

Quality of Life after Laparoscopic Fundoplication for Gastroesophageal Reflux Disease. Preliminary Study

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Rezumat

Calitatea vieții pacienților după fundoplicatura laparoscopică pentru BRGE

Fundoplicatura laparoscopică (FL) este tratamentul de elecție în boala de reflux gastroesofagian (BRGE). Lucrarea noastră analizează calitatea vieții pacienților (CVP) după FL. Pacienților operați cu BRGE în perioada ian. 2008 - mai 2011 de către același chirurg, le-a fost trimis chestionarul Velanovich, de evaluare a CVP lapacienții cu BRGE (GERD-HRQL). Pacientul a trebuit să răspundă la 10 întrebări asupra simptomatologiei specifice BRGE avută înainte de operație (A) și la momentul anchetei (B). Scorul Velanovich este 0 în absența simptomelor de BRGE și 50 în prezența acestora la intensitate maximă. Dintre cei 53 de pacienți operați în perioada amintită, au răspuns 32: 16 pacienți au avut esofagită erozivă (EE) și hernie hiatală (HH), 15 boală de reflux nonerozivă (BRNE) la 11 asociată cu HH și o pacientă a avut esofag Barrett (EB) și HH. Practic 27 de pacienți au avut HH (87,5%). La toți pacienții s-a efectuat secționarea vaselor gastrice scurte. La 12 pacienți s-a efectuat fundoplicatură parțială posterioară Toupet, iar la 20 fundoplicatură totală Nissen. Au fost 21 de femei și 11 bărbați cu o vârstă medie de 55,13 ani (24-76), intervalul mediu de la operație fiind de 25,2 luni. Scorul Velanovich A, preoperator a fost de $29,9 \pm 10,9$, iar cel postoperator, B, de $3,4 \pm 4,4$ (interval de confidență (95%) 22,9-30,9; $p < 0,05$). Nu au fost diferențe de scor B între sexe (3,9 vs 2,4) și variantele de FL

(Nissen 3,2 vs Toupet 4,1) ($p=0,375$ și $p=0,532$). 29 de pacienți sunt satisfăcuți postoperator (90,62 %). Principala indicație operatorie a reprezentat-o prezența HH și a EE, întâlnite la majoritatea pacienților. FL a ameliorat substanțial calitatea vieții pacienților cu BRGE postoperator. Nu au fost diferențe statistice ale scorului Velanovich în funcție de stadiul de BRGE (EE, BRNE cu sau fără HH), sex, respectiv tipul de FL, Toupet sau Nissen.

Cuvinte cheie: fundoplicatura laparoscopică, Nissen, Toupet, calitatea vieții

Abstract

Laparoscopic fundoplication (LF) is the treatment of choice for gastroesophageal reflux disease (GERD). Our paper evaluates post LF quality of life (QL). Patients treated between January 2008 and May 2011 by the same surgeon were asked to fill in the Velanovich questionnaires for Gastro - Oesophageal Reflux Disease - Health Related Quality of Life (GERD-HRQL). The 10 questions were designed to assess GERD specific symptoms prior to (part A) and after surgery (part B). The Velanovich score is 0 if the patient is asymptomatic and 50 if the symptoms are at maximum intensity. Only 32 out of the 54 patients operated during the study filled in the questionnaire: 28 patients (87.5%) had hiatus hernia (HH), 16 cases were associated with reflux erosive esophagitis (EE), 4 patients had non-erosive reflux disease (NERD) and one had Barrett's esophagus (BE). We used Toupet partial posterior fundoplication for 12 patients and Nissen total fundoplication for 20 patients. The short gastric vessels were divided in all patients. The female - male ratio was 21:11 with a mean age of 55.13

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years and the mean follow up period for questionnaire B was of 25.2 months. The Velanovich A score was 29.9 ± 10.9 , and the follow up B score was 3.4 ± 2.4 (CI (95%) 22.9-39.9; $p < 0.05$). There were no B score statistical differences between sex ratio (3.9 vs 2.4) and type of fundoplication (Nissen 3.2 vs Toupet 4.1). 29 patients (90.62%) declared that their QL improved after surgery. The main indication for surgery present in almost every patient included in this study was the presence of the HH and RE. LF improved the quality of life of patients with GERD. There were no statistical differences of the Velanovich score according to GERD stage (EE, NERD with or without HH), sex ratio and type of LF, Toupet or Nissen.

