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Heller myotomy versus endoscopic balloon dilatation for achalasia

A single center experience

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Abstract

This study aimed to compare clinical results, symptom relief, quality of life and patient satisfaction after the 2 most common procedures for achalasia treatment: laparoscopic Heller myotomy (LHM) and endoscopic balloon dilatation (EBD).

Patients treated at University Hospital of Heidelberg with LHM or EBD were included. A retrospective chart review of perioperative data and a prospective follow-up of therapeutic efficiency, Gastrointestinal Quality of Life Index (GIQLI) and patient satisfaction was conducted.

Follow-up data (mean follow-up: 75.1 ± 53.9 months for LHM group and 78.9 ± 45.6 months for EBD) were obtained from 36 patients (19 LHM; 17 EBD). Eckardt score (median (q_1,q_3): 2 (1,4) in both groups, $P = .91$, GIQLI (LHM: 117 (91.5, 126) vs EBD: 120 (116, 128), $P = .495$) and patient satisfaction (3 (2,3) vs 3 (2,4), $P = .883$) did not differ between groups. Fifteen patients (78.9%) in LHM group and 11 (64.7%) in EBD group ($P = .562$) stated they would undergo the intervention again. All patients with EBD had at least 2 dilatations (100%), whilst only 2 patients (10.5%) had dilatation after LHM ($P < .001$). There were no complications after EBD, but 2 after LHM (10.5%, $P = .517$).

Both LHM and EBD are able to control symptoms and provide similar quality of life and patient satisfaction. However, reintervention rate was higher following EBD, hence LHM provided a more sustained treatment than EBD.

Abbreviations: BMI = body mass index, EBD = endoscopic balloon dilatation, EGD = esophagogastroduodenoscopy, GERD = gastro-esophageal reflux disease, GIQLI = Gastrointestinal Quality of Life Index, LES = lower esophageal sphincter, LHM = laparoscopic Heller myotomy, POEM = per-oral endoscopic myotomy.

Keywords: achalasia, endoscopic balloon dilation, Heller myotomy, laparoscopy, quality of life

1. Introduction

Achalasia is a rare neurodegenerative disorder of the esophagus, affecting approximately 1/100,000 individuals in the western world. Achalasia results from loss of the inhibitory ganglion cells in the myenteric plexus.[1,2] The neurons are responsible for the coordination of the esophageal peristalsis and the relaxation of the lower esophageal sphincter (LES).[3] This disorder presents with symptoms such as: dysphagia, undigested food regurgitation, respiratory symptoms (nocturnal cough, recurrent aspiration, and pneumonia), chest pain, and weight loss.[4] Idiopathic achalasia is the most common form, which mostly occurs as sporadic cases. However, a similar clinical presentation can occur in 2% to 4% of patients with pseudoachalasia, characterized by achalasia-like symptoms caused by secondary etiologies like malignancies or rare benign diseases (i.e., Chagas).[5–7]

Idiopathic achalasia is diagnosed with a patients' well-documented medical history, barium esophagogram, observing aperistalsis, poor emptying and the lower esophagus resembling a "bird's beak", an esophagogastroduodenoscopy (EGD) to exclude mechanical obstruction and esophageal motility testing.[1,8,9] Manometry is the gold standard for establishing the diagnosis of achalasia. The manometric findings of aperistalsis and impaired LES relaxation are characteristic on conventional manometry.[10]

Treatment for achalasia includes pharmacological, endoscopic and surgical options. A more widely used treatment is the endoscopic injection of botulinum toxin in the LES, which leads to relaxation of the LES for 1 to 3 months.[11] Zaninotto et al

Editor: Valerio D'Orazi.

All procedures performed in studies involving human participants were 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. Informed consent was obtained from all individual participants included in the study.

The authors have no funding and conflicts of interest to disclose.

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How to cite this article: Nickel F, Müller PC, de la Garza JR, Tapking C, Benner L, Fischer L, Steinemann DC, Rupp C, Linke GR, Müller-Stich BP. Heller myotomy versus endoscopic balloon dilatation for achalasia. Medicine 2019;98:44(e17714).

