

Health-related quality of life after laparoscopic Heller myotomy and Dor fundoplication for achalasia



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Background. In addition to symptom scores, a person's perception of health and quality of life assessment is an important indicator of quality of treatment and can provide an efficient index to compare different therapeutic modalities in chronic disease states. Only a few studies have investigated quality of life comprehensively in patients with achalasia, and therefore the controversy regarding the best treatment algorithm continues. The primary study outcome was pre- and postoperative quality of life in patients with achalasia undergoing laparoscopic Heller myotomy and Dor fundoplication.

Methods. The study is a retrospective, observational cohort. The hospital registry and the updated research database were reviewed to identify all patients who were treated for achalasia between 2010 and 2015. Patients were eligible for the study if they had a minimum 1-year follow-up and had pre- and postoperative Eckardt, Short Form-36, and Gastro-Esophageal Reflux Disease Health-Related Quality of Life scores. Patients with previous operative and/or endoscopic treatments for achalasia were excluded.

Results. One-hundred and eighteen patients were identified. The median follow-up was 40 months (interquartile range 27). The proportion of patients with Eckardt stage II–III decreased from 94.9–13% ($P < .001$). The mean Eckardt score decreased from 6.9 ± 1.9 to 1.7 ± 1.2 ($P < .001$); the mean Short Form-36 scores significantly increased in all 8 domains; the mean Gastro-Esophageal Reflux Disease Health-Related Quality of Life score decreased from 13.9 ± 5.7 to 5.5 ± 5.4 ($P < .001$). Finally, 88% (confidence interval 81–93) of patients were satisfied regarding their present condition.

Conclusion. Quality of life assessed with generic and disease-specific validated instruments significantly improved after laparoscopic Heller myotomy combined with Dor fundoplication. (Surgery 2017;161:977-83.)

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ACHALASIA, A PRIMARY ESOPHAGEAL motility disorder, is a rare chronic condition causing dysphagia, regurgitation, aspiration, chest pain, and weight loss secondary to malnutrition. Heller myotomy with or without fundoplication has represented the standard treatment for achalasia throughout the past several decades.^{1,2} With the advent of laparoscopy, it became evident that the transabdominal approach is superior to the transthoracic in terms of dysphagia relief, and that an anterior

fundoplication combined with the myotomy provides high long-term success rate in terms of reflux control.³⁻⁵ On the other hand, the results of a recent European multicenter trial have shown that pneumatic dilation and laparoscopic Heller myotomy have comparable success rates at 5 years, that the choice between the 2 treatments should be dictated by available expertise, and that both techniques can be proposed as the first option, although a quarter of the dilated patients require subsequent dilations.⁶ Peroral endoscopic myotomy is a novel promising technique, but the follow-up still is limited and no randomized trials exist to allow meaningful conclusions. Preliminary studies suggest a rather high incidence of gastroesophageal reflux after this procedure.⁷

To date, only a few studies have focused on the patient's perception of health and the quality of life before and after therapy for achalasia. Indeed,

Accepted for publication October 20, 2016.

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0039-6060/\$ - see front matter

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<http://dx.doi.org/10.1016/j.surg.2016.10.023>

symptoms of achalasia have an important physical, emotional, and social impact. Comprehensive quality of life assessment in combination with a standardized grading system for symptoms can reduce the risk of over- or underestimating the effect of therapy, allows easier comparison of treatment outcomes, and has the potential to influence the choice of therapy particularly in chronic diseases.⁸⁻¹⁰ The primary study aim was to measure the impact of laparoscopic Heller myotomy and anterior fundoplication on quality of life beyond the first year of follow-up using a clinical symptom score system and both generic and disease-specific validated questionnaires.

METHODS

This study examines a retrospective, observational cohort. The hospital registry and the continuously updated research database were reviewed to identify all patients who were treated for achalasia at our institution between 2010 and 2015. Patients were eligible for the study if they had a minimum 1-year follow-up, had the Eckardt score recorded, and completed the Short Form-36 (SF-36) and the Gastro-Esophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) questionnaires pre- and postoperatively. Patients who had undergone previous operative or endoscopic treatments were excluded. Informed consent was obtained at the last follow-up visit from all patients who served as subjects of the study.

