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Laparoscopic Heller Myotomy Improves Achalasia-Disease Specific Quality of Life and Health Related Quality of Life in Patients with Achalasia

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Keywords: Achalasia; Laparoscopic heller myotomy; Achalasia-disease specific quality of life; Health related quality of life.

Abstract

Background: Achalasia is a rare chronic autoimmune motility disorder of the esophagus. A curative treatment restoring the motility does not exist, however there are good options for symptom control by laparoscopic Heller myotomy (LHM). The aim of this study was to evaluate the effect of LHM in patients with achalasia and to evaluate achalasia-disease specific quality of life (achalasia-DSQoL) and health related quality of life (HRQoL).

Methods: A chart review was performed for patients who underwent LHM from 2009 to 2015 at the Copenhagen University Hospital, Hvidovre. Pre-and postoperative data were collected through a prospectively collected database. HRQoL scores were measured by the Short form (SF-12) questionnaire and achalasia-DSQoL with the achalasia severity questionnaire (ASQ).

Results: Total of 207 patients underwent LHM. Operative morbidity was 2.9 %. There was no procedure related mortality. An inadequate response after LHM was found in 5.78 %. Adjusted success rate was 87 % after median of 21 months (IQR= 19). The median follow-up time was 3.9 years (IQR=3). Satisfaction after operation was 83.63 %. The mean improvement in ASQ score was 19.7 with a significant better achalasia-DSQoL and HRQoL on the mental health component score. Correlation between ASQ score severity and decrease in general HRQoL was found on all domains.

Conclusions: LHM in our center is a procedure with no mortality, low morbidity and high patient satisfaction that increases HRQoL and achalasia-DSQoL significantly. Quality of life after LHM is comparable with the normal and age matched healthy population after 3.9 years of follow up.

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Introduction

Achalasia is a rare benign chronic autoimmune motility disorder of the esophagus caused by the loss of ganglion cells in the plexus myentericus, with no function of the inhibitory neurotransmitter to LES (low esophageal sphincter), degeneration of nervus vagus and changed function of the dorsal motoric vagal root [1-3].

A curative treatment restoring the motility disorder and thereby gaining a normal esophageal function does not exist, however, there are good options for symptom control by laparoscopic Heller myotomy (LHM) or per oral endoscopic myotomy (POEM), with relief of swallowing difficulties, by dividing the LES fibers +/- anti-reflux procedure (Dor/Toupet). However, improvement in esophageal physiology does not necessarily translate into palliation of symptoms and satisfaction with symptoms. In addition, some studies have found no relationship between objective outcome measurements and subjective measurements [4]. Therefore, we need to highlight the importance of instruments aimed to objectively assess surgical outcome from the patient's perspective. Short form-36 (SF-36) and short form-12 (SF-12) questionnaire are well-validated instruments to access health related quality of life (HRQoL), which have been used to evaluate the surgical outcome[5]. Achalasia severity questionnaire (ASQ) is another measure of achalasia-disease specific quality of life (achalasia- DSQoL) for use as an outcome in clinical trials [6].

Due to the fact that one cannot cure the disease it is important to assess how surgery affects (HRQoL) and achalasia-DSQoL. Only one study to our knowledge has so far addressed achalasia-DSQoL as a primary outcome[7].

The aim of this study was to evaluate the effect of LHM in patients suffering from achalasia operated at the Copenhagen University Hospital Hvidovre, Denmark and to evaluate long term achalasia-DSQoL and HRQoL.

Materials and Methods

The study was conducted in accordance with the Danish institutional review board (IRB) recommendations, and an additional written approval was not required [8].

A chart review was performed for all patients who underwent LHM from January 2009 to December 2015 at the Copenhagen University Hospital, Hvidovre. Patients were eligible for the study if they had a follow up of minimum 1 year. Data was collected through a prospectively collected database. Medical and surgical reports were reviewed. Pre-operative data included demographics, ASA score, type of achalasia, duration of disease, diagnostic modality (manometry, HRIM, esophagogastroduodenoscopy, contrast swallowing x-ray and Computed Tomography (CT)), and a history of previous surgical therapy. Operative and postoperative data included operation time, intraoperative blood loss, intra-procedural adverse events, postoperative complications, and hospital stay. Long term clinical outcomes included recurrence of dysphagia, re-intervention with dilatation or Botox injection, re-operation with extended LHM with or without fundoplication.

HRQoL scores were measured by the SF-12 questionnaire and the achalasia-DSQoL score was measured with the ASQ. Patients were included if they had a registered Danish address and were registered alive in the database.

