Evaluation of Short-term Outcomes of Laparoscopic Heller Cardiomyotomy with Dor Fundoplication Versus Pneumatic Dilatation for Treatment of Achalasia

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Abstract

**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 or laparoscopic Heller's myotomy combined with an anti-reflux procedure. The study aim was to compare laparoscopic Heller cardiomyotomy plus Dor Fundoplication with pneumatic dilatation for treatment of achalasia.

**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: pneumatic dilation or laparoscopic Heller's cardiomyotomy with Dor's fundoplication (LHCM). Follow-up evaluations were performed after 8 and 16 months.

**Results:** In total, 50 patients with achalasia and an Eckardt symptom score > 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 pneumatic dilation group. There were no other statistically significant differences in the primary or secondary outcomes (Eckardt score, lower esophageal sphincter, and quality of life) 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 pneumatic dilation. We conclude that either treatment is suitable as an initial treatment for achalasia.

**Background**

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 approximately 0.5 to 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 bland undigested food or saliva, heartburn, and weight loss, which often lead to misdiagnosis of achalasia as 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 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 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 ≤ 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]. The main aim of this study was to compare LHCM with PD for the treatment of achalasia.

**Patients And Methods**

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 mm Hg) or by a barium study if their Eckardt symptom score was > 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.

| Symptoms       | Score       |
|----------------|-------------|
|                | 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         |

Table 1

Eckardt score: The final score is the sum of all 4 symptoms score, with range from 0–12.
### 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%)                    | 1.000   |
| Female                  | 14 (56.0%)                                                       | 15 (60.0%)                    |         |
| **Occupations**         |                                                                  |                               |         |
| Not Working             | 14 (56.0%)                                                       | 13 (52.0%)                    | 1.000   |
| Working                 | 11 (44.0%)                                                       | 12 (48.0%)                    |         |
| **Comorbidity**         |                                                                  |                               |         |
| 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**             |                                                                  |                               |         |
| 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   |
| **Body Mass Index (kg/m²)** | 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   |

The following data were obtained from each patient:

- Personal history: age, sex, weight, Body Mass Index (BMI), height, occupation, marital status, smoking, family history, and history of chronic diseases.
- A physical examination and standard hematological and blood chemical work up were also performed for all patients.
• 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. Four patients out of 50 did not meet the exclusion criteria, including patients unfit for surgery, patients previously treated for achalasia, mega-esophagus (diameter > 7 cm), and pseudo-achalasia. The patient selection flow chart is shown in Fig. 1.

Interventions:

• **Pneumatic dilation:**

At the esophagogastric junction, a Rigiex 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 > 3, a third dilation was performed weeks later with a 40-mm balloon. If the Eckardt score was persistently > 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 1–2 cm over the stomach. Then, anterior Dor fundoplication of 180° was performed. During the follow-up period, if the patients exhibited symptoms of Eckardt score > 3 after surgery, the treatment was considered to have failed.

Outcomes:

• The principle end result of the study was to keep the Eckardt score ≤ 3 during the follow-up period, which stretched to ≥ 18 months for all participating subjects. Therefore, esophageal manometry to assess the lower esophageal pressure along with barium swallow was performed at every follow-up attempt.

• 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 0–100, 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 symptoms scores > 3 underwent one of two different procedures. The mean ages of the patients who underwent the LHCM and pneumatic dilation procedures were 45.86 ± 15.25 years and 80 ± 12.35 years, respectively. The number of females in the LHCM and pneumatic dilation groups were 14 (56%) and 15 (60%), respectively. Furthermore, the mean BMI values were 25.35 ± 1.11 kg/m2 in the LHCM group and 25.79 ± 0.91 kg/m2 in the pneumatic dilation 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 3 shows the primary and secondary outcomes at 8 and 16 months of follow-up. There was a significant difference in the height of the barium-contrast column after 5 minutes between the two groups at 16 months. A comparison of the successful treatment rates, as shown by Kaplan–Meier survival curves, for PD with LHCM is shown in Fig. 2.
Table 3
Primary and secondary outcomes at 8 and 16 months of follow-up according to treatment