Received: 20 July 2019 / Received in final form: 24 September 2019 / Accepted: 28 September 2019

http://dx.doi.org/10.1097/MD.0000000000017714

demonstrated that the injection of botulinum toxin did not have a long lasting effect and recommended that it should only be used as bridging strategy or in inoperable patients.[12] Currently, the 2 most common treatments are endoscopic balloon dilation (EBD) or laparoscopic Heller myotomy (LHM). EBD produces a controlled tear of the LES with an air-filled balloon dilator that relieves distal esophageal obstruction, improving dysphagia but not reflux symptoms.[13,14] However, most patients with EBD require repeated treatments.

LHM was introduced in 1991,[15] and has since then played a major role for the treatment of achalasia.[13,16,17] Compared to EBD, LHM offers the potential of a single session treatment, avoiding multiple procedures, and can provide a better resolution for the patients' symptoms.[18,19] The objective of treatment for achalasia is to promote relief of dysphagia whilst avoiding side effects. Particularly in regard to reflux, LHM is frequently combined with fundoplication.[8,20] A rather new treatment for achalasia is the per-oral endoscopic myotomy (POEM), which seems to show acceptable short-term efficacy and safety comparable to LHM and is currently under further evaluation regarding symptomatic and long-term outcome.[21,22]

Currently, there is a controversy about the ideal choice of initial treatment. Therefore, the aim of the present study was to compare the efficacy and clinical long-term outcomes of EBD and LHM procedures in patients with achalasia treated at our center.

2. Material and methods

2.1. Study design

We searched for patients with treatment of achalasia at Heidelberg University Hospital's database. Patients were divided in 2 groups: one with surgical management (LHM) and one with endoscopic management by endoscopic balloon dilatation (EBD) exclusively. Eckardt score, Gastrointestinal Quality of Life Index (GIQLI) and patients' satisfaction was assessed by self-administered questionnaires sent to the patients by postmail. After completing each questionnaire, they sent them back to our institution to be analyzed retrospectively.

2.2. Patients

Patients were included in the study if they were over 18 years of age when giving consent, were diagnosed with achalasia via manometry, EGD and barium esophagogram and had LHM or EBD as a treatment for achalasia. Patients with insufficient follow-up data, or with treatments other than LHM or EBD, were excluded from the study. The trial was approved by the local ethics committees of the University of Heidelberg Hospital (S-206/2015). All patients provided written informed consent before enrollment.

2.3. Endoscopic Procedure – endoscopic balloon dilation

Under sedation, the esophago-gastric junction was identified by endoscopy. A pneumatic balloon was introduced and positioned at the esophago-gastric junction. The dilator was then held firmly in place while the balloon was inflated at a pressure of 1.3 bar for 30 to 120 seconds. The dilations were performed with the use of a 30 or 35 mm balloon. After removal of the device, a careful upper endoscopy was performed to inspect the patency of the esophago-gastric junction.

2.4. Surgical Procedure – laparoscopic Heller myotomy

After division of the phreno-esophageal ligament, the distal esophagus was mobilized on the lateral and anterior side, and a myotomy was performed, extending at least 6 cm above the gastro-esophageal junction and at least 1 to 2 cm over the cardia of the stomach. A fundoplication according to the Dor's (anterior 180 degree), Toupet's (posterior 270 degree) or Thal's (anterior 90 degree) method was performed up to the surgeon's choice.

2.5. Outcomes

The Eckardt score and GIQLI were applied using structured questionnaires. Regarding the Eckardt Score, a score between 0 and 3 was assigned for each of the symptoms of dysphagia, regurgitation, and retrosternal pain (Score 0: not present; Score 1: occasionally; Score 2: daily; Score 3: several times a day after each meal), and for the degree of weight loss (Score 0: none; Score 1: =< 5 kg; Score 2: 5–10 kg; Score 3: >= 10 kg). The highest possible Eckardt score of the four symptoms was 12 and the lowest score was 0.[23]

The GIQLI consists of 36 questions referring to different dimensions: abdominal symptoms, emotional status, physical functions, social activities, and inconvenience of medical treatment. A sub-score of 0 to 4 points may be achieved for each question. The maximum obtainable index score of 144 points reflects an unimpaired quality of life. The described testing procedure has proven to be a valuable tool in the evaluation of the quality of life of patients after different types of gastrointestinal surgery.[24]

Patients' satisfaction was assessed with a scale from 0 (very unsatisfied) to 7 (completely satisfied), and patients were asked whether or not they would undergo the same treatment again if needed.

