Comparison between outcome after laparoscopic Heller's myotomy with Dor fundoplication in patients who had or had not undergone previous trials of endoscopic balloon dilatation for cardiac achalasia

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Aim
The aim of this study is to assess the effect of prior endoscopic balloon dilatation on the outcome of laparoscopic Heller's cardiomyotomy with Dor fundoplication (DF) for treatment of cardiac achalasia.

Patients and methods
This study was conducted over 20 patients who underwent laparoscopic Heller's cardiomyotomy with DF between January 2018 and December 2020 in Ain Shams University Hospitals. These patients were divided into two groups: the first group included patients who underwent Heller's cardiomyotomy with DF with previous once or multiple failed sessions of balloon dilatation [pneumatic balloon dilatation (PBD) group]. The second group included patients who underwent Heller's cardiomyotomy with DF without previous balloon dilatation (non-PBD group). Each patient was seen for follow-up after 6 months. Preoperative and postoperative achalasia symptoms, including weight loss, dysphagia, heartburn, and regurgitation, were evaluated using the Eckardt score.

Results
When patients were compared according to whether they underwent preoperative endoscopic PBD or not, there was no significant difference in terms of age, sex, preoperative lower esophageal sphincter pressure, hospitalization period, and complications. Operative time had a statistically significant difference between the two groups of patients. The mean Eckardt score measured at 6 months postoperative was significantly lower than the preoperative Eckardt score (0.55 ±0.69 vs. 4.45±1.36, $P<0.001$). In contrast, there was no significant difference in the preoperative and postoperative Eckardt scores between patients who underwent preoperative endoscopic PBD and those who did not (pre was $P=0.637$ and post was $P=0.404$).

Conclusion
Laparoscopic Heller–Dor surgery is an effective procedure in relieving achalasia symptoms as a first-line therapy as well as in individuals with repeated previous endoscopic PBDs. Patients with previous PBDs (the PBD group) had a longer operative time with increased difficulty of dissection due to fibrosis and adhesions.

Keywords:
achalasia, balloon dilatation, laparoscopic Heller, 's myotomy

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Introduction

Achalasia is a primary esophageal motor disorder of unknown etiology. Its clinical presentation is characterized by progressive dysphagia, thoracic pain, and the regurgitation of partially digested food, having an important secondary impact on the nutritional status of the patients. High-resolution manometry is the criterion standard for making the diagnosis [1].

Achalasia is characterized manometrically by insufficient relaxation of the lower esophageal sphincter (LES) and loss of esophageal peristalsis. Radiographically, it shows aperistalsis, esophageal dilation with minimal LES opening, 'bird-beak' appearance, and poor emptying of barium. Upon endoscopy, there is dilated esophagus with retained saliva, liquid, and undigested food particles in the absence of mucosal stricturing or tumor. Achalasia

occurs equally in both sexes with prevalence that ranges up to 1 per 10 000 persons [2].

Complications of achalasia include esophageal perforation, recurrence, gastroesophageal reflux disease, bloating, and potential cancer risk [3].

Achalasia is a chronic condition without cure. Current treatment options in achalasia are aimed at reducing the hypertonicity of the LES by pharmacologic, endoscopic, or surgical means. No intervention significantly affects esophageal peristalsis, and despite therapeutic interventions, the LES hypertonicity returns over time, requiring repeated interventions [4].

Pneumatic dilatation and Heller's myotomy are two recognized treatment options that involve disruption of the LES to improve esophageal emptying and relieve dysphagia [5].

Pneumatic endoscopic dilatation uses air pressures to intraluminally dilate and disrupt the circular muscle fibers of the LES. Pneumatic endoscopic dilatation of the LES is considered the most effective nonsurgical treatment for achalasia [6].

The goal of surgery is to alleviate the distal esophageal obstruction by division of the circular muscle fibers comprising the LES. Myotomy can be accomplished via laparotomy, thoracotomy, and since the early 1990s, laparoscopically and thoracoscopically [7].

There is some debate about whether preoperative balloon dilation influences the outcomes of laparoscopic Heller–Dor surgery, with no consensus opinion yet [8].