All patients underwent a standard preoperative workup including medical history, physical examination, blood test analysis, electrocardiogram, chest x-ray, barium swallow study, and upper gastrointestinal endoscopy with biopsies. In most patients, standard or high-resolution esophageal manometry was performed. A computed tomography scan of chest and abdomen was performed in select elderly patients to exclude malignancy. A chest film and a Gastrografin swallow study were performed on postoperative day 1 to check the esophagogastric transit and exclude the presence of leaks. A soft diet then was allowed. The early postoperative outcome and the use of proton pump inhibitors (PPIs), calcium-channel blockers and/or pain medications were recorded throughout the follow-up. Clinical evaluation was performed at 1, 3, 6, and 12 months after operation, and then yearly. Upper gastrointestinal endoscopy and/or barium swallow studies were performed as needed after the first year or follow-up. Preoperative questionnaires were administered at the time of the first visit before hospital

admission. All patients completed the SF-36 and GERD-HRQL questionnaires at the time of the last follow-up visit.

The Eckardt symptom score depends on the frequency of esophageal symptoms such as dysphagia, regurgitation, chest pain, and degree of weight loss. Thus, completely asymptomatic patients had a score of 0, while the most severely symptomatic patients had a score of 12. According to these scores, the following clinical stages were defined: stage 0 (score 0–1); stage I (score 2–3); stage II (score 4–6); stage III (score >6).¹¹

SF-36 is a generic multidimensional questionnaire composing 36 items to determine the health-related quality of life. It consists of 8 different health quality domains: physical function (10 items), role limitations due to physical function role (4 items), bodily pain (2 items), general health (5 items), vitality (4 items), social function (2 items), role limitations due to emotional function (3 items), and mental health (5 items). The results from each standardized scale vary from 0–100 (worst to best possible health status). The 8 scales are aggregated into 2 summary measures: the physical component summary and the mental component summary. These range from zero (lowest well-being) to 100 (highest well-being). SF-36 data were mapped to 8 domain scores and showed in a standardized scale ranging from 0–100. The weights used to construct the summary scores were derived from both orthogonal and oblique factor rotations.^{12,13}

The GERD-HRQL questionnaire is a 10-item disease-specific tool focused on heartburn, dysphagia, and gas bloat. Each symptom has an assigned score between 0–5. A final score is assigned based on the summary of individual scores, so a complete asymptomatic patient has a score of 0, while the most symptomatic patient has a score of 50. An additional question, not included in the calculated score, concerns patients' satisfaction with their present condition.¹⁴ Both the SF-36 and the GERD-HRQL are self-administered questionnaires and take up to 15 and 5 minutes, respectively, to complete.

The Heller-Dor operation is performed under general anesthesia using a 5-port access. The pneumoperitoneum is established at 13 mm Hg. After incision of the peritoneal reflection, a limited anterior dissection is performed to expose the crura, the left vagus nerve, and the gastroesophageal junction. A 6-cm anterior myotomy extending for 1.5–2 cm onto the stomach is performed using the Harmonic scalpel (Ethicon, Somerville, NJ). An

anterior Dor fundoplication is then performed securing the anterior fundic wall to both crura and to the edges of the myotomy site.

Statistical analysis. Continuous and discrete variables are presented as median and interquartile range or mean and standard deviation, categorical variables with number and percentages. McNemar's test was performed as appropriate. Two-sided *P* value and 95% confidence intervals were computed. The Eckardt score and the SF-36 and GERD-HRQL questionnaires were analyzed with nonparametric bootstrap,¹⁵ resampling from the vector obtained by the difference between post- and preoperative scores for each patient. Point estimation of mean of the differences, bias-corrected and accelerated confidence intervals, and bootstrap *P* values were computed after 10,000 iterations. Double bootstrap and jackknife after bootstrap were used as diagnostics.¹⁶ For the SF-36 questionnaire, the clinical minimal important difference threshold were computed via normal approximation using standard error of measurement with Cronbach's α as reliability of measure; for the Eckardt score and the GERD-HRQL questionnaire effect size we used Cohen's classification.¹⁷ Confidence intervals for proportion were computed via normal approximation. All analyses were carried out with R 3.2.2.¹⁸

RESULTS

Between January 2010 and December 2015, 199 consecutive patients underwent laparoscopic Heller myotomy and Dor fundoplication. Of these, 139 patients had a minimum 1-year follow-up. Eighteen subjects were excluded because underwent previous endoscopic pneumatic dilation ($n = 13$) or an antireflux repair other than an anterior fundoplication ($n = 5$). Of the remaining 121 patients, 3 did not have both pre- and postoperative Eckardt score and the SF-36 and GERD-HRQL questionnaires and were excluded. The demographic and preoperative characteristics of the 118 patients finally included in the study are reported in Table I.