2.6. Follow-up

Patients prospectively filled in a standardized questionnaire assessing need for additional treatments, Eckardt-score, GIQLI and patient satisfaction. Follow-ups were carried out between September 2015and April 2016.

2.7. Statistical analysis

Data was collected in Microsoft Excel (Microsoft Office, Microsoft Corporation) and analyses were performed using Graphpad Prism 7 (GraphPad Software, Inc., La Jolla, CA). Continuous data is described by mean ± SD (standard deviation). For all scores and the number of previous treatments, median as well as the first and third quartile (q_1, q_3) are presented. Differences between the EBD and LHM group were assessed using student's t test and Wilcoxon rank-sum test, respectively. Binary data is described by absolute and relative frequencies, and differences between both treatment groups are compared using Chi-squared test. All P values less than .05 were considered statistically significant for the study. Due to the exploratory nature of the study, no adjustment for multiplicity was conducted.

3. Results

A total of 36 patients who had either LHM or EBD as treatment for achalasia were included in the study. Both groups were in

Table 1

Patient data.

Variable	Endoscopic balloon Dilation (n=17)	Laparoscopic Heller Myotomy (n=19)	–*P* value
Baseline			
Age (yr)*			.032
Mean ± SD	50.6 ± 15.8	37.8 ± 18.1	
Gender n (%)			1
Male	10 (58.8%)	11 (57.9%)	
Female	7 (41.2%)	8 (42.1%)	
BMI (kg/m^2) Pre-interventional			.115
Mean ± SD	26.1 ± 6.2	22.8 ± 4.5	
Number of Previous Treatments			.005
Median (q_1, q_3)	2(1, 3)	5 (3, 8.5)	

* In the LHM group, 4 patients were younger than 18 years at intervention (age: 9, 12, 15, 17), pre-interventional BMI of the patients at the age of 9 and 12 was missing.

gender and pre-interventional Body Mass Index (BMI), whereas the LHM group was older and had more previous treatments (Table 1). Nineteen patients with a mean age of 37.8 ± 18.1 years underwent LHM. After myotomy, an anterior 180-degree fundoplication according to Dor was performed in 9 patients (47.4%). LHM with Toupet and Thal fundoplications were performed in 5 (26.3%) and 3 patients (15.8%), respectively. 2 patients (10.5%) had their surgery done without fundoplication. The procedures were completed laparoscopically in 17 patients (89.5%), and 2 (10.5%) were converted to open surgery. There were no complications in the EBD-group, whereas in the LHM group, there were 2 (10.5%) intraoperative complications ($P = .517$, risk difference = 0.105, 95%-CI: [−0.033, 0.243], number needed to harm = 9.5); an esophagus perforation that was converted to open surgery and a pleura injury that was treated with a thoracic drain. There was one patient (5.3%) that had to be re-operated due to leakage from the esophagus. The mean operative time for LHM was 172.4 ± 74.4 min, while for the EBD group the mean intervention time was 56.3 ± 13.5 min ($P < .001$). The LHM group had a higher number of treatments before the observed procedure than the EBD group ($P = .005$, Table 1). 11 patients (57.8%) had EBD before LHM. All patients (100%) with EBD had at least 2 dilatations (range 2 to 9) whereas only 2 patients (10.5%) required an additional dilatation after LHM ($P < .001$, Fig. 1). The 2 patients who received LHM had an additional dilatation after 1 and 5.2 months. Patients in the EBD group received the next dilatation after a median of 3.4 months (range: 0.4–37.2 months), the second re-dilatation after a median of 18.6 months (range 0.6–130.6 months), and the third re-dilatation after a median of 3 months (range 0.4–101 months). The time from the initial EBD to the first re-dilatation was not significantly different to the time from the first to the second re-dilatation ($P = .15$). Correlation analysis showed that patients who had more time between initial EBD and first re-dilatation, had more time between the first and the second re-dilatation as well (r = 0.57, $P = .237$).

