

The Clinical Efficacy, and Long-Term Outcomes Between Pneumatic Dilation and Laparoscopic Heller Myotomy in Achalasia

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Rezumat

Rezultatele pe termen lung între dilatația pneumatică și miotomia laparoscopică Heller, în tratamentul acalaziei

Introducere: Acalazia cardiacă (AC) este cea mai cunoscută tulburare de motilitate, caracterizată prin lipsa relaxării optime a sfincterului esofagian inferior (SEI) la deglutiție și absența peristalticii corpului esofagian. Eso-cardiomiotomia Heller pe cale laparoscopică (LHM) împreună cu dilatația pneumatică (DP) au fost principalele opțiuni pentru tratamentul acalaziei, la ora actuală metodele terapeutice fiind completate de miotomia endoscopică per-orală (POEM – per oral endoscopic myotomy).

Material și Metodă: am efectuat un studiu retrospectiv, analizând datele și evoluția a 98 de pacienți cu acalazie, internați și tratați în Clinica de Chirurgie Generală și Esofagiană din cadrul Spitalul Clinic Sf. Maria-București în perioada ianuarie 2016 - iunie 2023. Tratamentul a fost prin DP sau LHM. Durata medie a simptomelor în cazul DP a fost de 48 luni, și de 24 luni în LHM. Pacienții au fost evaluați pre și post-terapeutic prin scorul clinic Eckardt și prin investigații precum tranzitul baritat seriat, manometria esofagiană. Tratamentul a fost eso-cardiomiotomia Heller-LHM pe cale laparoscopică în majoritatea cazurilor. DP a fost efectuată în 25 cazuri.

Rezultate: Pornind de la un scor Eckardt egal, s-a obținut scăderea semnificativă statistic a scorului Eckardt la evaluarea post-terapeutică după LHM față de DP. Recidiva simptomelor a fost mai frecventă în cazul DP, necesitând o altă intervenție terapeutică.

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Costul tratamentului precum și zilele de spitalizare au fost mai reduse în cazul DP.

Concluzii: Tratamentul acalaziei prin LHM este mai eficient din punct de vedere al recidivei, chiar dacă implică costuri mai mari și durată de spitalizare mai lungă comparativ cu DP.

Cuvinte cheie: acalazia cardiei, miotomie Heller laparoscopică, fundoplicatura Dor, dilatație pneumatică

Abstract

Introduction: Achalasia is the most well-known motility disorder, characterized by the lack of optimal relaxation of the lower esophageal sphincter during swallowing and the absence of peristalsis of the esophageal body. Laparoscopic Heller esocardiomyotomy (LHM) and pneumatic dilation (PD) were the main treatment options for achalasia. Currently, the therapeutic methods are complemented by per-oral endoscopic myotomy (POEM).

Materials and Methods: we performed a retrospective study, analyzing the data and evolution of 98 patients with achalasia, admitted and treated in the General and Esophageal Surgery Clinic of the St. Mary Clinical Hospital-Bucharest between January 2016 and June 2023. The treatment was performed by PD in 25 cases and the majority LHM. The average duration of symptoms in the case of PD was 48 months, and 24 months in LHM. The patients were evaluated before and after the treatment procedures by the Eckardt clinical score and investigations such as timed barium esophagogram (TBO) and esophageal manometry.

Results: Although patients had the same Eckardt score before treatment, a statistically significant decrease of the Eckardt score was obtained at the post-therapeutic evaluation after undergoing LHM compared to PD. Recurrence of symptoms was more frequent in the case of PD, requiring another therapeutic intervention. The cost of treatment, as well as the number of hospitalization days were reduced in the case of PD.

Conclusions: The treatment of achalasia with LHM is more effective regarding recurrence of symptoms, even if it involves higher costs and a longer hospital stay compared to DP.

