



A PROSPECTIVE OBSERVATIONAL STUDY ON MANAGEMENT OF ACHALASIA CARDIA WITH LAPAROSCOPIC HELLERS MYOTOMY AND ITS OUTCOMES USING ECKARDT'S CRITERIA IN A TERTIARY CARE CENTRE IN CENTRAL INDIA

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ABSTRACT

Introduction: Achalasia is a primary esophageal motility disease characterized by the absence of peristalsis in esophageal body and abnormal relaxation of the lower esophageal sphincter (LES) in response to swallowing. Surgical approaches for treating achalasia seek to overcome esophageal outflow obstruction by longitudinal division of the anterior muscle fibers of lower esophageal sphincter. This study was conducted to assess the surgical outcomes and post operative complications in post-operative patients of Laparoscopic Hellers Myotomy using Eckardt criteria.

Methods and Materials: A prospective observational study of 23 patients, with achalasia cardia who underwent Laparoscopic Heller's Myotomy, was performed in Department of General Surgery of Government Medical College and Hospital, Nagpur for a period of 2 years (From August 2020 to August 2022).

Results: In this study of 23 patients, most of the patients were from the age group of >50 years(60.87%) and were female(65.22%). Majority of the patients had the symptoms for >10 years (39.13%) with most patients having a preoperative dysphagia score of 2(69.6%). Most common symptoms were dysphagia(100%), regurgitation(52.17%), chest pain(30.43%) and weight loss(65.22%). Most patients showed dilated esophagus on gastroesophagoscopy(69.57%). Barium esophagogram was done in most of the patients(86.96%). Most patients(82.61%) showed type II on high resolution Manometry. 56.52% patients underwent fundoplication, only one showed mucosal injury. Most patients were initiated oral sips on Day1(86.96%) and oral feeds on Day 4(56.52%). Most patients(65.2%) had a hospital stay of 5 days. The overall pre-operative Eckardt score was 5.47±2.81. The overall Eckardt score at discharge and at 2 weeks follow up was 1.52±1.20. The overall Eckardt score after 3 and 6 months follow up was 0. All the 23 patients survived the procedure with 0% mortality.

Conclusion: This study demonstrates that laparoscopic hellers Myotomy is both safe and effective. Majority of patients will have symptom improvement with Hellers myotomy, and the majority of them have no recurrence even after very long-term followup.

KEYWORDS: Achalasia, Laparoscopic Hellers Myotomy, Eckardt Score, LES Division, Fundoplication.

Introduction

Achalasia is a primary esophageal motility disease that usually presents with progressive dysphagia, chest pain, regurgitation, and weight loss. Idiopathic achalasia is a primary esophageal motor disorder characterized by the absence of peristalsis in esophageal body and abnormal relaxation of the lower esophageal sphincter (LES) in response to swallowing. Its incidence is approximately 1 to 3 cases of 100,000 persons per year[1]. Although achalasia can be suspected using clinical, radiographic, and endoscopic information, definite diagnosis can only be made using esophageal manometry[2], which shows the absence of esophageal motility and in most cases inappropriate lower esophageal sphincter (LES) relaxation. High-resolution manometry can be used to further study esophageal motility in patients with achalasia by categorizing patients into three subtypes that can predict patient response to endoscopic or surgical treatment[3].

Treatment for patients with achalasia focuses on symptoms improvement. Endoscopic and surgical approaches for treating achalasia seek to overcome esophageal outflow obstruction while trying to prevent the development of gastroesophageal reflux disease (GERD) and its associated complications[4,5].

If candidates are fit for surgery, pneumatic balloon dilatation (PBD), peroral endoscopic myotomy (POEM), and laparoscopic Heller's myotomy are the mainstays of therapy that act by mechanical disruption of LES. On the other hand, botulinum toxin and pharmacotherapy (nitrates and calcium channel blockers) act by biochemical reduction of LES and are reserved for surgically unfit patients with limited life expectancy because of their short-lived efficacy. Oesophagectomy is reserved for treating refractory longstanding cases, who have previously failed multiple therapies[6]. The disease is usually presented in younger ages, and delayed treatment may result in more serious complications including esophageal cancer. Although modern endoscopic surgical interventions and per oral endoscopic myotomy are increasingly used for treating achalasia, the preferred surgical method is still laparoscopic myotomy as an accepted intervention[7,8].

The main objective in surgery for achalasia is the disruption of the LES muscular fibers[9,10]. The first description of an esophageal myotomy for achalasia was in 1913 by Heller[11], in which both anterior and posterior muscle fibers were divided. A modified procedure currently known as Heller myotomy is the longitudinal division of the anterior muscle fibers and has become the standard surgical approach for achalasia[4]. This study was conducted to assess the surgical outcomes and post operative complications in post-operative patients of Laparoscopic Hellers Myotomy using Eckardt criteria.