Patients and methods

After the approval of the local ethical committee, this comparative prospective clinical trial was conducted over 20 patients who underwent laparoscopic Heller's cardiomyotomy with Dor fundoplication (LHM +DF) between January 2018 and December 2020 in Ain Shams University Hospitals, with the last patient seen for follow-up that was in February 2021. These patients were divided into two groups:

Group A included patients who underwent Heller's cardiomyotomy with DF with previous once or multiple failed sessions of balloon dilatation [pneumatic balloon dilatation (PBD) group].

Group B included patients who underwent Heller's cardiomyotomy with DF without previous balloon dilatation (non-PBD group).

All patients in the study were fully informed about the procedure they had, it is possible sequelae, and its complications. An informed consent was taken from all patients who accepted to participate.

All patients were subjected to the following.

Preoperative assessment

(1) Full clinical history, including dysphagia for solids and liquids, regurgitation of undigested food, respiratory complications (nocturnal cough and aspiration), chest pain, heartburn, and weight loss.
(2) Full clinical examination: general and local abdominal examination.
(3) Investigations including:
    (a) Routine preoperative laboratory investigations: complete blood count, random blood sugar, liver-function tests, kidney-function tests, coagulation profile, serum electrolytes, and routine viral markers.
    (b) Routine preoperative radiological investigations (when needed): ECG, echocardiography, and plain chest radiograph.
    (c) Specific investigations: esophageal manometry evaluating esophageal peristalsis and LES pressure and upper gastrointestinal tract endoscopy commenting on esophageal peristalsis and LES (some patient did a barium swallow showing smooth tapering of the lower esophagus, leading to the closed LES resembling a 'bird's beak').

Procedure

All patients underwent LHM+DF. The myotomy length covered all narrowed segments and extended from the distal esophagus (6–8 cm) to at least 2–3 cm to the gastric fundus.

Postoperative management

The patient were transferred from postanesthesia recovery unit to the ward for vital data follow-up and follow-up of bowel movements. After 8 h, patients might be started on a clear liquid diet if there was no perforation of the esophagus during the myotomy.

On postoperative day number 2, a soft mechanical diet may be instituted. In the case of the patient in whom there was a perforation that was repaired

intraoperatively, it was prudent to order a gastrografin esophagram on the first postoperative day to ensure that there was no leak, if none was seen, the patient might begin a clear liquid diet with progression to the soft diet the following day.

Most of the patients were able to be discharged from the hospital on the second or third day after surgery after removing the drain. Generally, patients were maintained on the soft diet for 2–3 weeks after the operation, and if they were not experiencing any significant dysphagia at that time, they might fully liberalize their diet as tolerated.

Outcome assessment

The results of the two groups were compared as regards the following endpoints:

(1) Intraoperative difficulties (as prolonged operative time, adhesions, incidence of perforation, or bleeding) as well as early postoperative complications such as wound infection.
(2) Careful analysis of dysphagia-symptom relief in the patients during postoperative follow-up (after 6 months). The degree of symptoms, including weight loss, dysphagia, retrosternal pain, and regurgitation, was graded during the follow-up using the Eckardt score.

Statistical analysis

Data of patients' demographics, laboratory values, clinical presentation, radiological imaging findings, surgical treatment, perioperative complications, pathological features, and postoperative course were collected and analyzed. Data were analyzed using the SPSS for Windows, version 23.0 (SPSS Inc., Chicago, Illinois, USA), and the Kolmogorov– Smirnov test was used to determine whether the distribution of continuous variables was normal. Continuous variables were shown as mean±SD or median (minimum–maximum). Otherwise, the number of cases and percentages were used for categorical data. Independent *t* test was used to compare between PBD and non-PBD groups in quantitative data that were parametric, and χ^2 test was used to compare between PBD and non-PBD in qualitative data. The Wilcoxon signed-rank test was used to compare between the preoperative and postoperative Eckardt scores. The Mann–Whitney *U* test was used to compare the preoperative and postoperative Eckardt scores between patients who underwent preoperative endoscopic PBD and those who did not. The results were considered significant with *P* value less than 0.05 and highly significant with *P* value less than 0.01. *P* value more than or equal to 0.05 was considered nonsignificant.