Key words: achalasia cardia, laparoscopic Heller myotomy, Dor fundoplication, pneumatic dilation

Introduction

Achalasia is the most studied motility disorder characterized by the lack of optimal relaxation of the lower esophageal sphincter (LES) during swallowing and the absence of peristalsis of the esophageal body. The condition is characterized by the degeneration of inhibitory neurons in the myenteric plexus of the lower esophagus and esophageal sphincter (1).

Achalasia has received different names over time: cardiospasm, idiopathic dilation of the esophagus or megaesophagus. The disease was described for the first time by Willis, in

1674, who performed the first treatment, using whalebone for the esophageal dilation. The prevalence in general population is 8:100,000, with the incidence of 1:100,000 (2).

The diagnosis necessarily includes upper digestive endoscopy, timed barium esophagogram (TBO) and esophageal manometry, the last one being considered the gold standard of evaluation. Other investigations, such as computed tomography scan or endoscopic ultrasound, are necessary in selected cases (3).

Currently, the main treatment options are either endoscopic (such as balloon dilation and per-oral endoscopic myotomy) or surgical

(Heller esocardiomyotomy) performed laparoscopically or robotically, associated with a partial, anterior or posterior fundoplication (4).

Both LHM and PD are able to control symptoms and provide similar quality of life and patient satisfaction. In the literature, recurrence of the disease, defined by the need to repeat the procedure, was higher after PD, therefore LHM offered a more sustained treatment over time compared to PD (5). However, there are studies that show that LHM was not associated with higher rates of therapeutic success compared to PD and suggest that graded dilatation, starting with a 30 mm balloon, is a good protocol for the treatment of AC symptoms (17).

Each of these methods has advantages and disadvantages that directly affect the therapeutic response depending on gender, age, the initial treatment method (in cases of recurrence) and the disease-free interval.

Due to its less invasive nature, without requiring general anesthesia with intubation, pneumatic dilatation is a safe and easy method (6), with the main risk being mucosal perforation. One of the disadvantages of the method is the rapid recurrence of the symptoms in some patients (6). For this reason, multiple dilations may be necessary to obtain an adequate therapeutic response. A single session may be ineffective or may lead to a limited symptomatology improvement, which makes the method less durable. Another important factor in establishing the treatment plan and the number of pneumatic dilatation sessions required for each patient is the manometric type of achalasia (7).

LHM is considered more durable and, at the same time, allows the addition of an antireflux mechanism (8). There is a risk of intraoperative mucosal lesions. For this reason, as a safety measure, we have introduced intraoperative endoscopy as a standard.

The treatment of achalasia is recommended to be carried out in centers with experience, in order to offer the best chance of a favorable evolution and a better quality of life. In the case of LHM, the learning curve is 20 cases, difficult to obtain in a center without addressability (9).

Purpose of the study: was the evaluation and comparison of the therapeutic response following Heller esocardiomyotomy or pneumatic dilatation for achalasia, and the impact on the quality of life.

Material and Method

We performed a retrospective study, using a database collected from patients treated for achalasia cardia at the Center of Excellence in General and Esophageal Surgery of the St. Mary Clinical Hospital in Bucharest between January 2016 and June 2023.

The study population is represented by a batch of 98 patients, divided into two subgroups, depending on the chosen therapeutic method. Among the 98 patients, 25 (25.51%) were treated endoscopically by pneumatic dilations and the remaining 73 (74.49%) were treated surgically by Heller myotomy.

The patients were evaluated clinically, endoscopically and by imaging investigations. Endoscopically, esophageal stasis, the difficult passage through the gastroesophageal junction (GEJ), the esophageal dilation and the presence of retention esophagitis were appreciated.

Data Analysis

After entering the data regarding gender, age, pre and posttherapeutic Eckardt score, the recurrence, cost of the procedure and hospitalization days, and also the improvement of the quality of life, obtained from the study protocols into the database fields, they were processed using the SPSS version 23.0 and Excel software packages.