Aims and Objectives

- To assess the surgical outcomes in post-operative patients of Laparoscopic Hellers Myotomy using Eckardt criteria.
- To assess the post-operative complications after Laparoscopic Hellers Myotomy.

Materials and Methods

A prospective observational study was performed in Department of General Surgery of Government Medical College and Hospital (GMCH), Nagpur for a period of 2 years (From August 2020 to August 2022).

Study Population: All adult patients with achalasia cardia presented to GMCH Nagpur during the study period.

Inclusion Criteria: The study included patients of either sex, aged 18 years or more, with achalasia cardia who underwent Laparoscopic Heller's Myotomy, and patients willing to participate in the study and sign written informed consent form.

Exclusion Criteria: All patients under 18 years of age, or patients who underwent POEM or PBD, or patients who are unfit for general anaesthesia, or those patients refusing to sign informed consent form.

Sample Size: Applying the formula, $n = Z^2 \cdot p(1-p) / d^2$, where $P(\%$ reduction of dysphasia after Laparoscopic Heller's Myotomy) = 62.5%[12], and $d(\text{Absolute precision required on either side of the proportion}) = 20\%$ and $Z = 1.96$ for 95% confidence interval Thus, a minimum sample size was calculated to be 23 patients.

Sampling Technique: In this study, convenient sampling technique was used.

Ethics: The study protocol was approved by the Institutional Ethics Committee (IEC) and written informed consent was obtained from the patient prior to study initiation.

Study Procedure: Permission was taken from the Head of the department of surgery. The purpose of the study was explained to the study subjects. Informed written consent in local language was taken before enrolment for study.

Preoperative Assessment: Preoperative evaluation included barium esophagogram, upper GI endoscopy, and manometry in all the patients to establish the diagnosis of achalasia and to rule out esophageal malignancy. All the relevant hematological and biochemical investigations were also performed. Preoperative Eckardt Score were calculated to know about the severity of symptoms. Preoperative chest physiotherapy and pulmonary medicine evaluation is an integral part for the preparation of the patient for surgery.

All the patients underwent laparoscopic modified Heller myotomy with Dor fundoplication, and all the procedures were completed laparoscopically. Under general anesthesia,

the patients were placed in the French position, with the operator standing between the legs. A pneumoperitoneum with a constant 12 mmHg intra-abdominal pressure was created through a 10 mm supra-umbilical incision using a Veress needle. Four or five trocars were inserted in the upper abdomen. The left hepatic lobe was lifted up by a fan retractor inserted through the right upper quadrant port to expose the esophageal hiatus. After the gastroesophageal junction was identified, a longitudinal dissection was performed with the Kellies forceps and electrocautery hook. The myotomy was started in the middle third of the exposed esophagus, lateral to the anterior vagus nerve. First, the longitudinal muscle layer was separated by two forceps and the circular muscular layer was separated by the stretching and tearing method very gently. Once the submucosal plane was identified in one place, the circular muscular layer was separated from the submucosa, and it was lifted up by the hook diathermy and cut under direct vision all the time. When cutting the circular muscle layer, it was done only after it was lifted off the submucosa and always under vision. The myotomy was extended upward 7 cm on the esophageal side and downward 1–2 cm on the gastric side across the sling muscles of the gastroesophageal junction. The length of the myotomy was measured by the marks on the irrigation/suction tube. In the event of mucosal perforation, it was sutured with absorbable sutures laparoscopically. Then the anterior partial fundoplication was fashioned using the gastric fundus fixed to the edges of the myotomy with four to five absorbable stitches for each side. The patients were followed up in the outpatient department. The functional results were assessed by using an overall clinical score based on 4 clinical symptoms on specific intervals (dysphagia, chest pain, regurgitation, and gastroesophageal reflux) derived from Eckardt score. The functional results were considered as excellent (score = 0), satisfactory (score = 1 or 2 with 2 different symptoms), fair (score = 2 or 3), and poor (score > 3 or any patient requiring reoperation or postoperative pneumatic dilation).

Statistical Analysis: Data was collected and tables were tabulated by Microsoft Office Excel and analysed with SPSS V.24 software. Descriptive statistics were used. The categorical and continuous variables are represented as frequency (percentage) and mean (standard deviation, SD), respectively.