Before their procedure, both groups reported similar symptoms, with dysphagia being the most common one. When asked for the main symptom, in the surgery group, 15 patients (78.9%) had dysphagia, 2 (10.5%) had gastro-esophageal reflux disease (GERD) and 2 (10.5%) had chest pain. As for the EBD group, 13 patients (76.5%) had dysphagia, 4 (23.5%) had chest pain and no GERD was reported.

Mean follow-up for the LHM group was 75.1 ± 53.9 months while for the EBD group it was 78.9 ± 45.6 months. After treatment, Eckardt score and GIQLI were not different between the groups (Figs. 2 and 3). There was no significant difference between groups for patient satisfaction after the intervention (LHM 3 (2, 3), EBD 3 (2, 4); $P = .883$; scale from 0 (very unsatisfied) to 7 (completely satisfied)). 15 patients (78.9%) who had LHM said they would undergo the same procedure again, while 11 patients (64.7%) with EBD said they would undergo the same intervention again ($P = .562$).

4. Discussion

In the present study, 2 groups with similar baseline characteristics were compared. After a mean follow-up of 75 months in both groups, there were no significant differences regarding complications, relief of symptoms (Eckardt score), quality of life (GIQLI) and patients' satisfaction. However, patients with LHM

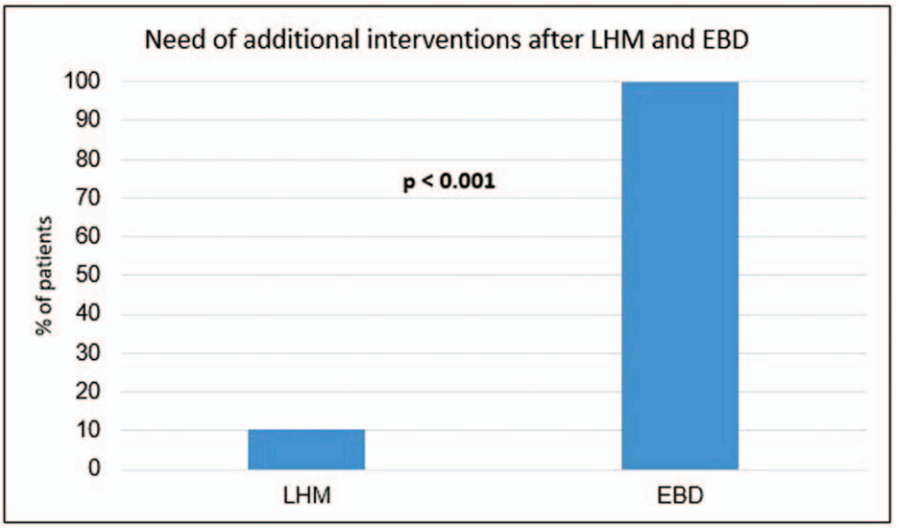

Figure 1. Need of additional of interventions after laparoscopic Heller myotomy (LHM) and endoscopic balloon dilatation (EBD).