For the descriptive statistics, the mean and standard deviation were calculated, respectively the medians and quartiles for the quantitative variables and for the qualitative variables frequencies and percentages. In the comparison of the quantitative data, depending on the normality of the data, Independent Samples T Test (for two groups with normally distributed data), Mann-Whitney U (for groups that do not have a

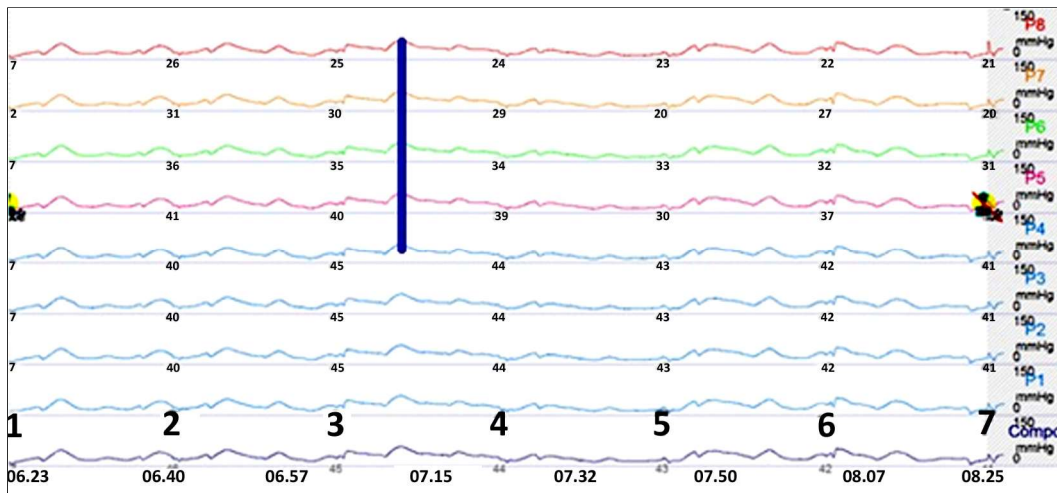


Figure 1. Conventional manometry – type II achalasia
(Collection of General and esophageal surgery clinic, Sf Maria Hospital)

normal distribution) were used. The quantitative data were tested to verify the normality and homogeneity of the variants using the Levene test.

Pearson Chi-Square and Fisher's Exact Test were used for categorical data (synthesized as frequencies and percentages).

The probability of error less than 5% ($p < 0.05$) was considered the threshold of significance.

Almost all patients presented with dysphagia 94.74%, other symptoms being retrosternal pain 31.58% and regurgitation 64.91%.

We used the Eckardt clinical score (10) which takes into account 4 criteria: dysphagia, regurgitation, retrosternal pain and weight loss, each criterion receiving between 0 and 3 points. Out of these, the first three are scored according to frequency, and the last one according to weight (kg).

Preoperative manometry was performed only in 59 patients (out of 98), because the other patients did not tolerate the investigation (Fig. 1). According to the Chicago 3.0 classification (11), 20 patients had type I achalasia and other 39 had type II achalasia.

Two of the patients undergone a classical surgical approach and other 71 a laparoscopic approach (with a 3D HD image trolley, using 5

trocars and standard instruments). Anterior Heller esocardiomyotomy was performed (Fig. 2) with restoration of the His angle and 180-degree Dor anterior hemifundoplication (Fig. 3). Intraoperative endoscopic control was performed routinely to control the integrity of the mucosa and evaluate the efficiency of the myotomy.