The mean operative time was 84 ± 28.1 minutes, and the mean length of hospital stay was 2.3 ± 2.7 days. One intraoperative mucosal tear occurred and was recognized immediately and repaired laparoscopically. Postoperative morbidity was 3.4% and consisted of perforation at the myotomy site requiring revisional laparoscopy ($n = 1$), atelectasis ($n = 1$), atrial fibrillation ($n = 1$), and urinary tract infection ($n = 1$). No clinical recurrences (Eckardt score >4) were observed during the study period. The median follow-up was

Table I. Demographic and preoperative clinical characteristics

Male (%)	57 (48)
Age, y, mean \pm SD	50.3 \pm 5.4
BMI, kg/m ² , mean \pm SD	23.3 \pm 4.2
Weight loss, kg, mean \pm SD	8.8 \pm 7.5
Symptom duration, mo, median (IQR, %)	69 (72)
Comorbidities (%)	
Cardiovascular	26 (22.0)
Autoimmune disease	20 (17.0)
Metabolic	10 (8.5)
Respiratory	7 (5.9)
Neurologic	6 (5.1)
Previous medical therapies (%)	
Proton-pump inhibitors	31 (26.8)
Calcium-channel blockers or nitrates	21 (17.8)
NSAIDs	64 (54.2)
Symptoms (%)	
Dysphagia	118 (100)
Regurgitation	101 (85.6)
Chest pain	64 (54.2)
Cough	49 (41.5)
Heartburn	31 (26.3)
Eckardt stage (%)	
0	0 (0)
I	6 (5.1)
II	41 (34.7)
III	71 (60.2)
Endoscopy (%)	
Esophagitis	15 (12.7)
Hiatal hernia	12 (10.2)
Manometry (68/118)	
LES pressure, mm Hg, mean \pm SD	37 \pm 16.1
Chicago subtypes (49/118, %)	
I	9 (18.4)
II	28 (57.1)
III	12 (24.5)
Barium swallow study (degree of esophageal dilatation, %)	
I (<4 cm)	60 (50.9)
II (4–6 cm)	43 (36.4)
III (>6 cm)	12 (10.2)
Sigmoid esophagus (%)	3 (2.5)

IQR, Interquartile range; BMI, body mass index; NSAIDs, nonsteroidal anti-inflammatory drugs; LES, lower esophageal sphincter.

40 months (interquartile range 27). The use of PPIs, calcium-channel blockers, nitrates, and nonsteroidal anti-inflammatory drugs decreased from 54.2 % to 20.3% after operation ($P < .001$). Grade A esophagitis was diagnosed in 2 (5.7%) of the 41 patients who underwent postoperative endoscopy beyond the first year of follow-up and both patients were otherwise asymptomatic. Also, the 3 patients with sigmoid esophagus were relieved from symptoms.

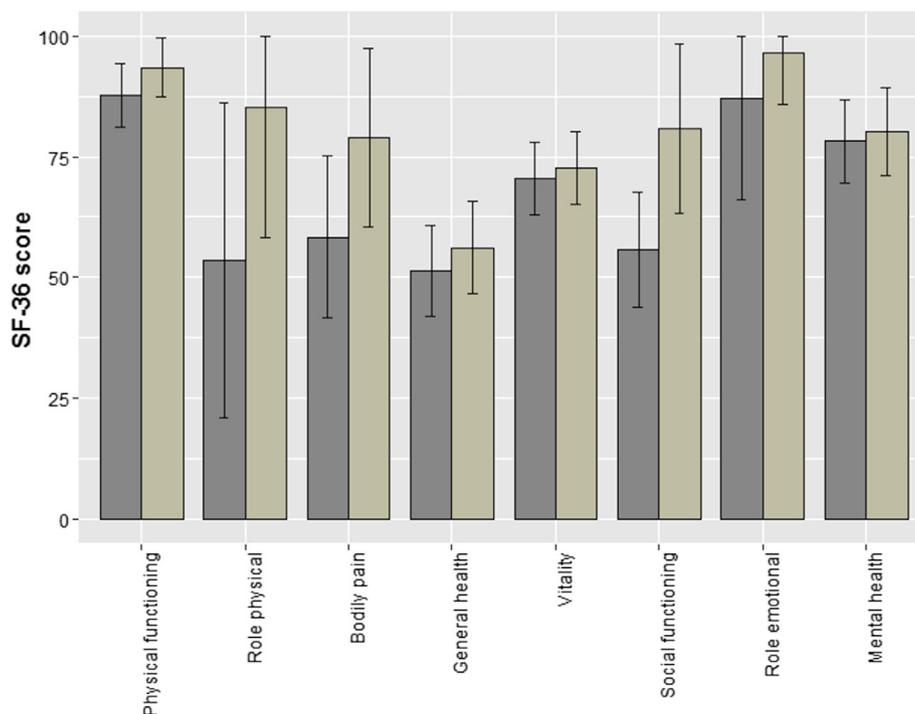


Fig. SF-36 scores for each questionnaire domain before (*dark bars*) and after (*light bars*) operation. Values are expressed as means and standard deviation.

