous intervention (all were also endoscopic balloon dilation) (Table 2).

Operative duration ranged from 90 to 160 min in LHM patients (group 1) (mean, 125.7 min), whereas it ranged from 75 to 180 min in POEM patients (group 2) (mean, 123.8 min). The myotomy length was 5 cm in the esophagus and 3 cm in the stomach in patients of group 1, whereas it ranged from 5 to 7 cm in the esophagus and 3 to 4 cm in the stomach in group 2

Table 1 Demographic data

Variable	Group 1 'LHM' (N=23)	Group 2 'POEM' (N=23)
Patient factors		
Age (years)	36.48±10.3	35.8±13.3
Sex (male : female)	9 (39.1) : 14 (60.9)	16 (69.6) : 7 (30.4)
Comorbidities	3 (12.9)	7 (30.1)
Duration of illness (years)	2±2.5	2±2.5
BMI (kg/m ²)	24.5±1.5	27.9±6.5

Data are expressed as mean±SD or n (%).

Table 2 Manometry and types of achalasia

Variable	Group 1 'LHM' (n=23)	Group 2 'POEM' (n=23)
Manometry		
LES pressure	38.2±7.6	38.3±17
IRP	30±5.5	26±16.6
Type of achalasia I, II, and III	6 (26.1)	8 (34.7)
Previous intervention	11 (47.8)	12 (52.2)
Endoscopic	6 (26.1)	3 (13.1)
Balloon dilatation	5 (21.7)	10 (43.7)

IRP, integrated relaxation pressure; LES, lower esophageal sphincter. Data are expressed as mean±SD or n (%).

patients. The hospital stay ranged from 2 to 5 days (mean, 2.78 days) in group 1, whereas in group 2, it ranged from 2 to 8 days (mean, 3.22 days) (Table 3).

In group 1, five (21.7%) patients complained of weight loss less than 5 kg, 15 (65.2%) patients complained of weight loss from 5 to 10 kg, and three (13%) patients complained of weight loss greater than 10 kg. In group 2, six patients (26.1%) complained of weight loss less than 5 kg, five (21.7%) patients complained of weight loss from 5 to 10 kg, and 10 (43.5%) patients complained of weight loss greater than 10, whereas two (8.7%) patients did not complain of weight loss. The mean Eckardt score preoperatively was 7.04 in

group 1, whereas in group 2, it was 8.6 ($P=0.0001$) (Table 4).

Eckardt score postoperatively ranged from 0 to 3 (median, 1) in group 1 and in group 2, with no difference. BMI postoperatively ranged from 25.2 to 30.9 kg/m² (mean, 26.9 kg/m²) in group 1, whereas in group 2, it ranged from 16.02 to 43.36 kg/m² (mean, 26.8 kg/m²) (Table 5).

On comparing the Eckardt score and BMI preoperatively with postoperatively in group 1 (LHM) using paired *t* test, we found that there was

Table 3 Operative details and intraoperative and postoperative complications

Variable	Group 1 'LHM' (N=23)	Group 2 'POEM' (N=23)
Operative time (min)	125.7±22	123.8±34.9
Myotomy length (cm) esophagus	5	5-7
Stomach	3	3-4
Hospital stay	2.78±0.7	3.22±1.2
Complications	1 (4.3)	1 (4.3)

Data are expressed as mean±SD or *n* (%).

Table 4 Eckardt score preoperatively

Variable	Group 1 'LHM' (n=23)	Group 2 'POEM' (n=23)
Eckardt score	7.04±1.5	8.4±1.9
Preoperative	23 (100)	23 (100)
Dysphagia	16 (69.6)	20 (86.9)
Chest pain	23 (100)	22 (95.6)
regurgitation		
Weight loss	23 (100)	21 (91.3)