Table 1: Demographic characteristics

Age (years)	N (=23)	%
< 20	2	8.72
20 - 50	7	30.43
≥ 50	14	60.87
Gender		
Male	8	34.78
Female	15	65.22

Results and Observations

Demographic characteristics Table 1

Most of the patients were from the age group of >50 years (60.87%) followed by 20-50 years (30.43%) and <20 years (8.70%). 34.78% were male and 65.22% were female.

Clinical characteristics Table 2

Among the 23 patients, most common symptom was dysphagia (100%), followed by weight loss (65.22%), regurgitation (52.17%) and chest pain (30.43%). Majority of the patients had the symptoms for >10 years (39.13%), followed by 5-10 years (30.43%), 1-5 years (17.39%) and <1 year (13.04%). 30.4% patients had preoperative dysphagia score of 3 while remaining 69.6% had a score of 2. In the upper GI scopy, 13.04% showed normal, 69.57% showed dilated esophagus and 17.39% showed inconclusive results.

Table 2: Clinical characteristics

Symptoms	N (=23)	%
Dysphasia	23	100
Regurgitation	12	52.17
Chest pain	7	30.43
Weight loss	15	65.22
Duration of Symptoms (years)		
< 1	3	13.04
1 - 5	4	17.39
5 - 10	7	30.43
> 10	9	39.13
Pre operative Dysphagia score		
Score 3	7	30.4
Score 2	16	69.6
Upper GI scope		
Normal	3	13.04
Dilated Esophagus	16	69.57
Inconclusive	4	17.39
Barium esophagogram		
Classical	20	89.96
Not done	3	13.04
High resolution manometry		
Type I	4	17.39
Type II	19	82.61
Type III	0	0

Barium esophagogram was done in 86.96% of the patients. 17.39% patients showed type I and 82.61% showed type II on high resolution manometry.

Surgery and Outcome characteristics Table 3

Among the 23 patients, 56.52% underwent fundoplication. Only one patient had mucosal injury. 86.96% patients were initiated oral sips on day 1, while 8.70% patients on day 2 and remaining 4.35% patients on day 6. 39.19% patients were initiated oral feeds on day 3, 56.52% patients on day 4 and remaining 4.35% patients on day 7. 65.2% patients had hospital stay of 5 days, while 21.74% patients had hospital stay of 6 days, 8.69% patients had hospital stay of 7 days.

One patient had intra-operative complication of esophageal perforation at level of lower esophagus for which intra-operative primary repair was done. Intra-operatively an abdominal drain inserted and distal feeding jejunostomy was done. The patient was managed conservatively and oral sips and oral feeds were initiated on day 6 and on day 7 respectively. The abdominal drain was removed on day 10 and the patient was discharged on day 12. Thus, 4.35% (1 patient) had hospital stay of 12 days. All the 23 patients survived the procedure with 0% mortality.

Table 3: Surgery and Outcome Characteristics

Fundoplication status	N(=23)	%
Yes	13	56.52
No	10	43.48
Mucosal injury		
Present	1	4.35
Absent	22	95.65
Initiation of Oral sips		
On Day 1	20	86.96
On Day 2	2	8.70
On Day 6	1	4.35
Initiation of Oral feeds		
On Day 3	9	39.19
On Day 4	13	56.52
On Day 7	1	4.35
Outcome		
Survived	23	100
Death	0	0
Hospital stay (days)		
5	15	65.22
6	5	21.74
7	2	8.69
12	1	4.35

Table 4: Eckardt score comparison

Symptoms	Pre operative	At discharge	At 2 weeks	After 3 months	After 6 months
Dysphasia	2.30 ± 0.47	0	0	0	0
Weight loss	1.52 ± 1.20	1.52 ± 1.20	1.52 ± 1.20	0	0
Regurgitation	1.04 ± 1.02	0	0	0	0
Chest pain	0.60 ± 0.09	0	0	0	0
Overall Score	5.47 ± 2.81	1.52 ± 1.20	1.52 ± 1.20	0	0

Preoperative vs Postoperative Eckardt Score Table 4

The mean pre-operative Eckardt score was 2.30 ± 0.47 for dysphagia, 1.52 ± 1.20 for weight loss, 1.04 ± 1.02 for regurgitation, 0.60 ± 0.09 for chest pain and 5.47 ± 2.81 for overall Eckardt score. The mean Eckardt score at discharge and at 2 weeks follow up was like 0 for dysphagia, 1.52 ± 1.20 for weight loss, 0 for regurgitation, 0 for chest pain and thereby overall Eckardt score was 1.52 ± 1.20 . The Eckardt score at 3 and 6 months follow up was 0 for dysphagia, weight loss, regurgitation, as well as for chest pain, thereby overall Eckardt score was 0.