|                        | Baseline    | After 8 Months | After 16 Months |
|------------------------|-------------|----------------|-----------------|
|                        | LHM (n = 25) | PD (n = 25)    | P Value         | LHM (n = 25)     | PD (n = 25)    | P Value |
| Eckardt score          | 8.04 ± 2.5  | 7.08 ± 1.89   | 0.141           | 1.04 ± 1.060     | 1.72 ± 1.275  | 0.053   |
| Lower esophageal       | 30.36 ± 1.4 | 34.20 ± 1.9   | 0.051           | 1.04 ± 1.25      | 11.60 ± 1.89  | 0.240   |
| sphincter (mmHg)       | 11          | 79            |                 | 8               | 3             |         |
| Height of barium       | 13.48 ± 3.4 | 14.72 ± 3.0   | 0.396           | 3.88 ± 2.522     | 5.48 ± 2.917  | < 0.001 |
| contrast column after 5 min (cm) |           |                |                 |                 | *            |
| 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   |
|                        | 00          | 35            |                 | 81              | 25           |         |
| Short-Form Health Survey (SF-36) |         |                |                 |                 |              |
| Physical component summary | 47.72 ± 1.3 | 48.08 ± 1.4   | 0.341           | 54.76 ± 0.7      | 51.92 ± 1.1   | 0.110   |
|                        | 70          | 12            |                 | 79              | 87           | 3       |
| Mental component summary | 41.60 ± 1.4 | 43.92 ± 1.8   | 0.451           | 49.44 ± 1.4      | 49.28 ± 1.5   | 0.735   |
|                        | 14          | 01            |                 | 74              | 42           | 8       |

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)

Complications of achalasia treatment are outlined in Table 4. The mucosal tear rate was 4.0% in the LHCM group, and the number of esophageal perforation complications was 8.0% in the PD group. The recurrence rates were 24.0% in the LHCM group and 32% in the PD group.
### Table 4
Comparison of the preoperative and postoperative complications between the two groups

|                          | Laparoscopic Heller Cardiomyotomy with Dor Fundoplication (n = 25) | Pneumatic Dilatation (n = 25) | 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** | [After 1 month]                                                   |                               |         |
| Recurrent                | 6 (24.0%)                                                         | 8 (32.0%)                     | 0.754   |

### Discussion

Heller cardiomyotomy and endoscopic PD are the two main treatments for achalasia and disrupt the circular muscle of the LES. 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 to 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 LHM was similar to that of PD after 2 years of follow-up [13]. 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 [14, 15]. Hence, the main objective of this study was to use a randomized study design to evaluate the two state-of-the-art treatments, PD and LHCM.

We conducted this study in a sample of 50 patients diagnosed with achalasia and who had an Eckardt symptom score > 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., [16], who conducted a study in 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. demonstrated that the post-procedure 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 [17] in contrast to a study by An 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. [16] 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. [16] 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 ≤ 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 An 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. [16] 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 Jan Persson et al. [7] using the Psychological General Well-being (PGWB) questionnaire showed that the total PGWB 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. [16] 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 An 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. [18] that showed no significant difference in the decrease in the LES pressure < 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 8% of patients, a rate that is comparable to that previously reported by Boeckxstaens et al. [16]. Esophageal perforation appeared in four (4%) of the 95 patients in the PD group, which is comparable to that reported by Emad Hamdy et al. [9]. Esophageal perforation occurred in two (8%) 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 the 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 MF et al. 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 [17]. In a study by Emad Hamdy et al., 16% and 28% of patients developed reflux symptoms after PD and laparoscopic Heller myotomy, respectively [9].

The current study showed no significant difference in recurrence of symptoms after 1 month between the two groups, which were 24% and 32% in the LHCM and PD groups, respectively. These findings were comparable to those reported by Emad 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 An Moonen et al. [6] that 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 Jan 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 a single center, 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 post-procedure motility studies.

**Conclusion**

This study showed that the therapeutic success rates of LHCM at different follow-up time points were not superior to those of PD, indicating that graded dilation starting with a 30-mm balloon is an appropriate procedure for PD.

**List Of Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| LHCM         | Laparoscopic Heller’s cardiomyotomy with Dor’s fundoplication |
| LES          | Lower esophageal sphincter |
| GERD         | Gastroesophageal reflux disease |
| PD           | Pneumatic dilatation |
| BMI          | Body Mass Index |

**Declarations**

**Funding**

No funding was received.
Ethical approval and consent to participate

All procedures performed in our study involving human participants was in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent for publication

We obtained consent from all the patients included in our study with institutional consent forms.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request. All data generated or analyzed during this study are included in this published article [and its supplementary information files].

Competing interests

The authors declare that they have no competing interests.

Authors’ contributions

IK, GMB, MF carried out and participated in the surgical procedures, MS carried out the pneumatic dilatation. MF, IK, MS conceived the study, participated in study design and sequence alignment, and drafted the manuscript. S Abdulaziz, LSO & S Alshafie helped to draft and critically revise the manuscript. GMB & IK participated in data collection and performance of the statistical analysis. S Abdulaziz, LSO & S Alshafie participated in study coordination, and critical revision. All authors have read and approved the final manuscript.

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