### **Original Research Article**

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## Clinical outcomes and quality of life following laparoscopic Heller's myotomy for achalasia cardia: an observational study from a tertiary care hospital

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#### **ABSTRACT**

**Background:** The clinical outcomes of Achalasia cardia (AC) following laparoscopic Heller's myotomy (LHM) in terms of improvement in clinical symptom scores as well as the quality of life (QOL) have not been investigated extensively in the literature, which has been analyzed in this study. The role of physiological tests after surgery, along with their relationship to symptom evaluation, was evaluated in the present investigation.

**Methods:** The 65 patients who had LHM with Dor's fundoplication (LHMD) between August 2014 and July 2022 were included in this retrospective analysis. Eckardt score (ES) calculation, ASHRQOL (Achalasia specific health-related QOL) questionnaire score, measurement of 5-minute column height in TBE (Timed barium esophagogram), as well as median IRP (Integrated relaxation pressure) in HRM (High-resolution manometry) were done. All patients then underwent LHMD.

**Results:** ES (8.18 $\pm$ 1.06 to 1.57 $\pm$ 1.06, p=0.005), ASHRQOL score (63.10 $\pm$ 11.84 to 7.29 $\pm$ 6.20, p=0.005), 5-minute column height on TBE (104.86 $\pm$ 16.42 mm to 11.43 $\pm$ 16.83 mm, p=0.005), along with IRP (25.58 $\pm$ 4.35 mm Hg to 3.88 $\pm$ 3.15 mmHg, p=0.005) all demonstrated substantial gains at a median follow-up of 24 months. ES correlated significantly with ASHRQOL scores ( $\rho$ =0.996, p=0.005), TBE height at 5-minute ( $\rho$ =0.921, p=0.005), as well as median IRP ( $\rho$ =0.866, p=0.005). The improvement in TBE height correlated strongly with median IRP ( $\rho$ =0.928, p=0.005).

**Conclusions:** LHMD leads to sustained symptom relief and significant enhancement in QOL. Clinical score improvement correlates among themselves as well as with physiological scores. Therefore, regular follow-up may not require physiological testing by manometry.

**Keywords:** Laparoscopic Heller's myotomy, Achalasia cardia, Clinical outcomes, Eckardt score, Quality of life, High resolution manometry

#### INTRODUCTION

Achalasia cardia (AC) is distinguished by irregular esophageal peristalsis as well as declined relaxation of LES (lower esophageal sphincter). These conditions have been caused by a number of factors that eventually contribute to the loss of inhibitory nerve endings at LES. The patient exhibits symptoms that include regurgitation,

weight loss, retrosternal pain, or else discomfort, along with dysphagia. Diagnostic evaluation comprises barium studies, manometry, and symptom assessment, along with esophagogastroduodenoscopy.

ES, which had been created to objectively evaluate the severity of symptoms, is still in use nowadays.<sup>3-4</sup> Weight loss, dysphagia, regurgitation, as well as retrosternal pain

have been among the main esophageal symptoms linked to achalasia that are asked about in the scoring system.

The ASHRQOL score is a recognized as well as validated scoring system that Urbach and colleagues had created for evaluating the QOL of patients suffering from achalasia during both initial evaluations along with follow-up period following intervention. <sup>4,5</sup> Patients can rate and categorize achalasia symptoms, especially dysphagia, to solids as well as liquids, food preferences, and other related symptoms, along with general health in connection with achalasia, by answering ten questions. On a scale of 10-33, which can be related to a 0-100 scale, scores were totaled, with greater scores indicating more severe achalasia symptoms.

The ability of TBE to more objectively evaluate esophageal emptying has made it a favored method over regular barium investigations.<sup>6</sup> Because of its greater sensitivity, HRM of esophageal pressure topography, which additionally measures median IRP, has supplanted standard manometry as the gold standard for diagnosing achalasia.<sup>7</sup> Achalasia has been distinguished by a median IRP of greater than 15 mmHg without esophageal peristalsis.

In this study, clinical scores included are ES and ASHRQOL scores, and they will provide a subjective evaluation of the condition, whereas 5-minute column height in TBE and median IRP in manometry are addressed as physiological scores and that will provide an objective assessment of the condition in both preoperative and post-operative setting.

Minimally invasive techniques are the preferred method of treatment that seeks to disrupt LES to allow food to enter straight into the stomach as a bolus. A LHM has been the preferred surgery in management<sup>8</sup> accompanied by the addition of a routine partial anti-reflux procedure, thereby reducing the incidence of pathological gastro-oesophageal reflux after surgery.<sup>4</sup>

The clinical outcomes of this disease following surgery in terms of symptom relief as well as the QOL have not been studied. According to an investigation of the literature, post-intervention evaluation is mostly predicated on the evaluation of symptomatic relief as demonstrated by the ES as well as improvement in QOL, even though the relevance of physiological tests in the diagnostic workup of individuals with suspected achalasia is well-established. The relevance of routine physiological evaluation for patients after endoscopic or surgical intervention is up for debate.

