Effects of preoperative endoscopic pneumatic balloon dilatation on postoperative achalasia symptoms after Heller esophageal myotomy plus Dor fundoplication

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ABSTRACT

Background/Aims: *Currently, forceful endoscopic pneumatic balloon dilatation (PBD), laparoscopic Heller myotomy (LHM) with or without an anti-reflux procedure, and peroral endoscopic myotomy are the preferred treatment options for achalasia. The aim of the present study was to retrospectively compare postoperative outcomes after LHM plus Dor fundoplication (DF) between patients who underwent prior endoscopic balloon dilatation and those who did not.*

Materials and Methods: *Sixty-five patients who underwent HM+DF between January 2008 and December 2016 were retrospectively analyzed. Of these, 45 had a history of endoscopic PBD. Pre- and postoperative achalasia symptoms, including weight loss, dysphagia, heartburn, and regurgitation, were evaluated using the Eckardt score.*

Results: *Fifty (76.9%) patients underwent laparoscopic surgery and 15 (23.1%) underwent open surgery. When patients were compared according to the presence of preoperative endoscopic PBD, no significant difference were observed in terms of age, sex, preoperative lower esophageal sphincter pressure, operation time, hospitalization period, and follow-up period ($p>0.05$). The mean Eckardt score at the first postoperative year was significantly lower than the preoperative Eckardt score (4.51±1.8 vs. 0.52±0.7; $p<0.001$). In contrast, no significant difference was found between patients with and without previous PBD on the pre- and postoperative Eckardt scores ($p=0.43$).*

Conclusion: *HM+DF is an effective procedure in relieving achalasia symptoms as a first-line therapy as well as in individuals unresponsive to repeated endoscopic PBDs.*

Keywords: *Achalasia, dysphagia, Eckardt score, pneumatic balloon dilatation, Heller myotomy, Dor fundoplication*

INTRODUCTION

Achalasia is a motor disorder characterized by a decreased or absent esophageal body peristalsis and inability to sufficiently relax the lower esophageal sphincter (LES). These features lead to a failure in the passage of bolus via the esophagogastric junction. Dysphagia, heartburn, aspiration, regurgitation, and weight loss are the most common symptoms (1).

Currently, forceful endoscopic pneumatic balloon dilatation (PBD) and laparoscopic Heller myotomy (LHM) with or without an anti-reflux procedure are the standard of care in achalasia treatment (2). Recently, peroral endoscopic myotomy (POEM) was introduced as a new treatment modality, which allows an adequate incision of the muscle layer alone, without scarring the body surface (3). However, there are no long-term outcomes of POEM for reaching a definitive conclusion regarding its efficacy.

Surgical management is based on disrupting LES by myotomy. The technique was initially described in 1913 by Ernst Heller (4). LHM was introduced in 1991 and has gained access (5). Endoscopic PBD has shown similar effectiveness; however, several patients need repeated PBDs to achieve response rates of 70%-80% (6).

The aim of this retrospective study was to compare postoperative outcomes after LHM+Dor fundoplication (DF) between patients who underwent prior endoscopic balloon dilatation and those who did not.

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Table 1. The Eckardt scores

	Symptoms			
Score	Weight loss (kg)	Dysphagia	Retrosternal pain	Regurgitation
0	None	None	None	None
1	<5	Occasional	Occasional	Occasional
2	5-10	Daily	Daily	Daily
3	>10	Each meal	Each meal	Each meal

MATERIALS AND METHODS

After the approval of the local ethical committee, 65 patients who underwent HM+DF between January 2008 and December 2016 in Türkiye Yüksek İhtisas Training and Research Hospital were retrospectively analyzed. A diagnosis of primary achalasia was established using esophageal manometer, barium swallow enema, and esophagogastroduodenoscopy (EGD) in all patients. The degree of symptoms, including weight loss, dysphagia, retrosternal pain, and regurgitation, was graded pre- and postoperatively during the follow-up visits using the Eckardt score (Table 1) (7). Patients were classified as having either classical or vigorous achalasia based on conventional manometry. Patients' demographics, laboratory values, clinical presentation, radiological imaging findings, surgical treatment, perioperative complications, pathological features, postoperative course, and long-term survival were collected and analyzed.

Endoscopic PBD

A rigiflex 30-mm balloon dilator (Boston Scientific, Natick, MA, USA) was used at the first endoscopic PBD procedure. With ongoing dysphagia symptoms, if LES pressure remained >10 mmHg, then a second endoscopic PBD with rigiflex 35-mm balloon dilator was performed after 4 weeks or longer. Patients with refractory dysphagia symptoms were referred for surgery following failure in relieving the symptoms of at least two prior endoscopic PBD procedures.