The proportion of patients with Eckardt stage II–III decreased from 94.9% ($n = 112$) at baseline to 13% ($n = 15$) postoperatively ($P < .001$). The mean preoperative and postoperative Eckardt score was 6.9 ± 1.9 and 1.7 ± 1.2 , respectively. The mean of differences of the Eckardt score between postoperative and preoperative values was statistically different from 0 (5.1, CI 3.6–6.0, $P < .001$), giving a large 2.7 Cohen's effect size.

The mean preoperative and 1-year postoperative SF-36 questionnaire domain scores for the study patients are shown in Fig and Table II. The mean of differences of SF-36 scores between postoperative and preoperative values was statistically different from 0 for all 8 domains, for the physical component summary, and for the mental component summary (Table III). Using the criterion of 1 standard error of measurement as a measure of the minimal clinically important difference, the point estimation of the mean of differences of 7 out of the 8 SF-36 domains exceeded its critical threshold.

The mean preoperative and postoperative GERD-HRQL score was 13.1 ± 5.7 and 5.5 ± 5.4 , respectively. The mean of differences of the GERD-HRQL score between postoperative and preoperative values was statistically different from 0 (8.3, CI 5.8–10.6, $P < .001$), giving a 0.95 Cohen's effect size. One-hundred-four (88%, CI 81–93) patients were satisfied regarding their present

condition; 8 (7%, CI 3–13) declared themselves neutral, and 6 (5%, CI 2–11) were unsatisfied.

DISCUSSION

This study shows a sustained improvement in quality of life after laparoscopic myotomy and Dor fundoplication for achalasia at a median follow-up of 40 months. All SF-36 domains significantly improved after operation and reached clinical significance, with the exception of the vitality domain. The most marked improvements were noted on the role-physical domain, followed by the social function and bodily pain. Also, the summary measures of SF-36 physical and mental components significantly increased. The parallel and consistent decrease in the Eckardt clinical score indicates that esophageal transit was restored in our patients regardless of the degree of esophageal dilation at the preoperative barium swallow study.

Adopting the GERD-HRQL questionnaire in our study allowed a more precise evaluation of the symptom heartburn which is neglected by other questionnaires and often is confused by the patients with the symptom chest pain. About one-third of our achalasia patients experienced preoperative heartburn refractory to PPIs and most likely related to stasis, food fermentation, and intraesophageal acidification.¹⁹ In addition, our study confirms that the

Table II. Pre- and postoperative mean scores with relative standard deviation of SF-36 domains

SF-36 domain	Preoperative	Postoperative	Cronbach's α	SEM
Physical function	87.8 \pm 6.6	93.5 \pm 6.2	0.87 (0.076)	2.3
Role physical	53.4 \pm 32.5	85.3 \pm 27.2	0.84 (0.083)	13
Bodily pain	58.4 \pm 16.7	78.8 \pm 18.5	0.85 (0.079)	6.4
General health	51.3 \pm 9.5	56.2 \pm 9.6	0.86 (0.081)	3.6
Vitality	70.5 \pm 7.6	72.8 \pm 7.5	0.82 (0.064)	3.2
Social function	55.8 \pm 11.9	80.9 \pm 17.6	0.84 (0.087)	4.8
Role emotional	87.2 \pm 21.0	96.5 \pm 10.5	0.85 (0.081)	8.1
Mental health	76.7 \pm 8.5	80.2 \pm 9.0	0.86 (0.080)	3.2

Cronbach's α is reported with its bootstrap standard error in brackets.
SEM, Standard error measurement.

Table III. Bootstrap analysis of SF-36 questionnaire

SF-36 domain	Point estimate	Standard error	BCa CI 95%	P value
Physical function	5.71	0.85	4.3–7.7	<.001
Role physical	31.8	6.40	19.8–44.3	<.001
Bodily pain	20.4	3.01	14.7–26.6	<.001
General health	4.9	1.33	2.5–7.9	<.001
Vitality	2.2	1.02	0.5–4.5	.023
Social function	25.0	3.50	18.1–31.9	<.001
Role emotional	9.3	4.33	1.1–17.2	.035
Mental health	3.5	1.30	0.7–5.9	<.001
SF-36 component summary (orthogonal rotation weight)				
Physical component summary	17.3	3.06	11.8–23.9	<.001
Mental component summary	20.1	3.90	14.3–25.9	<.001
SF-36 component summary (oblique rotation weight)				
Physical component summary	18.7	2.80	13.3–24.6	<.001
Mental component summary	19.3	2.30	14.9–24.1	<.001

Point estimate represent the mean of difference between post- and preoperative SF-36 single domains and relative component summary scores. Orthogonal rotations identify factor weights that minimize the correlation between the physical component summary and mental component summary; oblique rotations allow the composite measures to be correlated.