Additionally, there aren't many studies examining the relationship among physiological parameters as well as symptom alleviation, especially after Heller myotomy, and the ones that are conducted have produced unreliable outcomes.<sup>4,9-11</sup>

#### Aim

#### Primary objectives

Primary objectives were to evaluate outcomes of LHMD in terms of clinical improvement by using variable parameters such as ES, 5-minute column height in TBE and median IRP in HRM. The QOL of the patients before and after surgery is analyzed using the ASHRQOL questionnaire score

Secondary objective

Secondary objective was to evaluate the correlation between clinical and physiological outcomes.

#### **METHODS**

Sixty-five adult patients with AC who had LHMD at the institute of surgical gastroenterology at Rajiv Gandhi government general hospital in Chennai throughout eight-year period between August 2014 and July 2022 had been encompassed in this retrospective investigation. Among 77 patients who underwent LHMD, only 65 individuals with comprehensive records of preoperative as well as postoperative data were included in the analysis. The institution ethics committee approved the study.

#### Inclusion criteria

AC patients over the age of 18 years who had LHMD were included.

#### Exclusion criteria

Patients under the age of eighteen, patients who underwent redo surgeries and patients whose complete records were not available were excluded.

Preoperatively, ES calculation, ASHRQOL questionnaire scoring, TBE measurement, and HRM were performed. Using the conventional five-port approach, each patient received LHMD: one camera port, two working ports, one assistant port, along with one port for liver retraction. Myotomy has been done on the esophageal anterior wall, extending 2-3 cm on the stomach along with 5-6cm gastroesophageal above the junction. fundoplication is done in all patients. Follow-up was performed at 4 weeks, 6 months, 1 year, as well as 2 years. Eckardt, along with ASHRQOL scores were recorded at each visit and TBE and HRM were recorded at four weeks, at the end of 1 year and 2 years. Patients with raised ES in further follow-up were evaluated with TBE and HRM. Only patients with 2 years of follow-up had been comprised in this investigation. ES  $\leq 3$ ,  $\geq 50$ percent fall in 5-minute column height in TBE, median IRP <15 in manometry, and fall in absolute ASHRQOL questionnaire score <15 were considered as the parameters to deem treatment successful.

#### Statistical analysis

IBM SPSS statistics for Windows, version 29.0, had been employed for evaluating gathered data after it was entered into Microsoft excel 2016. (Armonk, NY: IBM Corp). Descriptive statistics were employed to describe data: mean and standard deviation were utilized for continuous variables and frequency analysis along with percentage analysis had been conducted for categorical variables. To determine whether there had been significant variation between bivariate samples in paired groups, a paired sample t test was employed. Spearman correlation had been employed to evaluate the connection between variables.

The probability value of 0.05 is regarded as significant level in 2 statistical techniques mentioned above.

#### **RESULTS**

Between August 2014-July 2022, 77 consecutive patients underwent LHMD. Of these, complete records of the data needed for analysis were not available for 11 patients and one patient expired due to a road traffic accident 6 months after surgery. The remaining 65 patients with complete records with 2 years of follow-up had been comprised in final investigation.

The  $37.86\pm13.49$  years had been the mean age of participants, and the sex distribution included 48% females (n=31) and 52% males (n=34). The HRM type distribution showed that type 2 was the most common (58.5%, n=38), followed by type 1 (33.8%, n=22), and type 3 (7.7%, n=5). The mean operating time had been  $133.22\pm12.02$  minutes. The average length of hospital stay had been  $3.65\pm0.78$  days (Table 1). In our investigation, there had been no Clavien Dindo grade 3/4 complications or perioperative mortality.

Table 1: Demographics and perioperative characteristics.

Variables		Mean±SD	N (%)
Age (in years) (mean)		37.86±13.49	
Gender	Female		31 (48)
	Male		34 (52)
HRM types	1		22 (33.8)
	2		38 (58.5)
	3		5 (7.7)
Operating time in minutes (mean)		133.22±12.02	
Conversions			0
Hospital stays in days (mean)		3.65±0.78	
Clavien-Dindo complications (grade 3/4)			0
Mortality			0
Follow-up (months)		24.3±1.2	

Mean ES significantly enhanced from  $8.18\pm1.06$  preoperatively to  $1.57\pm1.06$  postoperatively (p=0.005). Similarly, the absolute ASHRQOL score significantly improved, decreasing from  $24.51\pm2.72$  to  $11.68\pm1.43$  (p=0.005). When calibrated to a scale of 100, the ASHRQOL score significantly improved from  $63.1\pm11.84$  to  $7.29\pm6.20$  (p=0.005).

