

Health-Related Quality of Life and Long-term Results after Laparoscopic Heller Myotomy and Dor Fundoplication

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Abstract

Introduction: Laparoscopic Heller myotomy is currently considered the choice treatment for relief of dysphagia in Esophageal Achalasia (EA), showing a low incidence of gastroesophageal reflux and evident improvement in Health-Related Quality of Life (HRQL).

Objective: Evaluate Health-Related quality of life and clinic evolution after laparoscopic Heller myotomy and Dor fundoplication.

Material and method: Prospective longitudinal descriptive observational study, through the application of the Gastrointestinal Quality of Life Index questionnaire (GIQLI) to patients underwent surgery for EA from January 2010 to December 2017 at the National Center for Minimally Invasive Surgery. The questionnaire was applied before surgery and one year later.

Statistical analysis: Percentages for qualitative variables, mean \pm standard deviation or median and range, as appropriate for quantitative variables, for the comparison of the questionnaire results, we used student's t-test, with statistical significance level $\alpha=0.05$.

Results: 101 patients were included in the study, three of them were excluded. Age ranged from 18 to 78 years with an average of 47 years. The mean time of evolution of the symptoms was 62 months, with an average of 3.3 on the dysphagia scale and a Resting Pressure of the lower esophageal sphincter (mmHg) 38.7 ± 16.8 , an initial GIQLI of 85 was obtained, 3 ± 20.4 , which increased twelve months after surgery to 131.6 ± 10.5 .

Conclusions: Heller myotomy and Dor fundoplication improve Health-Related quality of life in patients with esophageal achalasia with good outcomes in time.

Keywords: Health-Related quality of life; Esophageal achalasia; Heller myotomy; GIQLI

Introduction

Laparoscopic Heller Myotomy (LHM) is currently considered the choice treatment for relief of dysphagia in Esophageal Achalasia (EA), proving a low incidence of gastroesophageal reflux and an evident improvement in Health-Related quality of life [1].

For the first time in 2015 at the National Center of Minimally Invasive Surgery (CNCMA), an investigation about Health-Related Quality of Life (HRQL) by using Gastrointestinal Quality of Life Index (GIQLI) in patients with EA who underwent LHM and Dor fundoplication was carried out [2]. Taking into consideration that this evaluation is considered a new strategy for the analysis of therapeutic programs results, especially to evaluate repercussion of the sickness according to the different levels of symptomatic intensity and monitoring the changes obtained with surgery treatment [3-5].

For all the aforementioned and to continue with the research done the objective of this investigation was to evaluate HRQL and clinic evolution after LHM and Dor fundoplication.

Materials and Method

A prospective longitudinal descriptive observational study was done in patients with a confirmed diagnosis of EA by using Barium esophagram (BE) and High Resolution Manometry (HRM) at the CNCMA between January 2010 to December 2017 who had LHM and Dor fundoplication. This protocol was approved by the Institutional Review Board (IRB) and the Ethical Review Board (ERB) at the CNCMA (Protocol #07-2015) as well as the authorization of the Head of the Department of Records and Statistics to review the histories and initiate the study.

Procedures

Pre-surgery evaluation: The clinic method was used to determine the diagnosis using a questionnaire where the personal pathologic antecedents and the history and evolution of the sickness were determined. A complete physical examination was done and the results of the previously indicated tests (HRM, endoscopy and BE) were evaluated and also the laboratory tests such as: Complete blood test, complete coagulogram, glycaemia, creatine, total Proteins and fractioned proteins, electrocardiogram and chest X-ray (PA view), if patients required those tests before surgery because of their ages or associated diseases. Once the diagnosis was confirmed and there is no presence of exclusive criteria, GIQLI was applied. This instrument includes 36 questions in five domains: gastrointestinal symptoms, emotional dysfunction, physical and social dysfunctions, and effects of treatment. Each question is marked from zero (the worst possible value) to 4 points (the best possible value). The sum-up of each of the answers to the questions from each scale is divided into the number of questions to give the punctuation of each one. The index has a theoretical rank from 0 points to 144 points and its original report for the healthy population was established a normal mark of 125.8 points (95% confidence interval 121.5-127.5) [6]. The French questionnaire validation obtained similar results of 126 points (95% confidence interval 122-130) for the controlled healthy population [7].

The clinical evaluation was obtained at the appointments with the medical staff who reflected the evaluation in the patient's medical records. Vantrappen and Hellemans classifications were used which divide the results into: Excellent: Completely asymptomatic patients, Good: Patients who presented dysphagia or an occasionally short duration thorax pain which only disappears when drinking liquids, Regular: When the previous symptoms are more intense and frequent, appearing more than once a week, and Bad: When dysphagia is accompanied by weight loss or regurgitation.

Post-operative evaluation: After 12 months of undergoing surgery, patients were re-evaluated; the GIQLI and the Vantrappen and Hellemans scales were applied again.

Statistical Analysis

The information is summarized applying summary measures for variables according to their nature (percentages for the qualitative, media \pm standard deviation or median and rank according to the quantitative). The statistic program IBM-SPSS (21st version for Windows in Spanish) was used for statistical analysis and database.

For the comparison of the questionnaire results, before and after the surgery hypotheses median comparison tests were employed (couplet student's t-test) with a level of statistical significance $\alpha=0.05$. The information was presented in a tabular way for a better understanding.