Discussion

Achalasia is the most frequent primary motor disorder of the esophagus. It is still a rare disease that may occur in both sexes at any age with a prevalence of less than 1/10,000 and with a new cases' incidence of 0.6–1/100,000 citizens/year. At the base of this disease there is a primitive neuromuscular alteration with a myenteric plexus degeneration causing a pathophysiological disorder consisting in the failure of the lower esophageal sphincter (LES) relaxation during swallowing and the complete loss of peristaltic coordination of the esophagus body[13]. Dysphagia is the typical symptom, consisting in the difficulty in swallowing food; usually the patients have a very long and often unrelated history. Other times the patients may show a sudden onset and, rarely, the symptomatology may be "paradoxical," more pronounced for liquids than solids. Patients may also feel chest pain and regurgitation. Pain is a less frequent symptom and it is usually observed in the early stages of the disease. It is probably related to the smooth muscles contraction of the esophageal body[14]. Regurgitation is the symptom occurring in later stages, when the esophagus is dilated, and may be misdiagnosed as a gastroesophageal reflux disease, leading to diagnosis delay. The therapeutic approach may be pharmacological, endoscopic, and surgical.

Age and Gender

In our study, demographic analysis showed a female predilection (65.22%). 60.875% of our patients fell between >50 years of age group. In a study of 36 patients, Mirsharifi et al.[15] reported mean age of the patients undergoing laparoscopic esophagocardiomyotomy as 36.64 ± 13.47 years with 19 women (52.8%) and 17 men (47.2%).

Symptoms

In our study, majority of the patients had the symptoms for >10 years (39.13%) followed by 5-10 years (30.43%), 1-5 years (17.39%) and <1 year (13.04%). 30.4% patients had preoperative dysphagia score of 3 while remaining 69.6% had a score of 2. 100% patients complained of dysphagia, 52.17% patients complained regurgitation, 30.43% complained chest pain, 65.22% complained weight loss. Among the patients, 56.52% underwent fundoplication, only one showed mucosal injury. 86.96% patients were initiated oral sips on day 1, while 8.70% patients on day 2 and remaining 4.35% patients on day 6. 39.19% had oral

feeds initiated on day 3, 56.52% had oral feeds initiated on day 4 and 4.35% had oral feeds initiated on day 7. Mirsharifi et al.[15], in their study of 36 patients, stated that the most common manifestation was dysphagia ($n = 33$), pain ($n = 3$), regurgitation ($n = 2$), and cough ($n = 1$).

Improvement in Symptoms

In our study, the pre-operative Eckardt score was 2.30 ± 0.47 for dysphagia, 1.52 ± 1.20 for weight loss, 1.04 ± 1.02 for regurgitation, 0.60 ± 0.09 for chest pain and thus overall Eckardt score was 5.47 ± 2.81 . The Eckardt score at discharge and at 2 weeks follow up was 0 for dysphagia, 1.52 ± 1.20 for weight loss, 0 for regurgitation, 0 for chest pain and thus overall Eckardt score was 1.52 ± 1.20 . The Eckardt score after 3 and 6 months follow up was like 0 for dysphagia, weight loss, regurgitation, and chest pain, thereby overall Eckardt score was 0.

In a study of 40 Myotomy patients by Hunter et al., Dysphagia and regurgitation improved in 36 (90%) and 38 (95%) patients, respectively. Retrosternal pain and heart burn also improved significantly and weight loss was reversed[16].

The results of a study by Mikaeli and others who reviewed western and Iranian studies about achalasia, showed that myotomy was a very effective procedure and laparoscopic myotomy with fundoplication was the best surgical treatment for achalasia. However, it was compared with other non-surgical treatments[17]. In another study by Popoff and colleagues in 51 patients with achalasia who underwent Heller myotomy and Toupet fundoplication, dysphagia, retrosternal pain, heart burn, and regurgitation improved in 63%, 12%, 27%, and 22% of the patients, respectively. Moreover, 80% of the patients reported that their overall satisfaction with the procedure was either excellent or good, and 90% stated that they would undergo surgery again[18]. According to the results of a study by Torres-Villalobos and colleagues, medical treatment of achalasia is associated

