Long-term quality-of-life assessment of gastrointestinal symptoms before and after laparoscopic Nissen fundoplication

Évaluation à long terme de la qualité de vie et des symptômes digestifs pré- et postopératoires après fundoplicature de type Nissen par cœlioscopie

F. Borie, A. Glaise, E. Pianta, M. Veyrac, B. Millat

Chirurgie digestive B, CHU Carémeau, place de Pr Debré, 30029 Nîmes, France
Pôle de l'appareil digestif, hôpital Saint-Éloi, Montpellier, France

Available online 31 May 2010

Summary

Purpose. — This was a prospective quality-of-life (QoL) assessment of gastrointestinal symptoms before laparoscopic Nissen fundoplication and during the 6-year postoperative follow-up.

Methods. — Over a 15-month period, 35 consecutive patients with gastroesophageal reflux disease (GERD) underwent surgery after failure of medical treatment with proton pump inhibitors. QoL was assessed using the Gastrointestinal Quality of Life Index (GIQLI) preoperatively, and at 3, 6, 12, 24, 48 and 72 months postoperatively.

Results. — The preoperative GIQLI score was lower than the ‘normal’ score (126 points), as were the scores overall and for each dimension (social integration, physical function, emotions and gastrointestinal symptoms; all $P < 0.001$). Also, although the GIQLI increased significantly ($P < 0.0001$) at 3, 6, 12, 24, 48 and 72 months, it remained below normal ($P < 0.01$). The symptom score also remained below that of the normal population (57 vs 67; $P < 0.0001$), while the percentages of patients with abdominal pain, dysphagia, modified eating habits and belching decreased non-significantly. However, GERD symptoms were significantly reduced (51% vs 4%; $P = 0.01$), although 20% of patients started taking proton pump inhibitors again during the follow-up period. Surgery eliminated 50% of the dysphagia symptoms reported preoperatively and, after 6 years, only 8% of patients still complained of dysphagia.

Conclusion. — Patients who undergo surgery after failure of medical treatment for GERD can expect an improved QoL, although they may not be able to achieve normal levels. Preoperative symptoms should be carefully recorded in order to better inform patients of the expected outcome following surgery.

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* Corresponding author.
E-mail address: frederic.borie@chu-nimes.fr (F. Borie).

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doi:10.1016/j.gcb.2009.10.023
Introduction

Fundoplication, considered the gold standard surgical cure for gastroesophageal reflux disease (GERD), is now widely performed using a laparoscopic approach [1,2]. As the main goal of the operation is to eliminate bothersome or disabling symptoms that have no direct impact on the vital prognosis, choosing the most appropriate surgical technique is based on long-term functional outcomes [3]. A vast number of quality-of-life (QoL) measures have been used to demonstrate the efficacy of surgical cure for GERD, and these tools provide an objective assessment of significant improvement in QoL [4–8]. Nevertheless, their validity may be questionable, particularly in the absence of long-term evaluation. Similarly, incomplete data collection—for instance, missing certain features that affect QoL—can compromise index quality, and the lack of relevance leads to a reduced incentive to modify clinical practices.

The purposes of the present study were to evaluate QoL after laparoscopic Nissen fundoplication, using the same adapted tool both pre- and postoperatively in a homogeneous group of patients followed regularly for 6 years, and to analyze the specific burden of their digestive symptoms on QoL in the long-term.

Patients and methods

Patient data

From 1st January 1998 to 31st March 1999, 35 consecutive patients underwent laparoscopic Nissen fundoplication. They included 25 men and 10 women, with a median age of 49.5 years (range 20–70 years), who had symptomatic GERD for an average duration of 11 years (range: 2–30 years) and had been taking proton pump inhibitors (PPIs) for an average of 3 years before surgery. Explorations (fibroscopy, esophageal manometry, pH monitoring) had been ordered as needed to establish the diagnosis. Two groups of patients were defined: PPI non-responders and PPI responders, who were considered to be ‘ideal’ for fundoplication (hiatus hernia, non-compliant with PPI treatment).

Quality of life

QoL was assessed using the French version of the Gastrointestinal Quality of Life Index (GIQLI) questionnaire (developed by Eypasch et al. [9]), which had been adapted and validated for the French population by Slim et al. in 1999 [10]. Each patient received seven questionnaires to be completed at the time of the preoperative visit, when the decision was made to perform the surgical cure, and at each postoperative visit at 3, 6, 12, 24, 48 and 72 months.