Results

Twenty patients underwent LHM+DF, of which nine (45%) were males and 11 (55%) were females. The mean age of patients was 36.25±7.83 years. The average duration of symptoms was 12.25 months (2–36), with dysphagia being the most common presenting symptom (*n*=16, 80%). The mean preoperative LES pressure was 36±8.23 mmHg. Fourteen (70%) patients underwent preoperative endoscopic PBDs. The mean ratio of repeated endoscopic PBDs was 2.07±1.38. A total of 29 endoscopic PBDs were performed in fourteen patients. Ten (71.43%) patients underwent up to two endoscopic PBD sessions, three (21.43%) underwent three sessions, and one (7.14%) underwent six sessions. The mean operative time was 105.5±16.13. Intraoperative bleeding occurred in three patients (one of them from the non-PBD group and two from the PBD group) from short gastric vessels, which stopped after sealing of these vessels and using the harmonic blade. Mucosal perforation occurred in one patient from the PBD group, and it was repaired by simple interrupted vicryl 3–0 sutures. Wound infection occurred in three patients, two of them from the non-PBD group. The mean duration of hospital stay was 2.35±0.59 days. There was no mortality (Table 1).

When patients were compared according to whether they underwent preoperative endoscopic PBD or not, there was no significant difference in terms of age, sex, preoperative LES pressure, hospitalization period, and complications. Operative time had a statistically significant difference between the two groups of patients (Table 2).

The mean Eckardt score measured at 6 months postoperative was significantly lower than the preoperative Eckardt score [0.55±0.69 vs. 4.45±1.36 ($P<0.001$)]. In contrast, there was no significant difference in the preoperative and postoperative Eckardt scores between patients who underwent preoperative endoscopic PBD and those who did not (pre was $P=0.637$ and post was $P=0.404$) (Table 3).

Discussion

Esophageal achalasia is a typical disease entity with primary esophageal motility disorder, with unknown pathology [2]. The incidence rate of this disorder does not differ between sexes [9], and no difference has been reported between races [10]. There is no peak age of

Table 1 Patient characteristics and demographic data

Patients who underwent surgery (*N*=20)		
Age (years)	36.25±7.83	20–48
Sex [*n* (%)]		
Males	9 (45)	
Females	11 (55)	
Preoperative symptoms: dysphagia [*n* (%)]	16 (80)	
Regurgitation	3 (15)	
Heartburn	1 (5)	
Duration of symptoms (months)	12.25±8.16	2–36
Lesser esophageal pressure (mmHg)	36±8.23	26–49
Preoperative endoscopic PBD: yes [*n* (%)]	14 (70)	
No	6 (30)	
Number of preoperative endoscopic PBDs	2.07±1.38	
Mean operating time (min)	105.5±16.13	75–135
Complications: bleeding	3 (15)	
Perforation	1 (5)	
Infection	3 (15)	
Hospital stay (days)	2.35±0.59	2–4

PBD, pneumatic balloon dilatation.

Table 2 Comparison of the patients who underwent preoperative endoscopic pneumatic balloon dilatation with those who did not

	Non-PBD *N*=6	PBD *N*=14	Test value	*P* value	Significance
Age					
Mean±SD	39.17±8.47	35.00±7.50	1.097	0.287	NS
Range	27–51	20–48			
Sex [*n* (%)]					
Female	5 (83.3)	6 (42.9)	2.780	0.095	NS
Male	1 (16.7)	8 (57.1)			
Lesser esophageal pressure (mmHg)					
Mean±SD	33.67±8.04	37.00±8.39	–0.823	0.421	NS
Range	28–49	26–49			
Mean operating time (min)					
Mean±SD	85.83±9.17	113.93±9.64	–6.051	0.000	HS
Range	75–100	105–135			
Hospital stay (days)					
Mean±SD	2.33±0.52	2.36±0.63	–0.081	0.936	NS
Range	2–3	2–4			
Complications [*n* (%)]					
Bleeding	1 (16.7)	2 (14.3)	0.019	0.891	NS
Perforation	0	1 (7.1)	0.451	0.502	NS
Wound infection	2 (33.3)	1 (7.1)	2.260	0.133	NS

PBD, pneumatic balloon dilatation.

onset [11]. The typical symptoms, such as dysphagia, regurgitation, and chest pain, markedly impair quality of life, and spontaneous resolution cannot be expected. Thus, young patients with this disorder are often treated, while favorable outcomes of surgical treatment have also been reported [12].