BCa, Bias-corrected and accelerate.

GERD-HRQL score significantly decreased after operation, indicating that the laparoscopic Heller-Dor operation relieved the outflow obstruction without inducing gastroesophageal reflux. This is in agreement with a meta-analysis of 7,855 patients showing that laparoscopic Heller myotomy combined with fundoplication does reduce the incidence of troublesome postoperative GERD to 8.8%.²⁰ The GERD-HRQL questionnaire, although not specific for achalasia, allows symptom improvement assessment and includes a satisfaction index. The fact that 88% of patients were satisfied with their present condition after a minimum 1-year follow-up indicates a true improvement in their quality of life and not a placebo effect as it could be the case when the assessment is made in the early postoperative phase. Notably, the postoperative use of drugs, mostly PPIs, was reduced significantly in our patients, and postoperative endoscopy showed a negligible evidence of esophagitis.

Most clinical studies on achalasia have adopted symptomatic scores for dysphagia and regurgitation calculated by simply adding a severity score to a frequency score for each symptom, and defining treatment failure as a post-treatment score exceeding the 10th percentile of the normal score. However, conversion of continuous measure to a dichotomous outcome can potentially result in loss of important clinical information. Based on these assumptions, a 10-item measure of disease-specific health-related quality of life for achalasia has been proposed by Urbach et al²¹ to evaluate food tolerance, dysphagia-related behavior modifications, pain, heartburn, distress, lifestyle limitations, and satisfaction. Although the questionnaire was found to be easy to use and was able to discriminate patients in clinical remission from those who are not, the question concerning heartburn did not correlate with the other items and tended to reduce internal validity.²²

Ben-Meir et al²³ first used the generic, internationally validated SF-36 questionnaire pre- and postoperatively to measure changes in health-related quality of life in 19 patients submitted to laparoscopic Heller myotomy and posterior (Toupet) fundoplication. Preoperative patients' scores were lower than the general population. After operation, at a median follow-up of 21 months, a significant increase in the scores for physical functioning, role-physical, bodily pain, vitality, and social functioning was found. Interestingly, the heartburn score, although measured with a frequency scale, was unchanged after operation.

Decker et al⁹ used the disease-specific Gastrointestinal Quality of Life Index in 40 patients undergoing laparoscopic Heller myotomy and Toupet fundoplication. At a median follow-up of 30 months, quality of life scores were most improved in patients with the lowest preoperative scores, suggesting that when preoperative scores are high there is even a risk of clinical deterioration should operation induce side-effects such as reflux.

Among the strengths of the present study is a fairly good sample size, considering that achalasia is a rare disease; the multidimensional patient assessment including 1 structured clinical scoring system and 2 validated questionnaires, 1 generic and 1 disease-specific, completed pre- and postoperatively in all patients to avoid the phenomenon of recall distortion²⁴; the use of analytical tools to assess not only statistical significance but also clinical significance; the standardized operative technique; and the fact that patients with previous treatments for achalasia were excluded. Also, longitudinal analysis is more reliable in establishing causality compared with cross-sectional studies.^{25,26} Finally, the present study could be used as a baseline for power/sample size calculation in planning future randomized clinical trials.

Limitations of the present study are the retrospective design, the potential selection bias, the lack of quality of life data measured in the early (3–6 months) postoperative period, the lack of sequential quality of life measurements over time, the limited overall duration of follow-up exceeding 1 year, the fact that the quality of life questionnaires used are not achalasia-specific, and the lack of postoperative manometric and pH monitoring assessment.

In conclusion, the Heller-Dor operation not only provides sustained symptom relief but also a satisfactory quality of life beyond the first year of follow-up. Future studies should use and compare validated generic and disease-specific quality of life tools in patients treated by laparoscopy and by endoscopic techniques, such as pneumatic dilation

and peroral endoscopic myotomy. Although the utility of quality of life scores is undeniable, objective outcomes also are necessary to establish the more appropriate initial treatment algorithm and possibly reduce the risk of failure. Hopefully, this will help patients, clinicians, and payers to make a tailored therapeutic decision based on more comprehensive outcome data.

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