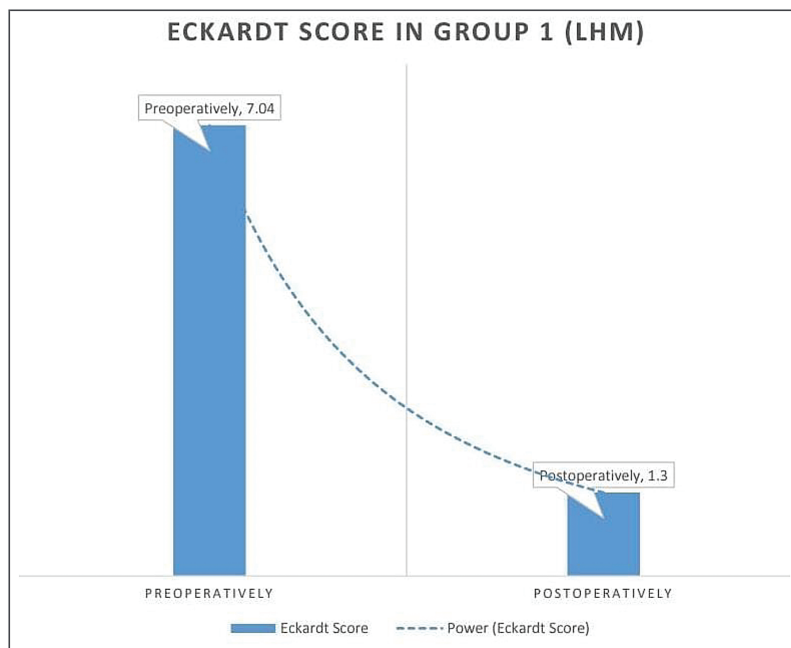
Data are expressed as mean±SD or *n* (%).

Table 5 Eckardt score and BMI postoperatively

Variable	Group 1 'LHM' (N=23)				Group 2 'POEM' (N=23)			
	Minimum	Maximum	Mean/median*	SD/IQR*	Minimum	Maximum	Mean/median*	SD/IQR*
Eckardt score (post)	0	3	1*	1*	0	3	1*	1*
BMI (post)	25.2	30.9	26.9	1.6	16.02	43.36	26.8	6.9

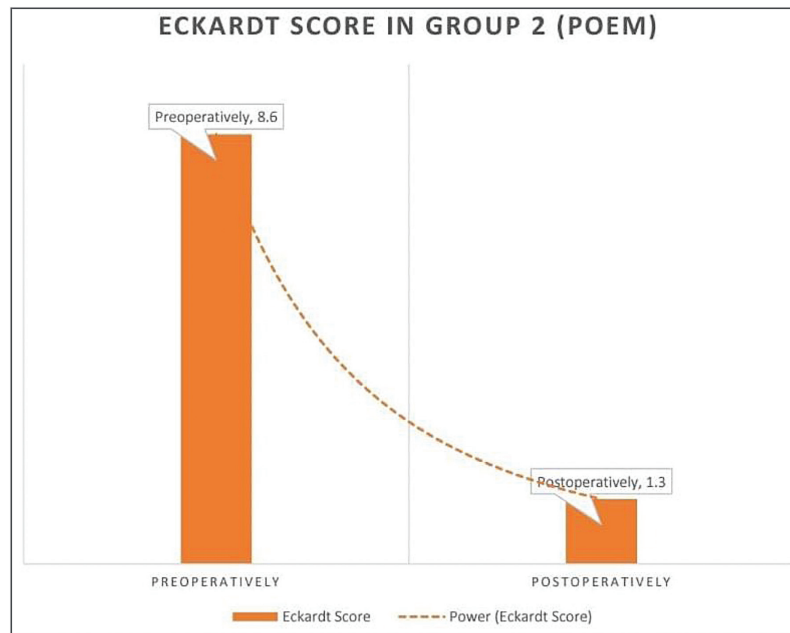
IQR, interquartile range. *Median and interquartile range.

Figure 3



Eckardt score in group 1 (LHM) preoperatively and postoperatively. LHM, laparoscopic Heller's cardiomyotomy.

Figure 4



Eckardt score in group 2 (POEM) preoperatively and postoperatively. POEM, peroral endoscopic myotomy.