Dilation with a pneumatic balloon was performed in 25 patients, after the insertion of the guide wire, under endoscopic control, with a 30 mm balloon (Fig. 4). Before the 2

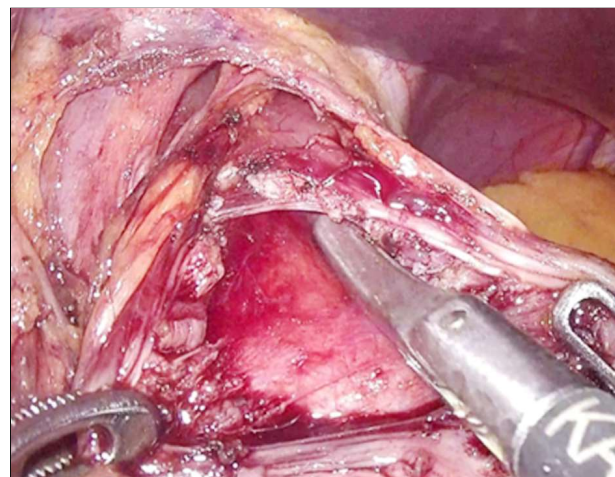


Figure 2. Esophageal Myotomy
(Collection of General and esophageal surgery clinic, Sf Maria Hospital)

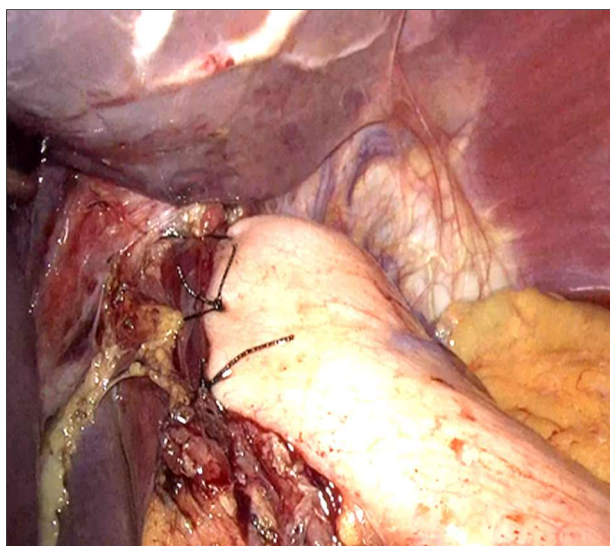


Figure 3. Dor fundoplication
(Collection of General and esophageal surgery clinic, Sf Maria Hospital)



Figure 4. Pneumatic dilation for achalasia
(Collection of General and esophageal surgery clinic, Sf Maria Hospital)

therapeutic methods, the patients consumed only clear liquids for 24 hours. Despite the pre-therapeutic preparation, in some patients aspiration on the Levin probe was needed.

All patients were reevaluated postoperatively using the Eckardt score and barium esophagogram at 3, 6, 12 months.

Results

The data obtained from the charts and from the telephone interview were included in a table in order to make the statistical analysis (*Table 1*).

Regarding the treatment, female patients undergone endoscopic pneumatic dilation more frequently, while men mainly benefited from LHM. It was probably due to general indications for a specific type of intervention, depending on age and gender.

The age was higher in the group with PD compared to the group with LHM.

Both groups had, on average, the same pre-therapeutic Eckardt score, but the post-therapeutic evaluation showed a lower score in LHM patients compared to PD patients (p -value <0.05). However, in both cases, the Eckardt score fell within the normal range.

Table 1. Patients evaluation

	Batch=PD (N=25)	Batch= LHM (N=73)	p_value
Gender			
f	16/25 (64%)	28/73 (38.4%)	
m	9/25 (36%)	45/73 (61.6%)	0.026090
Age	64.36±14.159	50.12±15.625	0.000115
pre-therapeutic Eckardt score	7.0 (4.0, 7.0)	7.0 (5.0, 8.0)	0.250863
post-therapeutic Eckardt score	3.00 (1.50, 4.00)	2.00 (1.00, 2.00)	0.006281
Disease recurrence	5/25 (20%)	3/73 (4.1%)	0.024186
Cost - lei	1597(857.7, 3881.5) lei	4124 (2893, 5285) lei	0.000250
Hospitalization days	3.00 (2.00, 6.00)	6.00 (4.00, 9.00)	0.000764
Improved life quality after treatment	13/25 (52%)	53/73 (72.6%)	0.057969

Thus, we can conclude that both procedures can be performed depending on the patients' preference, the medical history and the training of the medical centers (5).