The physiological parameters also showed significant improvements. The mean TBE height at 5-minute reduced from  $104.86\pm16.42$  mm to  $11.43\pm16.83$  mm (p=0.005). The median IRP showed a substantial decline, from  $25.58\pm4.35$  mm Hg to  $3.88\pm3.15$  mm Hg (p=0.005) (Table 2).

Table 2: Clinical and physiological outcomes before and after LHMD.

Parameters	Mean±SD Pre- operative	Post- operative	P value
ECKARDT	8.18±1.06	1.57±1.06	0.005
ASHRQOL score absolute	24.51±2.72	11.68±1.43	0.005
ASHRQOL score calibrated	63.1±11.84	7.29±6.20	0.005
TBE height at 5 min	104.86±16.42	11.43±16.83	0.005
Median IRP	25.58±4.35	3.88±3.15	0.005

The success rate of LMHD was 100% at the end of the first year, with all patient's symptom-free. At the end of 2 years of follow-up, three out of 65 individuals had a recurrence in symptoms with ES of more than 3, which correlated with raised median IRP and 5-minute column height in the barium study. They were subjected to endoscopic dilatation that relieved their symptoms and were on regular follow-up. So, the success rate of LHMD was 95.38 % at the end of the second year.

Postoperatively, a significant positive correlation was detected among improvements in symptomatic as well as physiological parameters. The ES strongly correlated with the absolute ( $\rho$ =0.996, p=0.005) as well as calibrated ASHRQOL scores ( $\rho$ =0.996, p=0.005) (Figure 1). It also demonstrated significant correlations with TBE height at 5 min ( $\rho$ =0.921, p=0.005) along with median IRP ( $\rho$ =0.866, p=0.005) (Figure 3 and 4).

There was a strong correlation among TBE height at 5 min along with median IRP ( $\rho$ =0.928, p=0.005) (Table 3) (Figure 2).

The absolute ASHRQOL score strongly correlated with TBE height at 5-minute ( $\rho$ =0.921, p=0.005) and the median IRP ( $\rho$ =0.863, p=0.005) (Figure 5 and 6).

Table 3: Correlation of preoperative and postoperative symptomatic and physiological parameters.

Variables	Preoperative		Postoperative	
variables	ρ	P value	ρ	P value
ECKARDT and ASHRQOL score absolute	0.965	< 0.001	0.996	0.005
ECKARDT and ASHRQOL scores calibrated	0.965	< 0.001	0.996	0.005
ECKARDT and TBE height at 5 min	0.961	< 0.001	0.921	0.005
ECKARDT and median IRP	0.95	< 0.001	0.866	0.005
ASHRQOL score absolute and TBE height at 5 min	0.996	< 0.001	0.921	0.005
ASHRQOL score absolute and median IRP	0.988	< 0.001	0.863	0.005
TBE height at 5 min and median IRP	0.996	< 0.001	0.928	0.005

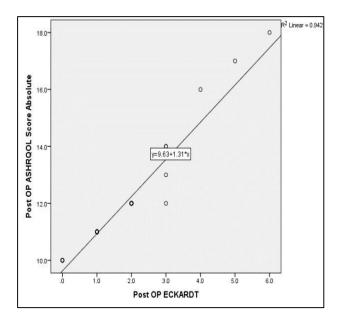


Figure 1: Correlation among clinical scores-ECKARDT and absolute ASHRQOL score.

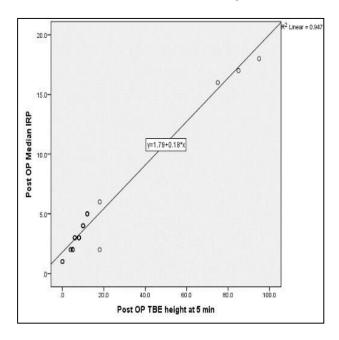


Figure 2: Correlation among physiological scores-post op TBE at 5-minute with post op median IRP.

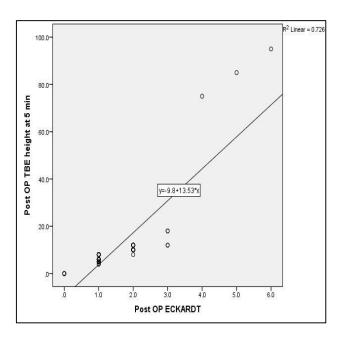


Figure 3: Correlation between clinical scores and physiological parameters-ECKARDT and TBE height at 5 min.