Results

Between January 2010 to December 31st, 2017, 253 patients with EA had surgery at the CNCMA. A female patient under 18 years old and 7 other patients, who had redo surgery because of LHM failure, were excluded. The sample was constituted by 101 patients who were followed at least one year after surgery. The 49.5% (50 patients) were male sex and 50.5% (51 patients) were female sex. Their ages were between 18 and 78 years old with a mean of 47 years old. Patients older than 40 years old represented 61.8% of the sample. The average time of the symptom evolution was 62 months, with a mean of 3.3 in the dysphagia scale and a rest pressure LES (mmHg) 38.7 ± 16.8 (Table 1).

When compared to initial GIQLI and the same analysis after the first 12 months, the initial GIQLI was 85.3 ± 20.4 which increased to 131.6 ± 10.5 , in a year. These differences found resulted significant ($p=0.000$), which evidence a global improvement of HRQL in these patients after twelve months of surgery (Table 2).

When the different domains of GIQLI were analyzed separately, the initial mean and standard deviation and values a year after surgery, showed as followed: Gastrointestinal symptoms $47.5 (\pm 8.62)$ and $69.03 (\pm 5.31)$; Emotional dysfunction $7.18 (\pm 4.27)$ and $17.95 (\pm 2.61)$; Physical dysfunction $15.86 (\pm 6.95)$ and $25.62 (\pm 2.75)$; Social dysfunction $11.04 (\pm 3.98)$ and $15.08 (\pm 1.60)$ (all of them with a value of $p=0.000$); and Effects of treatment $3.66 (\pm 0.93)$ and $3.96 (\pm 0.19)$ ($p=0.003$) (Table 3).

According to Vantrappen and Hellemans post-surgery clinic classification, the result is considered as excellent in 82 patients free of symptoms and 16 patients who seldom have light dysphagia with a short duration and a good evolution (Table 4).

Discussion

EA is a chronic disease without a definite etiology, whose treatment is palliative, addressed to relieve the symptomatology of patient through the reduction of the grade of LES obstruction. It is done, with the least possible therapeutic actions in order to improve HRQL and excellent clinic results in long term [8].

The incorporation of quality of life questionnaires to the clinic practice let us know, in a standard way, the own valuation of patients about their disease, how it affects their daily life and the results of surgery according to their appreciation [9].

The research proved the previous affirmation because the patients presented punctuations of the initial GIQLI scale below the levels considered as normal, what coincides with previous results by Ramos

Table 1: Demographics and Preoperative Data.

Variables	n=101
Gender	
Female	51(50.5%)
Male	50(49.5%)
Age (years)	47(18-78)
Race	
White	67(66.3%)
Black	21(20.8%)
Mixed race	13(12.9%)
Symptoms time of evolution (months)	62 \pm 72.5
Dysphagia scale	3.33
EEL rest pressure (mmHg)	38.7 \pm 16.8

Table 2: Couplet t-test comparison of GIQLI initial mean and the year of treatment with operated patient's of achalasia with laparoscopic surgery.

Statistics	Initial GIQLI	Annual GIQLI	Couplet t-test	P value
Mean	85.3	131.6	-20.716	0.000*
Median	84.0	136.0		
Standard deviation	20.4	10.5		
n	98	98		

Table 3: Couplet t-test of comparison of the mean of the initial GIQLI five dominions, after a year of treatment, with patients operated on achalasia with laparoscopic surgery.

GIQLI dominions	Mean	Standard deviation	Couplet t-test	P Value
Symptoms (19 variables)	47.52	8.621	-21.926	0.000*
	69.03	5.318		
Emotional function (5 variables)	7.18	4.273	-22.390	0.000*
	17.95	2.610		
Physical function physical (7 variables)	15.86	6.956	-13.778	0.000*
	25.62	2.756		
Social function social (4 variables)	11.04	3.987	-9.210	0.000*
	15.08	1.603		
Subjective evaluation of the treatment (1 variable)	3.66	0.930	-3.034	0.003*
	3.96	0.199		

*Significance level $\alpha=0.05$

Table 4: Distribution of patients operated of achalasia by laparoscopic surgery according to clinic post-operative evolution (Vantrappen and Helleman annual).

Degree of Esophagic Dilatation	No.	%
Good	16	15.8
Excellent	82	81.2
Lost	3	3.0
Total	101	100.0

RJ, et al. [2], in an evaluation carried out up to 3 months of post-surgery evolution.

Nowadays there are scarce publications which analyze the quality of life of patients underwent surgery from EA using GIQLI questionnaire. However the results are excellent, as the case of Marinello FG, et al. [10] and Rawlings A, et al. [11], whom in their research not only the post-operative GIQLI mean, is considerably elevated, but it reaches or increases what is considered normal (125 points).

Other researches also present good results because from very low initial GIQLI, they present GIQLI post-operative with superior punctuation, but without reaching equal or higher values to the ones considered as normal, such as the ones from: Ferulano GP, et al. [12], Decker G [7] and DeHaan RK, et al. [13]. Nonetheless but Nenshi R, et al. [14] present in his research a low GIQLI post-operative result, reflecting a bad HRQL.

A separate analysis was done from each domain which conforms GIQLI and there was evidence of improvement in all of them.

About the clinic evolution of these patients, it was observed that the majority had an excellent evolution with a complete resolution of the symptoms; similar results were observed by González RR, et al. [15,16].

Conclusions

LHM and Dor fundoplication improve HRQL in patients with EA; the post-operative improvement was evidenced in four of the five

domains of GIQLI which were studied: Gastrointestinal symptoms; emotional dysfunction; physical dysfunction, and social dysfunction. The majority of patients had good outcomes one year after the surgery treatment.

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