Table 6 Comparing group 1 and group 2 regarding follow-up Eckardt score and BMI using *t* test

Variable	Group A 'LHM' (N=23)	Group B 'POEM' (N=23)	<i>P</i> value
Eckardt score			
Preoperative	7.04±1.5	8.4±1.9	0.0001
Postoperative	1±1	1±1	0.878
BMI (kg/m ²)			
Preoperative	24.5±1.5	27.9±6.5	0.001
Postoperative	26.9±1.6	27±0.924	0.924

Data are expressed as mean±SD or *n* (%). LHM, laparoscopic Heller's cardiomyotomy; POEM, peroral endoscopic myotomy. **P* value less than 0.05, significant.

significant improvement in the Eckardt score (with $P<0.0001$) and BMI (with $P<0.0001$) (Fig. 3).

On comparing the Eckardt score and BMI preoperatively with postoperatively in group 2 (POEM) using paired *t* test, we found that there was significant improvement in the Eckardt score (with $P<0.0001$) and BMI (with $P<0.0006$) (Figs. 3 and 4).

On comparing Eckardt score and BMI postoperatively in group 1 (LHM) with group 2 (POEM) using paired *t* test, we found that there was no important variation regarding Eckardt score and BMI after procedure between both groups (Table 6).

On comparing the cost of the operation in group 1 (LHM) with group 2 (POEM), we found that the cost in group 1 ranged from \$1200 to 1500 and in group 2 from \$2500 to 3500.

Discussion

POEM method was developed to cure achalasia. Inoue and colleagues published the first results of POEM in 17 studied cases with achalasia in 2010. Endoscopic submucosal tunneling allows for myotomy without the need for skin incision in POEM [9].

In our study, 46 patients who were admitted with symptoms of achalasia were included after confirmation of inclusion criteria. The studied cases were divided into two groups, with 23 studied cases each. Group 1 included patients who underwent LHM. Group 2 included patients underwent POEM. Clinical assessment using the Eckardt score was done for all patients preoperatively and 3 months postoperatively.

Most of the patients in our study were females (65%), in their middle age. In the study by Bhayani *et al.* [10], 52% of the studied cases were females, with a median

age of 49.5 years. This indicates that achalasia is more prevalent in young and middle-aged people.

In the study by Schneider *et al.* [11], BMI was lower in the LHM group, with a mean of 23.6 kg/m², which goes in line with our study, in which BMI ranged from 22 to 28.2 kg/m² in group 1 (mean±SD, 24.5±1.5 kg/m²) and from 21.5 to 37 kg/m² in group 2 (mean, 27.9±6.5 kg/m²). However, in the study by Schneider *et al.* [11], the mean±SD BMI in LHM patients was 22.9±3.6 and in POEM patients was 23.3±3.7. LES pressure in our study ranged from 23 to 56 mmHg (mean, 38.2 mmHg) in group 1, whereas in group 2, it ranged from 18 to 76 mmHg (mean, 38.3 mmHg). In the study by Bhayani *et al.* [10], the mean LES in LHM patients was 37 mmHg and in POEM patients was 41 mmHg. In the study by Schneider *et al.* [11], the mean LES in LHM patients was 40.86 mmHg and in POEM patients was 46.08 mmHg.

The most common type of achalasia encountered in the study was type II (45.6%), followed by type I and type III (30.4 and 19.5%, respectively). In the study by Schneider *et al.* [11], the most common type was type II (52%) followed by type I and type III (24 and 24%, respectively) in both groups. In the study by De Pascale *et al.* [12], the most common type was type II (97%) followed by type I (3%) in both groups.

In our study, the myotomy length was 5 cm in the esophagus and 3 cm in the stomach in group 1 patients, whereas it ranged from 5 to 7 cm in the esophagus and from 3 to 4 cm in the stomach in group 2 patients. In the study by Bhayani *et al.* [10], the myotomy length was 8 cm in the esophagus and 3 cm in the stomach in the LHM group, whereas it was 4 cm in the esophagus and 0 cm in the stomach in the POEM group. In the study by De Pascale *et al.* [12], myotomy was longer for the POEM group [12 (range: 10–15) vs. 9 cm (range: 7–10); $P=0.0001$].