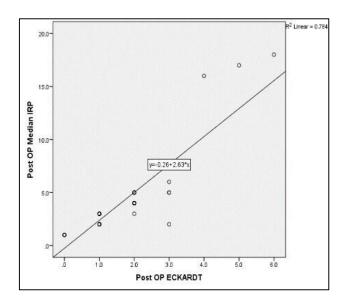


Figure 4: Correlation between clinical scores and physiological parameters-ECKARDT and median IRP.

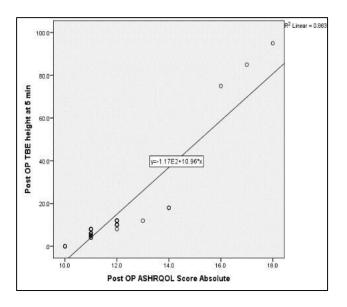


Figure 5: Correlation between clinical scores and physiological parameters (Continued)-ASHRQOL score absolute and TBE height at 5 min.

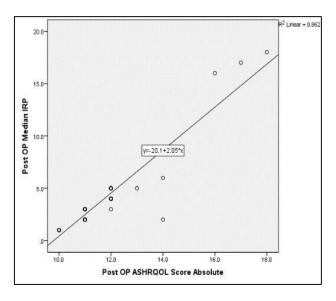


Figure 6: Correlation between clinical scores and physiological parameters (Continued)-ASHRQOL score absolute and median IRP.

Table 4: Correlation between changes in symptomatic and physiological parameters.

Change of pre to post	ρ	P value
ECKARDT and ASHRQOL score absolute	0.584	< 0.001
ECKARDT and ASHRQOL scores calibrated	0.552	< 0.001
ECKARDT and TBE height at 5 min	0.669	< 0.001
ECKARDT and median IRP	0.581	< 0.001
ASHRQOL score absolute and TBE height at 5 min	0.901	< 0.001
ASHRQOL score absolute and median IRP	0.924	< 0.001
ASHRQOL score calibrated and TBE height at 5 min	0.894	< 0.001
ASHRQOL score calibrated and median IRP	0.921	< 0.001
TBE height at 5 min and Median IRP	0.945	< 0.001

The change in preoperative and postoperative values of both the symptomatic and physiological parameters showed a significant correlation. The change in ES showed moderate to strong correlations with the change in the absolute ASHRQOL score ( $\rho$ =0.584, p<0.001). Additionally, it demonstrated strong correlations with the change in TBE height at 5-minute ( $\rho$ =0.669, p<0.001) as well as median IRP ( $\rho$ =0.581, p<0.001). Change in TBE height at 5-minute strongly correlated with change in median IRP ( $\rho$ =0.945, p<0.001) (Table 4).

#### **DISCUSSION**

The 95.38% of patients demonstrated clinical improvement in the form of improved ES, with mean ES enhanced from 8.2 to 1.6, at a median follow-up of 24 months. This outcome aligns with a few investigations in the literature that have documented improvements ranging from 71-100 percent, depending on the duration of follow-up.<sup>12,13</sup> In the European Achalasia trial, Moonen et al claimed 94% success at 1 year, but they additionally noticed a decline in success to 89% at 2 years along with 84 percent at 5 years.<sup>7</sup> Given the

progressive as well as irreversible nature of the disease, trials with shorter follow-ups revealed favorable outcomes than those with longer follow-ups. In our study, ES correlated with the ASHRQOL score and also with the improvement in physiological outcomes such as TBE and median IRP in manometry postoperatively.

Symptoms of achalasia may have a vital emotional, physical, as well as social influence on a patient's life. In reviewing the literature, only a few studies have focused on the patient's perception of health and QOL before and after therapy for achalasia. An important indicator of adequacy as well as quality of treatment is assessing the patient's QOL and satisfaction after surgery. According to Slone et al an effective outcome had been most closely correlated with an absolute ASHROOL score of ≤15.4 ASHRQOL scores showed improvement with an absolute score of  $\leq 15$  in every individual in this investigation. Garrigues et al noted similar findings with enhancement in HRQOL (Health related QOL) score post pneumatic dilatation or Heller myotomy.14 Asti et al used the GERD-HQL questionnaires to evaluate 118 patients with achalasia as part of a cohort study that examined QOL

following treatment of AC who underwent LHMD. $^{15}$  They discovered that mean ES dropped dramatically from  $6.9\pm1.9$  to  $1.7\pm1.2$ , as well as 88 percent of patients were pleased with outcomes.