Key words: laparoscopy, fundoplication, quality of life

Introduction

GERD is the most frequent gastrointestinal disease in developed countries; it comprises a spectrum of diseases that ranges from non-erosive reflux disease (NERD) with no esophageal lesions, to medium (Los Angeles A and B) or severe (Los Angeles C and D) erosive esophagitis (EE), and to Barrett's esophagus (BE), a precancerous condition. In 50 to 94% of cases it is associated with hiatus hernia (HH) (2,3). Even though the medical treatment is efficient for a short period of time as it relieves the symptoms, LF can rehabilitate the anatomic and physiologic reflux barrier to a definitive cure of the disease in most patients (2,4). LF is currently the treatment of choice for GERD (5). Patient quality of life (QL) is an essential factor to consider in evaluating the effectiveness of the surgical therapy (6). Our paper evaluates the improvement of QL using a specific questionnaire.

Methods

The patients who were operated for GERD by the same surgeon (A.E.N) between January 2008 and May 2011 were sent by mail an explanatory letter and two questionnaires, A and B. We used the Gastro-Oesophageal Reflux Disease-Health-Related Quality of Life Score = GERD - HRQL devised and popularised by Vic Velanovich (7). The questionnaire assesses the severity of GERD related symptoms. The questionnaire is made up of 10 questions which quantify on a scale from 1 to 5 the intensity of GERD symptoms. Questionnaire A evaluates pre-surgery and questionnaire B post-surgery symptoms, at the time of the survey (Table 1). The questionnaire has a minimum score of 0, if all symptoms are absent and a maximum score of 50, if all symptoms of GERD are present at maximum intensity.

In the GERD group there were included patients with typical symptoms, like heartburn and/or regurgitation, epigastric pain, dysphagia, and those with atypical symptoms, with or without oesophageal lesions, seen at esophagogastroduodenoscopy (EGD): reflux cough, reflux laryngitis, reflux

Table 1. Questionnaire about the QL for GORD (GERD-HRQL)

Symptoms intensity	
0- No symptoms	
1- Symptoms are present but do not bother	
2- Symptoms are present, bother, but not every day	
3- Symptoms that bother every day	
4- Symptoms that affect your daily activities	
5- Symptoms that prevent daily activities	
Common questions questionnaire A and B	
1. How strong is the heartburn?	0 1 2 3 4 5
2. Do you have heartburn when you lie flat?	0 1 2 3 4 5
3. Do you have heartburn when you stand up?	0 1 2 3 4 5
4. Do you have heartburn after meals?	0 1 2 3 4 5
5. Have you changed your diet because of heartburn?	0 1 2 3 4 5
6. Does the heartburn wake you up from sleep?	0 1 2 3 4 5
7. Do you find it difficult to swallow food?	0 1 2 3 4 5
8. Do you have pain when you swallow food?	0 1 2 3 4 5
9. Do you feel bloated?	0 1 2 3 4 5
10. If you take drugs, does this affect your everyday life?	0 1 2 3 4 5
Specific questions for questionnaire B (postoperative)	
- How satisfied are you about the current situation?	
Satisfied; similar as before operation; unsatisfied.	
- If you have to choose, will you have the operation again?	
Yes; No	

asthma, dental erosions, otitis media etc. (8). We included patients with axial and mixt HH, diagnosed endoscopically and radiologically. A hernia bigger than 5 cm was considered as voluminous.

Surgical indication

In our clinic we are currently unable to perform pH-meter, manometer, impedance or scintigraphic studies. The surgical indication was arrived at based on the presence of typical and atypical GERD symptoms, recurrence after medical treatment with proton pump inhibitors (PPI) as a therapeutic test, changes of the esophageal mucosa, confirmation of HH at EGD and oral contrast meal. The patients are categorised as follows:

- patients with EE and HH;
- patients with NERD and HH;
- patients with NERD who required surgical treatment after repeated PPI courses;
- patients with BE and metaplasia confirmed histopathologically.