In the study by Schneider *et al.* [11], the Clavien–Dindo grading system for postoperative problems revealed no statistical variations among processes ($P=1.00$). On postoperative day two after POEM, one studied case developed leakage into the abdominal cavity, which was closed with laparoscopic suturing. This goes in line with our study in which perforation was described in one (4.3%) studied case in group 1, whereas aspiration pneumonia was described in one (4.3%) studied case in group 2 ($P=0.386$). Therefore, there was no variation among both groups regarding complications.

In our study, the mean Eckardt score preoperatively was 7.04 in group 1, whereas in group 2 was 8.6. The

most common symptom was dysphagia, which was reported in all the patients in the two groups, followed by chest pain (78.2%), regurgitation (97.8%), and weight loss (97.8%). In the study by Bhayani *et al.* [10], the severity of symptoms in the studied cases, as measured by Eckardt score, was comparable between HMS and POEM groups (5.9 vs. 5.4, $P=0.5$). Nonepisodic dysphagia was the most common symptom, occurring at least weekly in 90% of the studied cases. Continuous regurgitation was more common in HMs (45 vs. 17%) than in POEMs ($P=0.01$). At the start, dysphagia, chest pain, and heartburn scores were all the same. In our study; there was a significant improvement in the Eckardt score in both groups. In group 1, the preoperative mean was 7.04.6 and the postoperative mean was 1.3, with $P<0.0001$, and in group 2, the preoperative mean was 8.6 and the postoperative mean was 1.3, with $P<0.0001$. There was also a significant improvement of the BMI (in group 1, the preoperative mean was 24.5 and the postoperative mean was 26.9, with $P<0.0001$, and in group 2, the preoperative mean was 26.2 and the postoperative mean was 27.2, with $P<0.0006$). There was no significant variation regarding Eckardt score and BMI after the procedure between both groups. In the study by Schneider *et al.* [11], therapy success was 91% (POEM) and 84% (LHM) ($P=0.444$) based on the Eckardt score of less than 3. Similar changes in Eckardt scores were seen in the research comparing these two processes, from preoperative scores of 6 or 7 to 1 or 2 after both processes. In the study by Park *et al.* [13], the POEM group had a lower (better) postoperative Eckardt score than the HM group. In the study by Zhang *et al.* [14], after surgery, studied cases in the POEM group had lower Eckardt scores than those in the LHM group.

In the end, it is important to emphasize that our study was not without limitations. Our limitations included the small sample size, the short follow-up, as well as the absence of some variables (e.g. postoperative manometry, postoperative upper endoscopy, and patients' compliance).

This study was a prospective randomized trial aiming to study clinical reflux using the Eckardt score, improvement of symptoms, and increase in BMI primarily. Therefore, we did not do follow the patients using neither endoscopy nor manometry, although they can be done in another study to confirm our data.

The small number and short follow-up duration are – surely – weak points, but they are because of rarity of this disease and scarce number of patients who can

afford and agree to go for laparoscopic cardiomyotomy or POEM. Yet, we recommend increasing the sample size in next studies and have a longer follow-up time.

In the end, we know that this study was designed for short follow-up duration and on a small sample size; however, our result was in favor with the Heller's cardiomyotomy over POEM regarding the occurrence of GERD symptoms postoperatively.

After all, we do recommend more research studies with longer follow-up duration, wider sample size, and a better subjective assessment in assessing the LES postoperatively using the endoscopy or the manometry to confirm these results.

Conclusion

There was no significant difference between LHM and POEM in terms of their resolution or improvement of symptoms of achalasia as measured by the Eckardt score, but there was a significant difference regarding GERD symptoms postoperatively between both groups in which GERD symptoms postoperatively occurred with POEM and did not occur with LHM.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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