Inclusion and exclusion criteria

Inclusion criteria were symptomatic GERD and failure of medical treatment, defined as GERD recurrence on withdrawal of medication, or non-responsiveness or intolerance to medication. Exclusion criteria were the presence, before starting the study, of: primary achalasia and other severe esophageal motility disorders, identified by manometry in patients with dysphagia; severe psychiatric disorders; major difficulty in understanding French; and conditions carrying the risk of a serious intercurrent event (bereavement, unemployment, severe co-morbidity). After starting the study, patients failing to answer more than 40% of the questionnaire items and those exposed to a serious intercurrent event (bereavement, unemployment, serious co-morbidity) were also excluded. In the 35 patients initially included, exclusion criteria were identified in three patients at the...
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3-month postoperative visit, in two patients at the 6-month postoperative visit, and in two at 12 months, one at 24 months, and three at 48 and 72 months. During the 6-year follow-up, 231 questionnaires were collected out of the initially distributed 245.

Surgical technique

Throughout the study, one operator carried out a standard surgical technique that consisted of total circular fundoplication (Nissen technique) using a laparoscopic approach. Open laparoscopy was used to create a pneumoperitoneum through a portal slightly to the left of midline, close to the rib cage. Three other trocars were inserted—specifically, two 5-mm trocars (one to raise the left border of the liver) and one 10-mm trocar. The operation continued by opening the pars flaccida of the lesser omentum, followed by dissection of the diaphragm pillars (first on the right, then on the left). Prudent dissection of the esophagus was followed by the creation of a retroesophageal window, and sectioning of the suspensory ligament of the greater tuberosity, and the first short gastric vessels and gastrophrenic ligament, to enable complete mobilization of the esophagus and greater tuberosity. An intra-abdominal portion of the esophagus was then recreated. A non-calibrated full-circle valve was formed from the posterior and anterior aspects of the fundus, and sutured together using three separate stitches (Ethibond 2-0). The diaphragm pillars were also closed using separate stitches (Ethibond 2-0).

Quality-of-life assessment

QoL was measured according to the absolute GIQLI score, and the overall and separate dimension scores determined: symptoms (19 items); physical function (seven items); emotions (five items); social integration (four items); and effect of treatment (one item). The absolute score was defined as the total number of points (maximum: 144 points). Symptoms accounted for 50% of the score, emotions 14%, physical function 19% and social function 11%. Slim et al. [10] determined that the absolute score for a normal population was 126 ± 18 points out of an ideal score of 144 points.

Statistical analysis

QoL was compared before and after surgery, using the mean absolute score and dimension scores. The study population was compared with the healthy French population as described by Slim et al. [10]. Student’s t test and the non-parametric Mann-Whitney test were used where appropriate. Preoperative symptom scores were compared with their postoperative counterparts, using the Chi-square test or Fisher’s exact test where appropriate. P < 0.05 was considered statistically significant.

Results

Patients and explorations

Fibroscopy was performed preoperatively in 82% of patients (n = 29) and revealed mild-to-moderate esophagitis (stages I–II) in 11 patients, severe esophagitis (stages III–IV) in four patients, Barrett’s esophagus in another four and hiatus hernia in 22. Fibroscopy was normal in five patients. Clinically, severe dysphagia was noted in 10 patients (28%) who underwent preoperative manometry, which revealed hypotonia of the upper esophageal sphincter (n = 3), abnormal esophageal motility (n = 2) and no manometry anomaly (n = 5). In 10 patients (28%), pH monitoring revealed longer-than-normal exposure to gastric acidity.

Indications for surgery

Fundoplication was performed because of non-responsiveness to PPIs in 45% of patients (n = 16), while 55% had an ‘ideal’ indication for fundoplication: PPI dependence (n = 11); severe complications of esophagitis (n = 6); disorders related to regurgitation (n = 2); and non-compliance with medical treatment (n = 1).