When the study was carried out it was already common practice to divide the short gastric vessels for patients who undergo Toupet posterior partial fundoplication (PPF). We have been dividing the short gastric vessels since 1996, when we first started Nissen total fundoplication (TF).

Surgical technique

The surgical intervention was performed with the patient

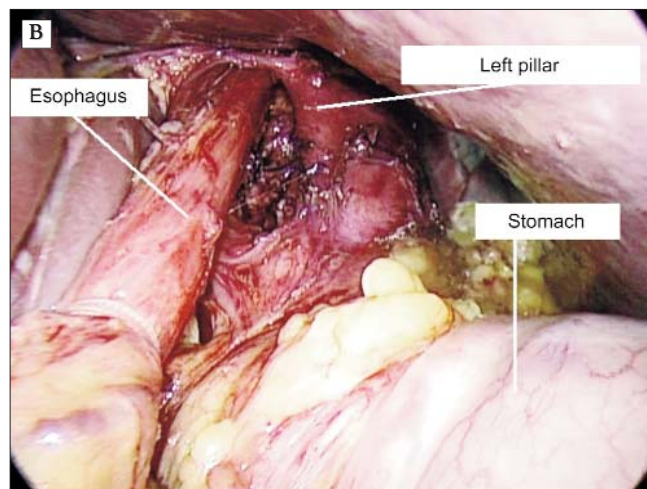
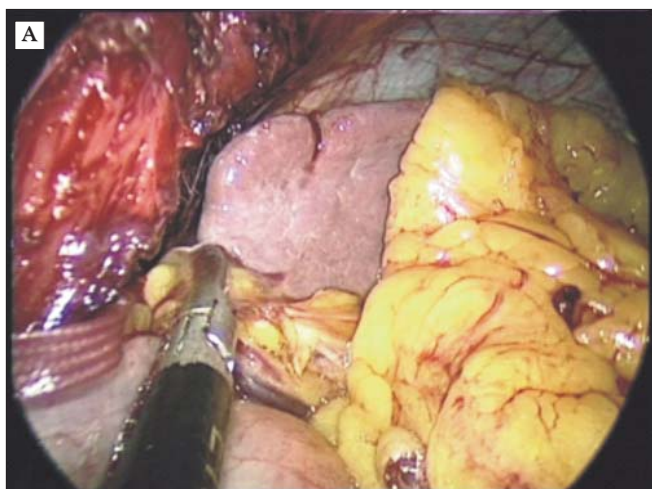


Figure 1. Division of the short gastric vessels

placed in the “French position” and reverse Trendelenburg, the surgeon standing between the patient’s legs, and the assistants to the right and to the left of the patient. The trocars were at first inserted according to B. Dallemagne’s scheme and, starting with 2010, according to G.B. Cadière (9, 10). We used a 30 degrees scope and the main steps during the procedure were: crus dissection, creation of the retro-esophageal window, dissection and lowering with minimum 2 – 4 cm of the terminal esophagus and of the gastroesophageal junction. For those with mixt and voluminous HH, we dissected and excised the hernia sac. Dissection and ligation of the short gastric vessels were performed using optimised bipolar coagulation (Liga-Sure™, Valleylab Inc., Boulder, Colorado, SUA) or the harmonic scalpel (Fig. 1). The cruroraphy and the esophageal hiatus calibration were performed in most cases with 1 – 3 posterior stitches using a non-resolvable 1-0 stitch. For calibration we used two 20 CH nasogastric tubes passed through the esophagus and the last stitch of the cruroraphy was placed such as to allow enough room for a 1 cm diameter forceps between the last stitch and esophageal wall.

In the PPF with the Toupet – Coster technique we used three non-resolvable 2-0 stitches for the right hemi valve, which included the esophageal wall and the gastric wall, the proximal suture including the right crus, and for the left hemi valve we used two stomach – esophagus sutures, the valve having a length of minimum 3 cm (Fig. 2).