Operative technique and follow-up

All patients underwent HM+DF by either open or laparoscopic approach. 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. A nasogastric tube was routinely placed postoperatively. Patients started liquid at the second postoperative day after an esophagram revealed no leak. A clinical follow-up was performed at 2 weeks, 6 months, 1 year, and then annually by esophagram.

Table 2. Patient characteristics and demographic data

Patients who underwent surgery (n=65)	
Age (years)	38.5±14.2
Sex	
Males	32 (49.2%)
Females	33 (50.8%)
Type of achalasia	
Classical	61 (93.8%)
Vigorous	4 (6.15%)
Preoperative symptoms	
Dysphagia	59 (90.8%)
Pyrosis	5 (7.7%)
Vomiting	1 (1.5%)
Duration of symptoms (months)	6 (1-38)
Preoperative dysphagia score	3.95±0.7
Lesser esophageal pressure (mmHg)	31.4±11.9
Preoperative endoscopic PD/BD	
Yes	45 (69.2%)
None	20 (30.8%)
Number of preoperative endoscopic PD/BDs	1.7±1.5
Previous surgical myotomy	4 (6.2%)
Type of surgery	
Laparoscopic surgery (LHM+DF)	50 (76.9%)
Open surgery (HM+DF)	15 (23.1%)
Mean operating time (min)	140±45.3
Intraoperative complication	
Esophageal mucosal perforation	3 (4.6%)
Bleeding from arteria gastrica breves	2 (3.1%)
Hospital stay (d)	6.2±1.40
Postoperative follow-up	36.3±23.4

HM: Heller myotomy; LHM: laparoscopic Heller myotomy; PD/BD: pneumatic dilatation/balloon dilatation

Table 3. Comparison of the patients who underwent preoperative endoscopic PBD with those who did not

Preoperative endoscopic PBD	(+) n (45)	(-) n (20)	p
Age	38.1±14.6	39.4±13.5	0.48
Sex (male/female)	21/24	11/9	0.53
Preoperative LES pressure (mmHg)	31.6±12.6	31.3±10.9	0.93
Operation time (min)	135.2±44.5	150.3±46.6	0.23
Esophageal perforation (n)	3		-
Hospitalization period (d)	6.2±1.5	6.2±1.3	0.94
Morbidity (wound infection)	5	0	-
Follow-up period (months)	40.2±23.5	30.3±21.4	0.11

PBD: pneumatic balloon dilatation

Table 4. Comparison of the pre- and postoperative Eckardt scores

	Eckardt Score		
	Preoperative	Postoperative	p
Overall (n=65)	4.51±1.83	0.52±0.70	<0.001
Preoperative endoscopic PBD			
Yes (n=45)	4.35±1.79	0.60±0.71	
None (n=20)	4.85±1.89	0.30±0.57	0.43

PBD: pneumatic/balloon dilatation

Statistical analysis

Data were analyzed using the SPSS for Windows, Version 17.0 (SPSS Inc.; Chicago, IL, USA), and the Kolmogorov-Smirnov test was used to determine whether the distribution of continuous variables was normal. Continuous variables are shown as mean±SD or median (min-max). Otherwise, the number of cases and percentages were used for categorical data. The Wilcoxon signed rank test was used to compare between the pre- and postoperative Eckardt scores. The Mann-Whitney U-test was used to compare the pre- and postoperative Eckardt scores between patients who underwent preoperative endoscopic PBD and those who did not. $p<0.05$ was considered statistically significant.

RESULTS

Sixty-five patients underwent HM+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. Sixty-one (93.8%) patients had classical achalasia, whereas four (6.2%) had vigorous achalasia (sigmoid achalasia) and did not receive preoperative endoscopic PBD because of the risk of perforation; they underwent LHM as the first-line therapy. The average duration of symptoms was 6 months (1-38), with dysphagia being the most common presenting symptom (n=59, 89.2%). The mean preoperative LES pressure was 31.4±11.9 mmHg. Forty-five (69.2%) patients underwent preoperative endoscopic PBD. The mean ratio of repeated endoscopic PBD was 1.7±1.5. A total of 106 endoscopic PBDs were performed in 45 patients. Thirty-nine patients (60%) underwent up to two endoscopic PBDs sessions, four (6.2%) underwent four sessions, and two (3.1%) underwent six sessions. Four (6.2%) patients had a history of HM. None of the patients received a botox injection. Fifty (76.9%) patients underwent laparoscopic surgery, whereas 15 (23.1%) underwent open surgery. Esophageal mucosal perforation occurred in three (4.6%) patients, which was detected during the operation and treated by primary repair. Intraoperative bleeding occurred in two patients from arteria gastrica breves, which stopped after the ligation of these vessels (Table 2).