Quality-of-life scores

The preoperative GIQLI score was 98 points, significantly lower than that of the normal population (126 points), and the respective differences were significant for the overall score and those for each dimension (P < 0.001): social integration, 11.7 vs 14; symptoms, 55 vs 67; treatment, 2.5 vs 4; physical function, 16 vs 23; and emotions, 13 vs 17 (Table 1 and Fig. 1). The preoperative GIQLI score was 91 ± 18 in patients non-responsive to PPIs, and 105 ± 20 in those with an ‘ideal’ indication. The most significant decrease in GIQLI score was in the social dimension, which was 11.6 preoperatively and 8.2 at 6 years. The other dimensions of the GIQLI

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Gastrointestinal Quality of Life Index (GIQLI) questionnaire scores.</th>
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<tbody>
<tr>
<td></td>
<td>Overall score</td>
</tr>
<tr>
<td>Preoperative (n = 35)</td>
<td>98</td>
</tr>
<tr>
<td>At 3 months (n = 32)</td>
<td>114</td>
</tr>
<tr>
<td>At 6 months (n = 33)</td>
<td>116</td>
</tr>
<tr>
<td>At 1 year (n = 33)</td>
<td>116</td>
</tr>
<tr>
<td>At 2 years (n = 34)</td>
<td>121</td>
</tr>
<tr>
<td>At 4 years (n = 32)</td>
<td>117</td>
</tr>
<tr>
<td>At 6 years (n = 32)</td>
<td>108</td>
</tr>
<tr>
<td>P value</td>
<td>0.1</td>
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(treatment, physical function, emotions) tended to decline over the 6-year follow-up but, nevertheless, remained above the preoperative scores.

**Symptoms**

The symptoms that changed following antireflux surgery were belching and intestinal disorders (Fig. 2). Preoperatively, belching was reported in 54% of patients. At 6 months, the prevalence was significantly reduced to about 6% \( (P < 0.05) \). However, at 6 years, 32% of the surgical patients reported a recurrence of this symptom. In addition, 29% of the surgical patients had functional disorders preoperatively; this increased to 53% at 3 months \( (P < 0.05) \), then returned to preoperative levels at 6 years (Fig. 3). The proportion of patients with GERD symptoms and modified eating patterns preoperatively (51%) was significantly improved at 6 years to 4% and 24%, respectively \( (P < 0.03) \; \text{Fig.} \; 2 \). Yet, despite the reduction in GERD symptoms, 20% of patients were taking PPIs at 6 years.

The curves for dysphagia and abdominal pain were non-linear during the 6-year follow-up (Fig. 4), with these symptoms observed in 43% and 37%, respectively, preoperatively. In addition, 10 patients presented preoperatively with severe clinical dysphagia, and five reported dysphagia on the GIQLI questionnaire. The proportion of patients with dysphagia decreased at 6 months to 12% and, at 6 years, 20% of the patients reported this symptom on the QoL questionnaire (not significant, NS). Postoperative dysphagia occurred in seven patients, five of whom had reported this symptom before surgery. Four of these five patients had esophageal manometry tests that revealed a hypotonic lower sphincter \( (n = 3) \) and motility disorders \( (n = 2) \), while surgery induced dysphagia in 6% of patients \( (n = 2) \). The proportion of patients with abdominal pain declined at 3 months and at 1 year, and the proportion at 6 years was 24% lower than preoperatively (NS).

**Discussion**

The present study followed the course of the patients' QoL following laparoscopic Nissen fundoplication, using the French version of the GIQLI, originally developed by Eypasch et al. [9] and known to be appropriate for all gastrointestinal disorders. As in earlier reports by Hauters et al. and Kamolz et al. [4,5], the preoperative QoL in the present study's patients was lower than that observed in the reference population. In a report limited to patients with no resistance to antacid treatment, Glise et al. [11] could find no difference between their study population and the healthy population. Selection of an ideal population had an effect on the outcome of antireflux surgery, with better outcomes in this population compared with those non-responsive to medical treatment [12,13]. In our present series, 16 patients (45%) were PPI-resistant. Preoperatively, the QoL of these PPI-resistant patients was lower than that of patients with an 'ideal' indication for surgery. However, although their QoL was improved 6 years after Nissen fundoplication, it still remained lower than that of the 'ideal' population.