The Nissen fundoplication was performed as per Dallemangen’s technique, by suturing the valve created from the stomach fundus with the esophageal wall, using 2 – 3 non-resolvable 2-0 stitches, with a valve length of less than 2 cm (Fig. 3) (9).

The nasogastric tubes used for cruroraphy calibration were removed postoperatively and oral liquid intake was permitted 8 hours postop, with only clear fluids in the first 48 hours. The discharge was made 2-3 days postop. Oral intake of liquids and semi solids was recommended for two weeks postop. The patients were prescribed a diet on the day of discharge. Six

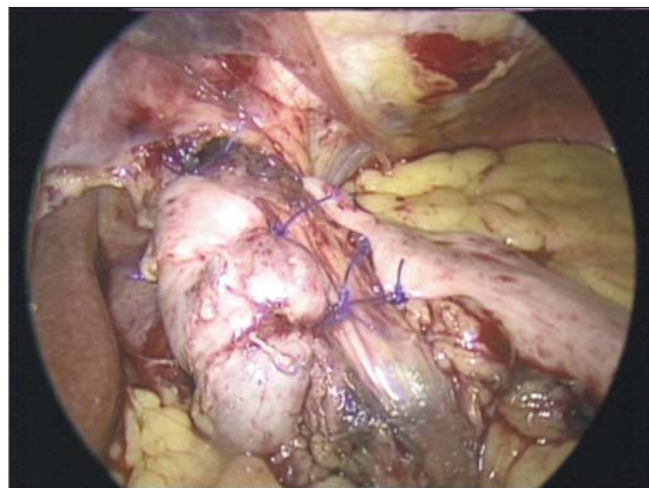


Figure 2. PPF Toupet - Coster (270°)

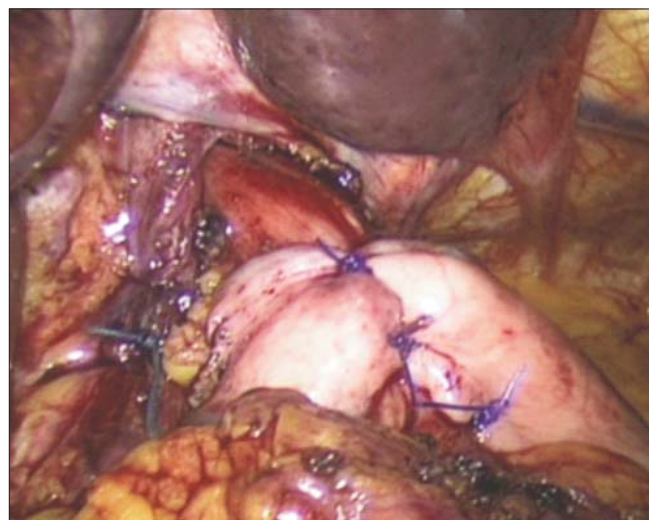


Figure 3. Nissen TF

weeks postop the patients were followed up clinically and endoscopically.

The statistical analysis was performed using SPSS 13.0 (Chicago, IL, USA). The statistical differences were evaluated using t-test, Mann-Whitney and Chi square, and a p value of less than 0.05 was considered as statistically significant.

Results

During the study period, a number of 53 patients underwent LF and all received our questionnaire. 32 patients (60.38%) answered the questionnaire, 21 female and 11 male, with a median age of 55.13 (± 13.56) and age limits 24 to 76 years. 16 patients had EE and HH, 11 just HH without esophagitis, 4 had NERD (no HH or EE) but 2 of them had had EE in the past, and a patient had BE with HH. Hiatus hernia was present in 28 patients (87.5%), out of which 26 were axial and 2 mixt. 6 patients out of 28 had a voluminous HH (21.43%). Regarding the EE classification, all patients had mild esophagitis: 11 had Los Angeles A and 5 Los Angeles B. All patients presented reflux at the contrast meal study. The incidence of the GERD stages versus patient sex, clinical symptomatology and type of LF is presented in Table 2.

In the study group there were 2 complications, both presented after TF (6.25%): severe postop dysphagia, which needed esophageal dilatations, and postop paraesophageal

hernia, which requested reintervention with recalibration of the oesophageal hiatus and PPF after six months from the first LF. Only 29 patients had follow up endoscopy, which did not show any pathological changes.