The average post-therapeutic follow-up interval was 54 months.

We addressed a 4-questions survey, besides Eckardt score: 1-What post-operative symptoms did you have (when did they occur, what kind of symptoms did you have and for how long)?; 2-Did you have any other treatments/medication in the meantime?; 3-Did you have other symptoms other than the post-operative ones?; 4- How improved was the quality of life after the procedure?. The telephone method of addressing the survey led to a high response rate, being easy to carry out by the staff and without inconvenience for the patient. The questions were asked for the first time in 2022 and again in 2024.

Discussion

A study conducted in 2013 showed that the therapeutic response and success rates of PD and LHM are similar in achalasia type I ($P = .84$). PD has a significantly higher success rate in achalasia type II ($P = 0.03$), but both treatments are very effective. In type III patients, a difference was observed between the two methods, but it was not statistically significant ($P = .12$) (12).

Data from scientific literature recommends surgical intervention as the first therapeutic option for men under 40 years old, respectively dilation for female or over 40 years old patients (13). We also tried to keep these recommendations, but taking the decision after consulting the patient.

There is a subject of debate in literature, related to the assessment of the treatment response and if the absence of symptoms is enough (in this case, the Eckardt score should be less than or equal to 3) or if it is also necessary to confirm the complete evacuation of the esophagus with the help of timed barium esophagogram or the normalization of LES pressional response using manometry.

There are authors who demonstrated, on a

limited number of cases of achalasia, a correlation between the clinical score and timed barium esophagogram (at 1 and 5 minutes) (14). Other authors recommend a more complete evaluation, using several surveys (including one regarding the gastro-esophageal reflux) as well as the results of investigations.

It is certain that clinical results are usually better than those obtained following investigations (15). In patients with achalasia, treatment is palliative, symptomatic. From here, the question arises as to whether the relapse should be taken into account after the clinical evaluation or after the investigations. It is also worth discussing the decision of a new therapeutic session, establishing its indications and the results we expect to obtain.

In our group, the recurrence of symptoms was more frequent in the case of PD, which required another therapeutic intervention.

Some authors consider that PD and LHM are equally effective, even after 10 years of follow-up, with a limited risk of developing gastro-oesophageal reflux. Based on these data, we conclude that PD and LHM can both be proposed as initial treatment of achalasia (16).

The cost of the treatment, as well as the number hospitalization days were lower in the case of PD.

The advantage of our study was the remote follow-up of the results, respectively the re-evaluation with the help of the Eckardt score, after a mean interval of 4.5 years. Both therapeutic methods had advantages and disadvantages, the results being maintained over time. We found that the assessment of the quality of life was better in the case of surgical patients, but without being a statistically significant difference.

The limits of the study are the retrospective type and the lack of standardization in choosing the therapeutic method.

Conclusions

Both surgical treatment and pneumatic dilation lead to improvement of the symptoms

of patients with achalasia. In the case of dilations, extra procedures were often needed. The post-procedural Eckardt score was lower in the case of laparoscopic myotomy compared to dilations, which could suggest a recommendation for surgical treatment as the first option.

Conflict of Interest

The authors declare no conflict of interest.

Ethical approval

The study protocol was approved by the Ethical Committee of “Sf. Maria” Clinic Hospital of Bucharest, no 17/22.01.2024. The need for individual informed consent was waived owing to the retrospective study design.

Consent to participate

The participants were informed about the study aims and as assured of data confidentiality. Participation was voluntary, and written informed consent was obtained from all participants before data collection.

Authors' Contributions

A.A. and P.H. developed the study concept and design. M.G., C.G., F.A., E.P. collected and analyzed the data. S.C., D.P., R.B., M.M., R.V. detailed the methodology. A.A., P.H. wrote and edited the original draft. All authors read, corrected and approved the final manuscript.