SF-12 questionnaire is a multipurpose short form survey with 12 questions all selected from the SF-36 health status questionnaire, which is weighted and summed to provide easily interpretable scales for physical and mental health. The twelve scales of the questionnaire are designed to assess 8 health care domains that include; 1) general health, 2) physical functioning, 3) role functioning physical, 4) bodily pain, 5) vitality, 6) role functioning emotional, 7) mental health and 8) social functioning. Scores range from 0–100, with higher scores indicating better quality of life (QoL). Scoring is designed so that the average American individual would score on average 50 with 10 points standard deviation [5].

The ASQ consists of 10 items addressing common achalasia symptoms (dysphagia, heartburn, pain, food tolerance, dysphagia related behavior modifications, lifestyle limitations and satisfaction). The total raw score (10-31) is recalibrated onto a 0-100 interval level scale. A higher score indicates a greater level of disease severity. The ASQ score is a reliable measure of achalasia-DSQoL [6].

Patient satisfaction regarding surgery was assessed by the agreement with the statement 'I am satisfied with my surgical treatment of achalasia'.

All patients provided informed consent. Patients were examined before surgery by surgeons specialized in treating achalasia disease and preoperative evaluation included esophagogastroduodenoscopy, contrast swallowing x-ray of esophagus and esophagus manometry or high-resolution impedance manometry (HRIM- Chicago classification) which was implemented in 2014. Elderly patients had an additional CT to exclude pseudo achalasia due to malignancy.

Surgical technique

All the LHM were carried out with the patient in the supine and reverse Trendelenburg position. Five trocars in the upper part of the abdomen including a liver retractor for the left liver lobe. Optical lens 30 degree. The right crura and only the upper 1/3 of the left crura was dissected free so that the Angle of Hiss was preserved. The Gastroesophageal Junction (GEJ) was exposed after dividing the "fat pad". A longitudinal myotomy was carried out with ultracision, dividing the LES fibers and extending up a minimum of 6 cm proximally on the esophagus, and 1.5-2 cm distally on the ventricle. Fundoplication was only performed in specific cases if patients developed reflux symptoms after Botox injection prior to the operation, or if a hiatal hernia was detected during endoscopy.

Patients were discharged the day after the operation if they had a good swallowing function for liquids and good general condition.

Follow up Assessments

Patients were interviewed in the outpatient clinic by the same 3 surgeons who performed the operation within a 3month period. Clinical success was defined by normal eating function without bothersome reflux. Patients in remission were terminated to a follow up protocol of endoscopy every second year. Patients symptoms regarding dysphagia, reflux and pain and additional interventions were recorded at the visits.

Statistics

Continuous variables are presented as median with inter

quartile range (IQR) and as means ± SD. Categorical variables as counts or proportions (%). Median and means of continuous variables were compared by appropriate parametric or nonparametric tests. Correlation analyses were performed. Statistical significance was set at $p<0.05$. Statistical analysis was performed in SAS 9.4.

Results

From 2009 to 2015, a total of 207 patients underwent LHM at the Copenhagen University Hospital, Hvidovre. Patient demographics and outcome is summarized in Table 1.

Hundred-and eighteen of the 207 patients (57 %) were men. The median age was 56 years (IQR =18). The median duration of symptoms before procedure was 2 years

(IQR = 6). The Median Body mass index (BMI) was 23. 30 (IQR = 4.96). Most of the patients were ASA 2 106/207 (51.20 %) followed by ASA I 87/207 (41.03 %) and ASA III 14/207 (6.76 %). History of smoking was present in 45/207 (21.74 %) of the patients. From 2014 we registered 154 patients with Chicago classification, which were distributed as type I achalasia being the most frequent 80/154 (53.24 %), followed by type II 52/154 (33.77 %) and type III 11/154 (7.14 %). Grave achalasia was defined as dilatation >6 cm of esophagus and sigmoid shape at contrast swallowing x-ray of esophagus and was diagnosed in 49/207 (32 %). Other treatments with Botox injection and pneumatic dilatation prior to the operation was performed in 87/207 (42 %) without symptom relief.