The mean duration of hospital stay was 6.2±1.40 d. There was no morbidity or mortality. The mean follow-up time was 36.3±24 months.

When patients were compared according to whether they underwent preoperative endoscopic PBD, there was no significant difference in terms of age, sex, preoperative LES pressure, operation time, hospitalization period, and follow-up period ($p>0.05$) (Table 3).

The mean Eckardt score measured at the first postoperative year was significantly lower than the preoperative Eckardt score [4.51±1.8 vs. 0.52±0.7, ($p<0.001$)]. In contrast, there was no significant difference in the pre- and postoperative Eckardt scores between patients who underwent preoperative endoscopic PBD and those who did not ($p=0.43$) (Table 4).

DISCUSSION

This retrospective study evaluated outcomes of HM in achalasia patients who underwent preoperative endoscopic PBD and showed that HM+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. The open approach has a perioperative mortality rate of 1.2%, whereas laparoscopic approach has a lower mortality rate (8). In the present study, LHM replaced open surgery over time because of the widespread application of laparoscopic interventions and experience.

An ongoing debate in the literature regarding the surgical treatment of achalasia is whether fundoplication should be added to HM. If yes, which procedure should be followed? It has been previously shown that 47.6% of patients undergoing HM without fundoplication have pathologic acid exposure in the distal esophagus (9). In another comparative study, although the long-term results were comparable, the gastroesophageal reflux (GER) and dysphagia scores were slightly worse after HM than after HM+DF (10). Selecting the type of fundoplication is another topic for discussion. A randomized controlled study has shown a significantly lower incidence of postoperative dysphagia after LHM+DF than after LHM+Nissen fundoplication (11). A retrospective study comparing DF with Nissen fundoplication has demonstrated that DF is associated with a lower incidence of postoperative dysphagia and a negligible incidence of postoperative gastroesophageal reflux disease (GERD) (12). A retrospective study compared the Toupet fundoplication with DF for the quality of life, and overall satisfaction was superior with DF (13). In the present study, all patients underwent DF following LHM. We prefer anterior DF because of its simplicity, decreased need for extensive dissection, and protection against potential intraoperative unrecognized mucosal leaks.

We prefer extended cardiomyotomy (extending 2-3 cm to the gastric wall) with the aim of better and sustained resolution of dysphagia than the traditional cardiomyotomy (1-1.5 cm). However, there is a proportional relationship with myotomy length and GERD development (14). DF is added to relieve this undesirable side effect.

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 (15). The results of a meta-analysis including 361 patients showed that LHM may provide greater response rates than graded endoscopic PBD in the treatment of newly diagnosed idiopathic achalasia (5). Two recent meta-analysis comparing the outcomes of endoscopic PBD and LHM revealed similar results at 5-year intervals (16, 17). An evidence-based approach study, which searched PubMed/Medline electronic databases and the Cochrane Library, stated that LHM+partial fundoplication was associated with lower complication rates and provided excellent long-term results with lower need for the additional treatment of recurrent dysphagia than endoscopic PBD (18). Furthermore, in a study by Zagory et al. (19), LHM was found to be superior to balloon dilatation or botulinum injection in children and was recommended as a first-line therapy. Recently, a retrospective study has claimed that multiple preoperative endoscopic treatments affect the outcomes of LHM (20). Repetitive endoscopic PBDs may cause submucosal hemorrhage, resulting in fibrosis and adhesion formation over a time period, which makes surgical myotomy difficult and increases the risk of esophageal mucosal perforation (21, 22). Tsuboi et al. (23) reported in their retrospective study that a fragile esophagus because of advanced age, preoperative endoscopic PBD, or a novice surgeon is a risk factor for esophageal perforation during HM. In our study, although not statistically significant, the postoperative mean Eckardt score was slightly higher in patients who underwent prior endoscopic PBD than in those who did not. Further, 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.

New options for achalasia, such as POEM, self-expanding metal stents, and endoscopic sclerotherapy, have shown promising results (24-26). However, their efficacy was stated in a few prospective observational studies and should be further supported in large randomized controlled trials with long-term results. A meta-analysis including 53 studies reporting data on the efficacy of LHM and 21 studies on POEM revealed that POEM was more effective in relieving dysphagia than LHM but was associated with a higher incidence of pathologic reflux (27).

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 our 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.

The present study had some limitations. First, it was a retrospective study, and second, the sample size was small. However, our study is valuable because it demonstrated the short- and long-term effects of preoperative endoscopic PBD on the outcomes of HM+DF.

In conclusion, 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.

Ethics Committee Approval: Ethics committee approval was received for this study from the Local Institutional Ethical Committee.

Informed Consent: Written informed consent was not obtained due to the retrospective nature of the study.

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