References

- Cheng JW, Li Y, Xing WQ, Lv HW, Wang HR. Laparoscopic Heller myotomy is not superior to pneumatic dilation in the management of primary achalasia: Conclusions of a systematic review and meta-analysis of randomized controlled trials. *Medicine (Baltimore)*. 2017;96(7):e5525.
- Constantinoiu S. Surgery of the Esophagus. Achalasia. Bucharest: Editura Academiei Romane; 2019. p. 391-403.
- Riccio F, Costantini M, Salvador R. Esophageal Achalasia: Diagnostic Evaluation. *World J Surg*. 2022;46(7):1516-1521.
- Vaezi MF, Pandolfino JE, Yadlapati RH, Greer KB, Kavitt RT. ACG Clinical Guidelines: Diagnosis and Management of Achalasia. *Am J Gastroenterol*. 2020;115(9):1393-1411.
- Nickel F, Müller PC, de la Garza JR, Tapking C, Benner L, Fischer L, et al. Heller myotomy versus endoscopic balloon dilatation for achalasia: a single center experience. *Medicine (Baltimore)*. 2019;98(44):e17714.
- Chuah SK, Lim CS, Liang CM, Lu HI, Wu KL, Changchien CS, et al. Bridging the Gap between Advancements in the Evolution of Diagnosis and Treatment towards Better Outcomes in Achalasia. *Biomed Res Int*. 2019;2019:8549187.
- Chuah SK, Wu KL, Hu TH, Tai WC, Changchien CS. Endoscope-guided pneumatic dilation for treatment of esophageal achalasia. *World J Gastroenterol*. 2010;16(4):411-7.
- Costantini M, Salvador R, Costantini A. Esophageal achalasia: pros and cons of the treatment options. *World J Surg*. 2022;46(7):1554-1560.
- Costantini M, Salvador R, Capovilla G, Vallese L, Costantini A, Nicoletti L, et al. A thousand and one laparoscopic Heller myotomies for esophageal achalasia: a 25-Year Experience at a Single Tertiary Center. *J Gastrointest Surg*. 2019;23(1):23-35.
- Eckardt AJ, Eckardt VF. Treatment and surveillance strategies in achalasia: an update. *Nat Rev Gastroenterol Hepatol*. 2011;8(6):311-9.
- Kahrilas PJ, Bredenoord AJ, Fox M, Gyawali CP, Roman S, Smout AJPM, et al. The Chicago classification of esophageal motility disorders, v3.0. *Neurogastroenterol Motil*. 2015;27(2):160-74.
- Rohof WO, Salvador R, Annese V, des Varannes SB, Chaussade S, Costantini M, et al. Outcomes of treatment for achalasia depend on manometric subtype. *Gastroenterology*. 2013;144(4):718-25; quiz e13-4.
- Richter JE, Boeckxstaens GE. Management of achalasia: surgery or pneumatic dilation. *Gut*. 2011;60(6):869-76.
- Hong SJ, Lee YJ, Lee SJ, Hong BK, Kang WC, Lee JY, et al. Treat-to-target or high-intensity statin in patients with coronary artery disease: a randomized clinical trial. *JAMA*. 2023;329(13):1078-1087.
- Shemmeri E, Aye RW, Farivar AS, Bograd AJ, Louie BE. Use of a report card to evaluate outcomes of achalasia surgery: beyond the Eckardt score. *Surg Endosc*. 2020;34(4):1856-1862.
- Boeckxstaens G, Elsen S, Belmans A, Annese V, Bredenoord AJ, Busch OR, et al. 10-year follow-up results of the European Achalasia Trial: a multicentre randomised controlled trial comparing pneumatic dilation with laparoscopic Heller myotomy. *Gut*. 2024;73(4):582-589.
- Boeckxstaens GE, Annese V, des Varannes SB, Chaussade S, Costantini M, Cuttitta A, et al. Pneumatic dilation versus laparoscopic Heller's myotomy for idiopathic achalasia. *N Engl J Med*. 2011;364(19):1807-16.