with a high rate of recurrence and failure, and laparoscopic heller's Myotomy is the recommended procedure for initial treatment of achalasia[19]. Almost 90% of the patients experienced improvement in the signs and symptoms of achalasia after Heller myotomy, and a considerable number of patients were asymptomatic during a long-term follow-up. Reoperation or PBD was recommended in a few the patients who experienced persistent symptoms or recurrence[20]. Kumar et al.[21] conducted a study to evaluate the role of physiological testing in achalasia patients undergoing laparoscopic hellers cardiomyotomy (LHCM) and its correlation with symptomatic evaluation. They stated that, at a median follow-up of 16 months following LHCM, there was a significant improvement in Eckardt score (7.03 ± 1.53 to 0.93 ± 1.10 , $P < 0.001$), achalasia-specific health-related quality-of-life (58.34 ± 7.81 to 14.57 ± 13.45 , $P < 0.001$), column height on timed barium esophagogram (115.14 ± 46.9 to 27.89 ± 34.31 , $P < 0.001$) and median integrated relaxation

pressure(23.95 ± 8.26 to 4.61 ± 4.11 , $P < 0.001$). Eckardt score correlated significantly with achalasia-specific health-related quality-of-life scores preoperatively ($\rho = 0.410$, $P < 0.001$) and on follow-up ($\rho = 0.559$, $P < 0.001$).

Study Limitations

1. The study's small sample size of 23 patients limits the generalizability of the findings and introduces potential selection bias, as the cohort may not adequately represent the broader population of achalasia patients.
2. Present study conducted at single center which reduces the applicability to other populations or settings.
3. The absence of a control group hampers the ability to evaluate the correlation between surgical vs endoscopic approaches and patients reported outcomes.

Summary

In this study of 23 patients, most of the patients were from the age group of >50 years (60.87%) followed by 20-50 years (30.43%) and <20 years (8.70%). 34.78% patients were male and remaining 65.22% were female. Majority of the patients had the symptoms for >10 years (39.13%) followed by 5-10 years (30.43%), 1-5 years (17.39%) and <1 year (13.04%). 30.4% patients had preoperative dysphagia score of 3 while remaining 69.6% had a score of 2. 100% patients showed dysphagia, 52.17% patients showed regurgitation, 30.43% patients showed chest pain and 65.22% showed weight loss. 13.04% patients showed normal upper GI scopy while 69.57% patients showed dilated esophagus and 17.39% patients showed inconclusive results. Barium esophagogram was done in 86.96% of the patients. 17.39% patients showed type I and 82.61% showed type II on high resolution Manometry.

56.52% patients underwent fundoplication, only 1 showed mucosal injury. 86.96% had oral sips initiated on day 1, 8.70% had oral sips initiated on day 2 and 4.35% had oral sips initiated on day 6. 39.19% had oral feeds initiated on day 3, 56.52% had oral feeds initiated on day 4 and 4.35% had oral feeds initiated on day 7. 65.2% had hospital stay of 5 days, 21.74% had hospital stay of 6 days, 8.69% had hospital stay of 7 days and 4.35% (1 patient) had hospital stay of 12 days. All the 23 patients survived the procedure with 0% mortality.

The pre-operative Eckardt score was 2.30 ± 0.47 for dysphagia, 1.52 ± 1.20 for weight loss, 1.04 ± 1.02 for regurgitation, 0.60 ± 0.09 for chest pain and thus Overall Eckardt score was 5.47 ± 2.81 . The Eckardt score at discharge and at 2 weeks follow up was like 0 for dysphagia, 1.52 ± 1.20 for weight loss, 0 for regurgitation, 0 for chest pain and thereby overall Eckardt score was 1.52 ± 1.20 . The Eckardt score after 3 and 6 months follow up was 0 for dysphagia, for weight loss, for regurgitation, as well as for chest pain and thereby Overall Eckardt score was 0.

Conclusion

The Achalasia can be diagnosed with appropriate clinical history as it is often misdiagnosed as GERD. Endoscopy and barium swallow can be helpful to rule out mechanical dysphagia. HRM is diagnostic and useful in classification, which affects prognosis and guides treatment. Medical treatment for achalasia is mainly reserved for patients with very high surgical risk given its low longterm success for improving symptoms. This study demonstrates that laparoscopic hellers Myotomy is both safe and effective. Majority of patients will have symptom improvement with Heller-myotomy, and the majority of them have no recurrence even after very long-term followup.

Nevertheless, a minority of cases will have persistent or recurrent symptoms, and one should thoroughly evaluate these patients in order to adequately provide interventions such as pneumatic dilation or reoperation while reserving esophagectomy for patients with very severe esophageal dilation.

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- Dr. Siddhant Shrivastav and Dr. Kartik Sharma have contributed equally to the work and should be considered co-first authors.

Declarations

- All authors declares that they have read and approved this manuscript and that they believes this manuscript represents their honest work.
- All authors confirms that this study did not involve animal subjects or tissue.
- All authors declares that no financial support was received from any organisation for the submitted work.
- All authors declares that there are no competing interests.

Conflict of Interest

None

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