The Velanovich scoring before and after surgery in relation with sex and type of LF is presented in Table 3. There were no statistical differences regarding postop scoring (B) by gender, 3.95 versus 2.45 ($p=0.373$) and type of procedure PPF or TF, 4.08 versus 3.05 ($p=0.532$). The preoperative Velanovich scoring in relation with different stages of GERD is presented in Table 4. There were no statistical differences of the preoperative Velanovich scoring ($p>0.05$). Regarding the postoperative scoring, a statistical difference was noted for the patient with BE compared with the patients with HH and EE ($p=0.043$) and with those with HH without esophageal lesions ($p=0.000$).

29 patients out of 32 declared themselves as satisfied with the operation (90.62%). 2 patients operated in 2008 declared themselves unsatisfied: a patient with BE who underwent a TF and a patient with mixt voluminous HH who underwent PPF. For the first patient, the symptoms recurred and at present he is following a PPI course continuously. The second patient experienced sporadic episodes of GERD symptoms and he is following an intermittent PPI treatment. Another patient with TF for HH and EE, operated in 2011, has frequent epigastric pain but with normal EGD, and normal manometer and pH meter studies. All patients declared that they would have the

Table 2. Operated GERD stages

	EE + HH	NERD+ HH	NERD	BE+HH	Total (%)
Female	11	6	3	1	21(62.65)
Male	5	5	1	-	11(34.37)
Typical symptoms	14	9	3	1	27(84.37)
Atypical symptoms	2	2	1	-	5(15.62)
PPF	3	6	3	1	12(37.5)
TF	13	5	1	1	20(62.5)
Total	16(50%)	11(34.37%)	4(12.5%)	1(3.12%)	32

Table 3. Velanovich scoring (GERD- HRQL) by gender and type of fundoplication

	A	B	CI (95%)	p
F	30.14 \pm 8.99	3.95 \pm 4.94	21.67-30.71	$p<0.001$
M	29.36 \pm 12.90	2.45 \pm 3.24	18.54-35.27	$p<0.001$
PPF	32.50 \pm 9.51	4.08 \pm 3.60	22.33-34.51	$p<0.001$
TF	28.21 \pm 10.94	3.16 \pm 5	19.94-30.56	$p<0.001$
Total	29.88 \pm 10.29	3.44 \pm 4.43	22.47-30.39	$p<0.001$

Table 4. The value of the Velanovich scoring pre and postoperative by operated GERD stages

	n	Score A	Score B	p
HH +EE	16	26.9 \pm 10.1	3.6 \pm 4.6	$p<0.001$
NERD+HH	11	32.4 \pm 9.7	1.5 \pm 2.2	$p<0.001$
NERD	4	34.5 \pm 9.7	3.5 \pm 5.1	$p=0.006$
BE+ HH	1	26	14	

surgery again.

Before surgery, all patients except 2 with mixt voluminous HH, had followed medical treatment with PPI for a minimum period of 30 days, with improvement or complete cure of GERD symptoms. After discontinuation of PPI's, all patients stated that GERD symptoms had recurred.

Discussions

GERD affects 15 – 20% of the adult population of the U.S. and Western Europe (12). GERD is defined as a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications (8). Medical treatment, although effective in most of the cases, does not solve the functional changes characteristic to GERD or the anatomy induced by HH. PPI's are more efficient for patients with EE, these patients enjoying a more substantial improvement of their symptoms after LF (12). The medical treatment is ineffective in 20 – 30% of patients (refractory GERD), and after discontinuation, symptoms recur in over 80% of cases (13,14,15). In our series, after discontinuation of PPI's, GERD symptoms recurred for all patients. The main surgical indication for our patients was HH, anatomical change present in 87.5% of the operated patients, out of which 50% also presented EE. Only four patients had NERD and had repeated courses of PPI's without a complete resolution of symptoms, to of them had a history of EE. One patient with typical symptoms of GERD had BE and HH and in her case LF was recommended to stop the reflux and dysplasia progression (16,17). We did not use pH-metry preoperatively in order to identify the acid reflux. It is not mandatory for patients with typical symptoms of HH and EE (4,18). It is now essential, together with impedance study, in patients with NERD, in those refractory to PPI's treatment and in case of GERD recurrence (19). Manometry is not currently mandatory when TF can be used successfully in patients with moderate esophageal hypomotility (4).