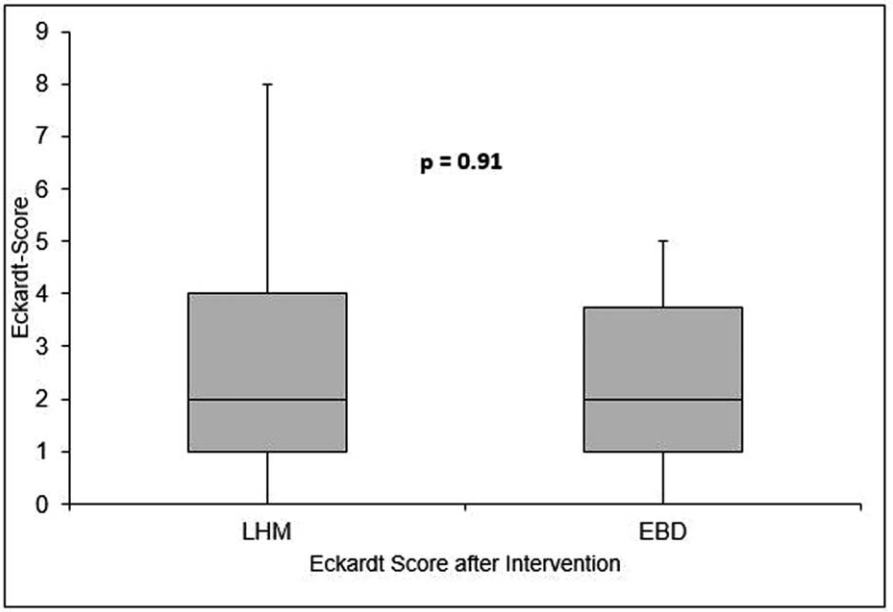

Figure 2. Eckart score after laparoscopic Heller myotomy (LHM) and endoscopic balloon dilatation (EBD).

received significantly less additional dilatations after the intervention than patients with EBD.

In the present study, the patients had similar Eckardt scores (median (q_1, q_3): 2 (1,4) in both groups) in the follow-up assessment. This is in line with a trial with 201 patients, in which Boeckxstaens et al showed a similar therapeutic success rate of LHM and EBD after 1 year (93% vs 90%) and 2 years (90% vs 86%, $P = .46$), defined as a drop in Eckardt score to ≤ 3.[25] Vela et al also reported similar success rates in a cross-sectional follow-up evaluation.[26] In contrast to this, Campos et al reported in a meta-analysis of 105 articles reporting on 7855 patients that LHM provided better symptom relief than EBD (90% vs 68.2%; $P < .001$), but that LHM had a higher complication rate than EBD (6.3% vs 1.6%; $P = .004$). Complications were mainly perforations of the esophagus (1). In the present study, there were only 2 complications (10.5%) in the LHM group versus none in the EBD group, but this did not reach a statistically significant difference between the groups probably due to the sample size. Assuming a difference in the complication rates of 6.3% vs 1.6% as reported in Campos et al[1], a sample size of 269 patients per group would be needed to show a significant difference with a power of 80% and $\alpha = 0.05$. Both LHM and EBD provide relief

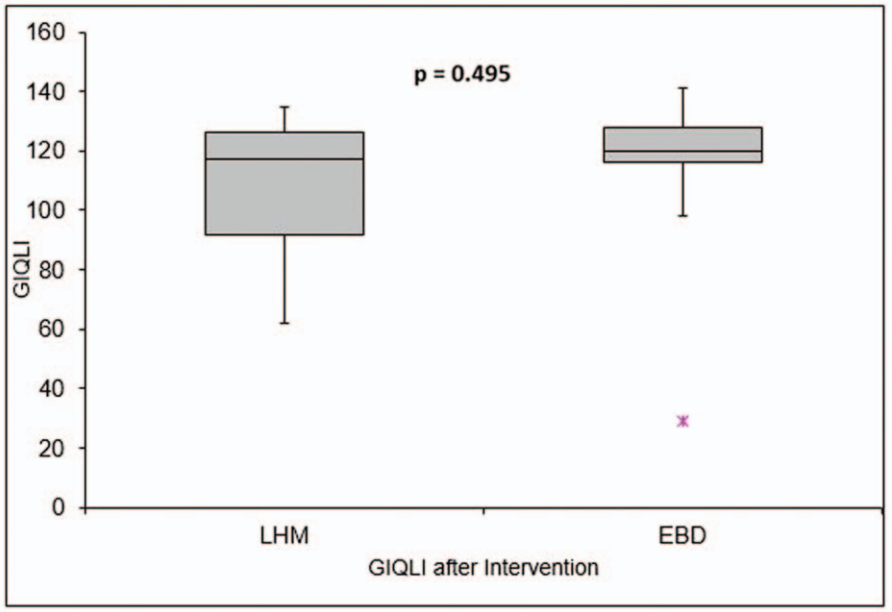

Figure 3. Gastrointestinal Quality of Life Index (GIQLI) after laparoscopic Heller myotomy (LHM) and endoscopic balloon dilatation (EBD).

of symptoms at relatively low complication rates, but the possibility of an esophageal perforation should be in mind when treating achalasia.