LHM was successfully completed in all 207 patients, with a median operation time of 41 minutes (IQR=78). Median myotomy length was 8 cm (IQR=11). Ten patients had an additional fundoplication, where 9/207 (4.3 %) had Toupet and 1/207 (0.5 %) had Dor procedure. There were no conversions performed. The overall median hospital length of stay after operation was 1 day (IQR=0). The overall operative morbidity was 6/207 (2.9 %). Three intra-procedural adverse events (AE) were identified during the procedure. Two patients had a small esophageal mucosa lesion, which was sutured during the procedure. They were discharged the following day. One patient had a tension pneumothorax due to displacement of a Veress needle during insufflation under left curvature. This was handled with emergent chest decompression with a needle. The patient did not need a chest tube after operation but had a hemoglobin (Hb) drop postoperatively and needed 2 units of blood during hospital stay. There were 3 AE´s post procedurally, all requiring reoperation. Two patients had a small perforation of the myotomy, which were treated successfully with TachoSil. The patients were discharged after 5 days. The third patient had morphine resistant pain and a long hospital stay. Diagnostic laparoscopy and CT showed no intraabdominal pathology.

In the follow-up period all patients were seen in the outpatient clinics. The 6 patients with complications recovered completely with no signs of postoperative sequelae. Median time to termination of outpatient follow-up from operation was 3 months (IQR=0). Twelve patients (5.78 %) had an inadequate response after LHM. Additional 26 (12,5 %) had recurrence of dysphagia during the whole study period. Additional therapy was performed in 38/207 (18%) during the follow up period because of lack of improvement and recurrence, 8 patients had pneumatic dilatation, 19 patients had Botox injections and 11 patients had both Botox injections and dilatation. Reoperation was performed successfully in 11/207 (5.31 %). One patient had the Toupet procedure as endoscopy encountered hiatal hernia. Nine patients were offered a reoperation with an extended myotomy due to a stenosis on the ventricle side and 1 patient had the Goretex sutures taken down due to nerve affection. The adjusted overall clinical success rate of LHM was 180/ 207 (87 %). Multiple regression analysis showed no variables that could predict a bad outcome in remission of achalasia. There was no in hospital mortality. Nine patients died due to other causes more than 30 days after the operation.

Procedure impact on HRQoL and achalasia-DSQoL

Of the 207 patients who underwent LHM during the study period from 2009-2015, 198 patients were still alive. Procedure impact on HRQoL and achalasia-DSQoL are summarized in Table 2.

Table 1: Demographics and outcome details.

Pre-operative data	
Male, n/N (%)	118/207 (57.0)
Age , median (IQR)	56 (28)
BMI, median (IQR)	23,30 (4.96)
Dysphagia, median (IQR), years	2 (6)
Alcohol, median (IQR), weekly units	0 (5)
History of smoking n/N (%)	45 (21,7)
ASA-type, n/N (%)	
I	87/207 (42.0)
II	106/207 (51.2)
III	14/207 (6.8)
Chicago classification, n/N (%)	
Type 1	80/155 (51.6)
Type2	52/155 (41.3)
Type 3	11/155 (7.1)
Grave achalasia	49/207 (32.0)
Prior treatment, n/N (%)	
Dilatation, Botox	87/207 (42.0)
Postoperative data	
Operation time, median (IQR), min	41 (14)
Myotomy length, median (IQR), cm	8 (2)
Hospital stay, median (IQR), days	1 (0)
Fundoplication, n/N (%)	
Toupet	9/207 (4.3)
Dor	1/207 (0.5)

Table 2: Results of SF-12 and achalasia severityquestionnaire.

SF-12"	Pre-operative	Post-operative		General population
n (Number of respondents) Generel health	51	51	157	7069
Physical functioning Role Physica l	64.31±26.40	71.37±25.14	66.26±26.27	72.19±23.19
Role emotionel Bodily pain Vitality	82.84±25.45	81.86±29.32	79.80±29.33	81.18±29.11
Menta l health Social functioning	66.67±41.62	79.41±37.65	67.10±44.90	80.52±27.14
Mental health, mea ns ±SD	69.61±39.70	81.37±34.58	78.10±35.05	86.40±22.36
Physical health, means ±SD	73.53±29.75	79.90±26.90	76.77±30.47	81.74±24.53
	44.12±27 .38	57.84±28.05	57.74±27.32	55.59±24.84
	64.22±21.86	75.0±21.36	75.66±20.09	70.18±20.05
	72.55±29.81	89.22±22.50	84.63±24.88	83.74±24.76
	46.52±11.62	51.98±10.24	51.79±9.03	49.37±9.75
	47.69±9.05	48.95±9.97	46.75±10.62	49.63±9.91
ASQb	Pre-operative	Post-operative		
n (Number of respondents)	57	51	160	
ASQ score, means ±SD	58.46±14.85	38.75±19.29	40.84±17.10	