This study evaluated the outcomes of LHM in achalasia patients who underwent preoperative endoscopic PBD and showed that LHM+DF is an effective procedure in relieving achalasia symptoms as a first-line treatment, as well as in patients unresponsive to repeated endoscopic PBDs. LHM is the treatment of choice in patients undergoing surgery. In the present study, all patients underwent DF following LHM. Anterior DF is preferred because of its simplicity, decreased need for extensive dissection, and protection against potential intraoperative unrecognized mucosal leaks.

Extended cardiomyotomy is preferred too (extending 2–3 cm to the gastric wall) with the aim of better and

Table 3 Comparison of the preoperative and postoperative Eckardt scores

	Eckardt score		Test value	*P* value	Significance
	Preoperative	Postoperative			
Overall (*N*=20)					
Mean±SD	4.45±1.36	0.55±0.69	–3.962≠	0.000	HS
Range	2–8	0–2			
Preoperative endoscopic PBD					
Yes (*N*=14)					
Mean±SD	4.29±1.27	0.64±0.74	–3.336≠	0.000	HS
Range	2–6	0–2			
No (*N*=6)					
Mean±SD	4.83±1.60	0.33±0.52	–2.226≠	0.026	S
Range	4–8	0–1			
Mann–Whitney test					
Z	–0.472	–0.834			
P value	0.637 (NS)	0.404 (NS)			

PBD, pneumatic balloon dilatation. ≠Wilcoxon rank test.

sustained resolution of dysphagia than the traditional cardiomyotomy (1–1.5 cm). Jara *et al.* [13] showed a proportional relationship with myotomy length and GERD development. DF is added to relieve this undesirable side effect.

Vaezi *et al.* [14] reported that endoscopic PBD has a good initial response; however, the risk of a potentially life-threatening perforation has been reported in up to 2% of patients in experienced hands (range, 0–16%). Further, GERD occurred in 15–33% of patients after this procedure, which was usually managed with proton-pump inhibitors. Karamanolis *et al.* [15] claimed that PBD is an effective therapeutic procedure for selected patients. However, its long-term outcomes are less favorable, and some patients require repeated treatment.

In this study, twenty achalasia patients underwent LHM+DF. Fourteen (70%) patients underwent preoperative endoscopic PBD. The mean ratio of repeated endoscopic PBD was 2.07±1.38. A total of 29 endoscopic PBDs were performed in 14 patients. Öter *et al.* [16], had a similar study, over 65 patients underwent LHM+DF, of which 32 (49.2%) were males and 33 (50.8%) were females. The mean age of patients was 38.5±14.2 years. Forty-five (69.2%) patients underwent preoperative endoscopic PBDs. The mean ratio of repeated endoscopic PBD was 1.7 ±1.5. A total of 106 endoscopic PBDs were performed in 45 patients. Tsuboi *et al.* [17], had a study, including 100 men and 101 women with a median age of 31 years, of whom 158 patients without a history of pneumatic dilatation (79%, non-PBD group) and 43 with a history of pneumatic dilatation (21%, PBD group).

In this study, the mean operative time for the PBD group was higher than the non-PBD group. Öter *et al.* [16], showed no statistically significant difference between the two groups concerning the operative time. Tsuboi *et al.* [17], reported that operative time did not show any differences between the two groups.

Concerning complications, in this study, intraoperative bleeding occurred in three patients from short gastric vessels, which stopped after the ligation of these vessels and using the harmonic device. Two of these patients were from the PBD group and one from the non-PBD group. Öter *et al.* [16], reported intraoperative bleeding in two patients from arteria gastrica breves, which stopped after the ligation of these vessels. Tsuboi *et al.* [17], did not report significant blood loss during operations, and so, intraoperative blood loss did not show any differences between the two groups.