HRM performs an essential role in short-term follow-up subsequent surgical intervention, in addition to TBE, in evaluating esophageal emptying along with lower esophageal sphincter pressure reduction. Functional testing must be chosen over symptom assessment, as advised by the ACG (American College Gastroenterologists)<sup>16</sup> clinical guidelines. This has been because postinterventional improvement in symptoms may be accompanied by an inadequate LES pressure reduction, which raises the risk of megaesophagus development in these patients' clinical course. In all of the patients in our study, median IRP, which had been greater than 15 mm Hg before surgery, declined from a mean of 25.6-3.9 mm Hg. The investigation by Salvador et al and Pooshani et al revealed comparable results, with median IRP dropping from 27.4-7.1 mm Hg as well as 16.24 mm Hg, correspondingly. 11,17 Improvement in median IRP correlated strongly with clinical outcome score and TBE in our study.

TBE has been a useful instrument that offers a noninvasive evaluation of esophageal emptying. It provides repeated measures of esophageal function in both preoperative settings and during routine follow-up. Success has been defined in TBE utilizing a number of characteristics, that include surface area, column height, along with column width. Similar to previous investigations by Neyaz and Kachala et al we defined success in the present investigation as a drop in column height of more than 50 percent at 5-minutes. Similar to research by Kachala et al 40 percent of patients attained less than 5mm height at 5-minutes on follow-up TBE at 2 years. 19

Although both symptomatic and physiological improvements are well documented, there is little evidence to establish a correlation between them in the literature. At a correlation value of 0.9, our study's ES, along with ASHRQOL scores in preoperative as well as postoperative settings, had been comparable to the latest research by Slone et al.<sup>4</sup> A substantial correlation between ES along with ASHRQOL scores in individuals going through POEM (Per oral endoscopic myotomy) has been reported by Perbtani et al.<sup>20</sup>

The outcomes from various achalasia therapies are increasingly being evaluated physiologically utilizing manometry along with barium tests. Bolus retention is best evaluated by TBE. However, manometry can reliably determine the completeness of myotomy. It is uncertain, nevertheless, if they should be utilized for tracking patients who are asymptomatic following surgery. Research examining the relationship among physiological characteristics as well as symptoms or QOL has produced inconsistent outcomes. Anderson et al

found a significant correlation between clinical symptom score (Watson dysphagia score) and TBE in individuals treated with pneumatic dilatation along with LHMD.

North-Western group displayed a weak relationship among ES with IRP as well as bolus retention on TBE At 5-minutes.<sup>21</sup> Cho et al showed a correlation between TBE and median IRP comparable to our investigation.<sup>22</sup> Ross et al studied the correlation of ASHRQOL with physiological parameters, but they found no correlation, which is as opposed to our investigation.  $^{23}$  ES (7.03±1.53 to 0.93±1.10, p<0.001), ASHRQOL, column height on TBE, as well as IRP  $(23.95\pm8.26 \text{ to } 4.61\pm4.11, p<0.001)$ all indicated a substantial improvement, as reported by a study by Kumar et al.24 There was a substantial correlation among ES along with ASHRQOL both preoperatively (ρ=0.410, P<0.001) as well as follow up (ρ=0.559, p<0.001). Nevertheless, no relationship had been found between physiological and clinical features. In our study, a significant positive correlation had been observed among improvements in symptomatic parameters as well as physiological parameters. Thus, there may be no need for postoperative routine physiological testing when patients have clinical symptom scores within the normal range. The advantages of outcomes of this investigation are that patients may avoid undergoing cumbersome manometry testing and also from unnecessary anxiety in asymptomatic cases if manometry shows discordant findings. Also, it is costeffective. Thus, it would seem reasonable and equitable to save physiological tests, for instance, manometry, for individuals whose complaints are persistent or else reoccurring. Our study resolves the largely unexplored idea of routine physiological testing after Heller's myotomy and proposes that there is no need for routine testing of functional outcomes. Limitations of our investigation, however, have been the bias associated with retrospective study, comparatively shorter followup, as well as, consequently, fewer treatment failures on follow-up.

#### **CONCLUSION**

Even in this era of endotherapies that include POEM (Per oral endoscopic myotomy), LHM is considered the surgical standard of care for AC. This procedure leads to sustained symptom relief and significant enhancement in QOL, as evidenced by this investigation. This study also observed that manometry could be substituted with a TBE as an objective tool if needed following surgery, as it is non-invasive and cost-effective. Improvement in clinical scores correlates among themselves as well as with physiological scores. So, for routine follow-up, physiological testing might not be required.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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