[a]Short from survey with 12 questions all selected from the Short from-36 health status questionnaire
[b]Achalasia seveerity questionnaire

Sixty- four patients completed a preoperative questionnaire, but only 51 were eligible for the calculation of HRQoL with a fully pre-operative SF-12 questionnaire and respectively 57 were eligible for the calculation of achalasia- DSQoL with a fully ASQ. At the follow up 173/198 (87.37 %) responded to the survey but likewise only 157 patients were eligible with a fully post-operative SF-12 questionnaire, and 160 with a fully postoperative ASQ. The median follow-up time from operation to survey was 3.9 years (IQR= 3.3). We found a significant decrease in ASQ score on all domains after LHM.

Mean improvement in ASQ score was 19.7, with a significant better achalasia-DSQoL. Correlation analyses showed a significant correlation between ASQ score severity and decrease in general HRQoL on all domains.

Mean Mental Health Composite Score (MCS) increased from 46.52±11.62 pre-operatively to 51.98±10.24 post-operatively, giving a significant improved mental health status after LHM from the baseline for those 51 matched patients that had a before and after questionnaire. Mean Physical Health Composite Score (PCS) after operation was 48.95±9.97 and there was no statistical difference from the baseline of mean 47.69±9.05.

No significant differences in demographics (gender, age, ASA score, BMI, tobacco and alcohol consumption, operation time, Chicago classification) between non-respondents and respondents were found.

Based on these findings we concluded that results of increased mental health and increased achalasia-DSQoL after LHM can be interpreted to the whole study population. Total MCS for the 157 postoperative responders was mean 51.79±9.03 and PCS mean 46.75±10.62. Figure 1. Illustrates that our HRQoL measures, especially the domains summarized in MCS are comparable with the gender and age matched healthy population [9]. Correlation analyses showed that the ASA score has a negative impact on the total HRQoL. Patients with an inadequate response to LHM that subsequently underwent Botox injection after operation had also significant decrease in MCS compared to those that had solely a LHM or subsequent pneumatic dilatation, p=0.33.

All together 143/171 (83.63 %) patients were satisfied regarding their present condition and only 28/171 (16.37 %) were unsatisfied. A significant decrease in gastroesophageal reflux (GER) was seen from baseline. Only 12/173 (7 %) had bothersome symptoms every day, and all except 4 patients could control their reflux with proton pump inhibitors (PPI) or mild food modifications.

Discussion

We found a significant increase in achalasia-DSQoL and in HRQoL on the MCS after LHM. Interestingly and not demonstrated earlier we have shown that there is no correlation between achalasia subtype and achalasia-DSQoL and HRQoL. One would expect that achalasia type I and II had a better outcome than type III, but it might be due to the fact that we first introduced the Chicago classification from 2014 and the low number of type III achalasia in this study. We used the SF 12 and pre- and postoperative ASQ to calculate valid change scores and to minimize the effect of recall bias. Our mean decrease of 19.7 in ASQ score is in accordance with findings in a randomized controlled trial, which is the only study so far that has addressed achalasia-DSQoL as a primary outcome[7]. Our patients represent a relative homogenous group and no demographic differences were seen between the patients that had a pre- and postoperative questionnaire, and those who only had a postoperative questionnaire, therefore our findings of statistical increase in both achalasia- DSQoL and HRQoL after LMH can be interpreted to the whole study group of patients that responded to the survey.

The main strength of our study is the use of both achalasia-DSQoL and HRQoL, which in combination is the most informative outcome measurement, guiding the treatment decision of achalasia [10]. Achalasia is a rare disease and over a period of 6 years we have followed a population of 207 achalasia patients at the same center and to our knowledge presented the largest estimation of LHM impact on HRQoL and achalasia-DSQoL. We have also demonstrated that patients after LHM are comparable with the age matched healthy population, which shows that patients after LHM can live with their achalasia without any effect on their quality of life, see Figure 1.