In 2011 we celebrated 20 years since the first laparoscopic Nissen fundoplication, performed by B. Dallemagne in January 1991 (20). Unfortunately, the surgical indication, approach and technique remain controversial. I would like to point out the controversy about cruroraphy, TF or PPF, with or without division of short gastric vessels. Cruroraphy is recommended as a principle (9). TF is a more efficient antireflux method compared to PPF, but is associated with a higher incidence of dysphagia, postop gas-bloating, and inability to belch. In different published RCTs the degree of satisfaction is the same (21,22). Currently, esophageal hypomotility is not a contraindication for TF, the TF or PPF leading to its improvement postoperatively (18,19). The division of the short gastric vessels, which we do as a matter of principle, allows a release and an optimal mobilisation of the gastric fundus. Although it does not improve the postoperative evolution statistically, the division of the short gastric vessels is especially recommended for TF in order for the valve not to be in tension, and to include both sides of the gastric fundus (20,23,24). We performed TF especially for patients with HH and EE (13/16) and PPF in

female patients with preoperative bloating post meals and in patients with NERD. It is essential that the total or partial LF, which is a reconstructive intervention, is correctly done.

There are different questionnaires used in order to assess the QL after an operation. These can be generic ones, for all surgical interventions, and specific to gastrointestinal diseases like the Gastrointestinal Quality of Life Index (GIQLI) and specific to GERD (5,25). The most used questionnaire specific to GERD is the GERD-HRQL, the one we used in this study (7). In our series, the postoperative satisfaction was extremely good, 90.62%. In other published series, the satisfaction index ranged from 71 to 96.7% (26, 27,28,29). The dissatisfaction after LF is mainly the result of the recurrence of GERD symptoms, dysphagia or pain. Dissatisfaction can also be the consequence of an inappropriate surgical indication, patient's associated conditions (atypical symptoms, psychiatric issues), patients with longstanding symptomatology, fibrosis of the oesophagus muscularis consequence of repeated inflammation, short oesophagus (30,31,32). Inappropriate operative technique is an important cause which can lead to recurrence of HH: no cruroraphy, a too wide cruroraphy, jerking of the cruroraphy, incomplete dissection of the esophagus, tension suture of the valve, torsion or ascending of the valve etc. (31,33). The three patients who declared themselves unsatisfied in our series had BE, a mixt voluminous HH and a HH with EE. The patient with BE noticed heartburn recurrence after two years from her Nissen procedure and restarted PPI's treatment; in her case repeated EGD showed a small recurrence of the HH, with no esophageal lesions. The Velanovich scoring for this patient was statistically different compared with the mean scoring for the patients with HH and EE, and HH respectively. There was no case of persistent postoperative dysphagia and the only case with early severe dysphagia occurred in a patient after TF and it was resolved with oesophageal dilatations. Post-operative dysphagia and gas-bloating syndrome are more frequent in women (25). The incidence of early postoperative complications related to the technique was 6.25%. Good and very good results after LF are cited in 90% of cases, with a rate of complications of about 5%, a conversion rate of 3.7% (0 – 14.3%), GERD recurrence rate of 5.5 - 9% and a rate of reoperation of 3.7% (0 – 15%) (34, 35).

We believe that our results were good. Selective and adequate surgical indication and appropriate surgical intervention are the decisive factors in the LF success in patients with GERD. Of course, our study has its own limitations, due to the low number of cases analysed, high dropout rate and the lack of association with a quality of life generic questionnaire, and specific investigations (pH meter, impedance, manometry) pre and postoperative.

Conclusion

LF has proven to be effective on operated patients, with good postoperative results, even despite specific investigations. Most operated patients had HH and EE. There were no statistical differences of the postoperative Velanovich score according to

gender, GERD stage (EE, NERD, BE), association with HH, Toupet or Nissen fundoplication respectively.

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