In the present study, patients had a median GIQLI score of 117 and 120 after LHM and EBD, respectively. This is in line with a study by Decker et al who found significant improvement of GIQLI from median 84 to 109 at 31 months after LHM.[27] Boeckxstaens also reported an improvement of quality of life to a similar extend after the same treatments in both groups. In the present study, gastrointestinal quality of life was not assessed prior to the intervention, but confirmed the improved values of the other available studies after the interventions. These findings show the importance of the treatment of achalasia and the efficacy of both LHM and EBD.

In the present study, the patients were asked if they would undergo the same intervention again, if necessary. 15 patients (78.9%) in the LHM group and 11 patients (64.7%) in the EBD group agreed. Under the assumption that the observed rates are equal to the true rates, a sample size of 103 patients per group would be needed to show a significant difference for undergoing the procedure again with a power of 80% and $\alpha = 0.05$. Patients satisfaction measured on a scale from 0 (very unsatisfied) to 7 (very satisfied) did not differ between the groups, probably also due to the small sample size). Comparable data for the outcome of LHM were published by Resemurgy et al who found 93% of the patients feeling that they would re-undergo LHM if needed.[28] In a study by Tabola et al, 52.4% rated the outcome of EBD as good or very good.[18]

Patients with LHM received significantly less further interventions than patients with EBD (10.5% vs 100%; $P < .001$) in the present study. Patients in the EBD group also showed a moderate correlation between a longer interval from the initial EBD to the first re-dilatation and a longer interval between first and second re-dilatation ($r = 0.57$, $P = .237$). In a study with a larger number of patients (LHM: 73 and EBD: 106), Vela et al showed that multiple dilations were more often necessary and more effective than single dilatations and led more often to relief of symptoms (82% vs 50% after two years).[26] On the other hand, a systematic review by Katzka et al reported that multiple dilatations may lead to a higher rate of esophageal perforations.[29] They also reported that multiple dilatations were needed over a lifetime in most of the patients. In contrast to this, LHM can be a definitive treatment in most patients with a relief of symptoms in up to 91.2% of patients 24 months after surgery and rarely needs another intervention.[30]

Patients that received EBD were significantly younger than patients receiving LHM. It has been reported that older patients undergoing LHM often present with a longer and more indolent course than younger patients. Furthermore, age and duration of symptoms had an impact of symptoms before and after the intervention but did not impact subjective measures outcomes reported by the patients.[31] Yet, the significant difference in age reported in the present study is mainly due to four patients being under the age of 18 years in the LHM group at the time of surgery (9, 12, 15, and 17 years).

4.1. Limitations

One limitation of the present study is that the patients were treated by different surgeons and gastroenterologists over a longer period of time. Surgeons and gastroenterologists only performed either LHM or EBD but not both procedures. All treating physicians were fully trained and accredited according to national standards. As a limitation, individual information on procedural volume and learning curves for the respective procedures is not available which could have influenced outcomes due to individual performances. Furthermore, prior to the intervention, the EBD group presented with a higher BMI compared to the LHM group ($26.1 \pm 6.2\,kg/m^2$ vs $22.8 \pm 4.5\,kg/m^2$). This could have influenced the occurrence of symptoms, the need of reinterventions, the outcome of the patients and questionnaire scores in the EBD group. However, given the limited sample size, the difference in BMI was not statistically significant.

5. Conclusions

In conclusion, LHM and EBD both seem to be effective in the treatment of achalasia concerning relief of symptoms and patients' satisfaction. However, LHM showed a lower reintervention rate than EBD. Both procedures should be performed depending on the patients' preference, medical history and the centers' expertise. This underlines the results of former studies which showed that LHM, rather than EBD, could be considered as a definitive treatment for achalasia.

Acknowledgments

We would like to thank Carly R. Garrow for proofreading the manuscript.

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