After surgery, the QoL improved steadily throughout the 6-year follow-up. Nevertheless, the overall GIQLI scores remained below those observed in the normal population. This difference was entirely attributable to the symptoms
and social dimensions, both of which remained significantly lower than those of the normal population. Hauters et al. [4] reported similar results using the same GIQLI questionnaire, and Capelluto et al. [14] reported on the only series where no improvement was observed in the social dimension. The specificity of the GIQLI questionnaire might explain this difference, as other reports involving other questionnaires (SF-36, PGWB+GSR) revealed no significant differences between study and reference populations. Kamolz et al. [5] showed that, when the surgical technique (Nissen vs Toupet fundoplication) is adapted according to the results of preoperative function tests, the outcome in patients is the same as in the reference population. For this reason, other authors also advocate such a strategy [13,15], although no consensus has been reached on the topic [15,16]. All of our patients underwent Nissen fundoplication, irrespective of their results on preoperative function tests, which included five out of 10 patients whose preoperative manometry tests revealed esophageal motility disorders.

Few reports have compared pre- and postoperative symptoms, despite the fact that gastrointestinal symptoms are present in a large percentage of patients consulting for GERD. In the literature, GERD symptoms are reported to improve significantly, regardless of the amount of time after surgery [2,7,8,14]. In our present series, GERD symptoms were improved after surgical treatment by 3% at 3 months and by 4% at 6 months. Also, the long follow-up of 6 years allowed the assessment of recurrence, which appears to increase from this point onwards. In fact, 20% of patients in the present study were taking PPIs at 6 years, whereas Kelly et al. [17] and Fein et al. [18] reported that 21% and 28%, respectively, of their patients who had undergone Nissen fundoplication were taking PPIs at 10 years. This finding is also in agreement with the report by Draaisma et al. [19], which compared the 5-year outcome of laparoscopic vs conventional Nissen fundoplication. In the laparoscopic arm, 13.9% of patients were taking antisecretory drugs (PPIs or H2-receptor antagonists) at 5 years. In addition, at 5 years, the majority of patients had undergone 24-h pH monitoring, which revealed no significant correlation between the use of such antisecretory drugs and total exposure to gastric acid. Furthermore, there was no significant link between daily medication after antireflux surgery and the index correlating with symptoms. Thus, the reasons for resuming antisecretory treatment remain unclear.

While the proportion of patients presenting with dysphagia is generally reported for the postoperative period (0–40%), data from the preoperative period are scarce, although 20–30% of patients with GERD appear to have dysphagia [3,20]. Consistent with our present data, Bloomston et al. [21] found that their postoperative scores were lower than the preoperative scores. In our series, 12% of patients complained of dysphagia at 6 months and 20% at 6 years, which was not significant compared with the preoperative rate of 43%. However, half the patients complaining of dysphagia preoperatively again reported this symptom at 6 years, and the surgery itself induced dysphagia at 6 years in 6% of patients. This suggests that dysphagia cannot be considered a frequent complication of GERD surgery.

Functional impairment—mainly, the gas—bloat syndrome—was significantly increased after Nissen fundoplication, but only at 3 months. However, these functional symptoms had already been present prior to surgery. Many patients with GERD also suffer from digestive dysmotility, although it is masked by the more disabling symptoms specifically related to GERD [4]. Few reports in the literature have provided data on these aspects: functional signs have been reported in 0–83% of patients, and they are not commonly seen after surgery [4,21].

The belching symptom (eructation) is difficult to interpret with the GIQLI questionnaire. Consistent with Hauters et al. [4], the present study found a significant decline in belching at 6 months postoperatively, which improved over time (32% at 6 years). In the literature, the percentages for belching range from 2.5 to 28%. Also, creating a short loose valve reduces the prevalence of this symptom [13]. Gastric distention, which correlates with being unable to belch, was no different between the pre- and postoperative periods, although there was a trend towards a decrease. As shown in Fig. 2, the time course for intestinal functional disorders was inversely proportional to eructation over the 6-year period.

In conclusion, the present study demonstrates a significant improvement in QoL after laparoscopic Nissen fundoplication, albeit not achieving levels seen in the normal population. The difference was related to the symptom and social dimension scores, which remained below normal postoperatively, while the other dimensions exhibited no differences at all. Thus, the preoperative gastrointestinal symptoms constitute an important negative prognostic factor for the long-term success of antireflux surgery.

Conflict of interest statement

None.

References