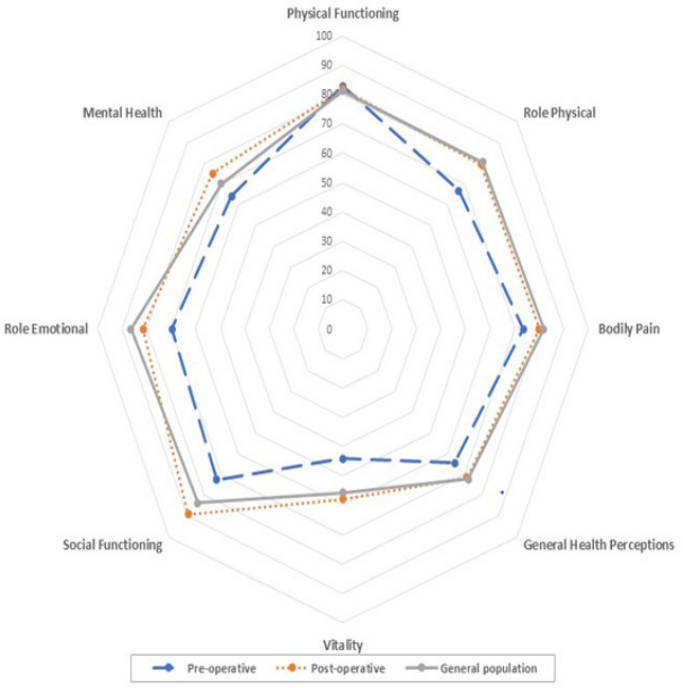

Figure 1: Pre-and postoperative HRQoL in achalasia patients compared to general population.

A limitation of this study is that we were not able to obtain preoperative questionnaires from all the patients, and the fact that the study is a retrospective study. Even though all our patients were seen prospectively in the outpatient clinics and symptoms and interventions were recorded, we did not use the Eckardt score when addressing recurrence of dysphagia.

To date, only a few studies have focused on the patients' perception of HRQoL before and after therapy for achalasia. Asti et al. [11] and Youssef et al. [12] found an increase in HRQoL after LHM on all domains after a follow up of 3.3 years. Ben-Meir et al. [13] found similar statistical improvement in role limitation and social function and demonstrated that achalasia patients after LHM are comparable with the age matched and healthy population. This is in accordance with our findings.

Early result with LHM with a short follow up of time of approximately 2 years seemed to be promising by achieving success rates between 90-100 % [14] . A retrospective study (RS) with 500 patients has shown decrease in success rate over time with an improvement in 49.8 % patients after a follow up > 6 years [15]. Studies of similar patient size and follow up time as our study have shown success rates between 77.1-91.8 %, which is comparable to our adjusted success rate of 87 % [16–19]. In addition to the RS there are 3 RCT with a much smaller patient size that have evaluated LHM [20–22]. In 2008 Rebecchi et al. [20] reported a success rate of 91 % in 138 patients after a follow up of 10 years. The Swedish trial [21] showed a success rate of 92 % and the European trial [22] showed at success rate of 84 % . Both studies had a follow up of 5 years.

Currently, an alternative to performing LHM via the endoscopic route (POEM) is under intensive investigation in several centers worldwide.

POEM procedure was first described in 2010 and has shown very promising initial results and warrants further clinical evaluation [23].

A recent POEM study has also shown improvement in HRQoL on the mental component [24]. Another newer prospective non randomized study has shown sustained HRQoL on both the MCS and PCS after >1 year follow up [25]. Studies of POEM still lack impact on achalasia-DSQoL.

Many centers use an additional anti reflux procedure when performing LHM as a higher rate of gastroesophageal reflux has been reported in early RCT, when a myotomy alone was performed [26,27]. Long term outcomes from the same RCT after a follow up of median 11.8 years has shown that LHM alone actually are comparable with LHM plus Dor [28]. We performed relatively few LHM with additional fundoplication, therefore statistical analysis was not possible, but earlier studies of HRQoL and GERD-HRQoL showed no difference between groups that had only a LHM and those who had an additional fundoplication [29].

Even though an anti-reflux procedure was not performed routinely in our center we still showed a significant improvement in GER from the baseline and only 1,9 % had therapy resistant reflux postoperatively .

Further studies on quality of life in achalasia would obviously benefit from inclusion of GERD- HRQoL and more standardized measurement of dysphagia as the Eckardt score. Based of our findings we will not recommend antireflux procedure as standard when performing LHM.

Weather LHM or POEM should be the treatment of choice; We are still awaiting results from ongoing prospective studies. We might expect that these two procedures will complement each other in the long-term as achalasia is a chronic disease.

Conclusion

Our conclusion is that LMH in our center is a procedure with no mortality and low morbidity that increases HRQoL and achalasia-DSQoL significantly and quality of life after LHM is comparable with the normal age matched healthy population after a follow up of approximately 4 years.

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