In this study, a small esophageal mucosal perforation occurred in one patient from the PBD group, and the perforation was sutured using 3–0 vicryl suture. Öter *et al.* [16], claimed that esophageal mucosal perforation occurred in three (4.6%) patients, which was detected during the operation and treated by primary repair. The three patients with esophageal perforation were those who underwent prior repetitive endoscopic PBDs. Endoscopic PBD causes fibrotic changes in the esophageal muscular layers, which may complicate the myotomy and decrease the success of LHM+DF. Tsuboi *et al.* [17], reported that injury of mucosa occurred in 13% of the non-PBD group of patients and in 14% of the PBD group of patients. So, in their study, the incidence of esophageal/gastric mucosal injury, was not statistically different between the two groups. Bonavina *et al.* [18] reported that the incidence

of intraoperative mucosal tears was 5% in the non-PBD group and 12.5% in the PBD group.

In this study, the mean duration of hospital stay was 2.35±0.59 days. In Öter *et al.* [16] study, the mean duration of hospital stay was 6.2±1.40 days. Tsuboi *et al.* [17], claimed that postoperative hospital stay did not show any differences between the two groups.

In this study, the mean Eckardt score measured at 6 months postoperative was significantly lower than the preoperative Eckardt score [0.55±0.69 vs. 4.45±1.36 ($P<0.001$)]. In contrast, there was no significant difference in the preoperative and postoperative Eckardt scores between patients who underwent preoperative endoscopic PBD and those who did not (pre was $P=0.637$ and post was $P=0.404$). Öter *et al.* [16], reported that the mean Eckardt score measured postoperatively was significantly lower than the preoperative Eckardt score [4.51±1.8 vs. 0.52±0.7 ($P<0.001$)], but there was no significant difference in the preoperative and postoperative Eckardt scores between patients of the two groups ($P=0.43$). Tsuboi *et al.* [17], reported that in both groups, all symptom scores for dysphagia, regurgitation, chest pain, and heartburn were decreased after surgery (dysphagia: non-PBD, 12.5–1.7, $P<0.0001$; PBD, 11.1–2.5, $P<0.0001$) (regurgitation: non-PBD, 8.6–0.6, $P<0.0001$; PBD, 5.0–0.3, $P=0.0004$) (chest pain: non-PBD, 3.9–1.1, $P<0.0001$; PBD, 4.0–1.0, $P=0.001$) (heartburn: non-PBD, 1.2–0.4, $P=0.0039$; PBD, 1.8–0.1, $P=0.0051$). A comparison of postoperative symptom scores between the two groups revealed no differences. Moreover, both groups expressed equally high satisfaction with surgery [non-PBD vs. PBD (median)=5 vs. 5, $P=0.8535$].

A retrospective study, Schlottmann *et al.* [19], has claimed that multiple preoperative endoscopic treatments affect the outcomes of LHM. According to Souma *et al.* [20], repetitive endoscopic PBDs may cause submucosal hemorrhage, resulting in fibrosis and adhesion formation over time, which makes surgical myotomy difficult and increases the risk of esophageal mucosal perforation.

Which treatment should be considered as a first-line therapy? The answer to this question is not obvious because of similar long-term results in the literature and the findings of this study. Endoscopic PBD, LHM, and POEM can be offered with certain advantages. However, LHM may be considered in patients in whom dysphagia persisted, despite two or more endoscopic PBD sessions.

To conclude, our study seems to indicate that dysphagia significantly improves after LHM+DF. Although endoscopic PBD is a less invasive method and is associated with a quicker recovery, dysphagia does not resolve or recur in a proportion of patients. LHM+DF is equally effective in patients unresponsive to repetitive endoscopic PBDs and should be considered in patients whose dysphagia symptoms persist even after two or more endoscopic PBD sessions. However, previous PBD sessions negatively impact the LHM+DF in terms of operative time and difficulty of dissection due to increased adhesions and fibrosis.

The present study had some limitations. At first, some of the patients in our study had performed balloon dilatation at other hospitals. Because they were not performed in accordance with coherent protocol of preoperative balloon dilatation, we could not completely remove the selection bias in our study. Second, the sample size was small.

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Conflicts of interest
There are no conflicts of interest.

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