



Quality of life and patient satisfaction after laparoscopic antireflux surgery using the QOLARS questionnaire

Zs. Zéman, T. Tihanyi

First Department of Surgery, Semelweis University, Üllői u. 78, Budapest, Hungary

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Abstract

Background: Currently, evaluation of patient satisfaction and quality-of-life data to estimate the outcome of laparoscopic antireflux surgery is an important issue. This study aimed first to report the midterm results for the surgical management of gastroesophageal reflux disease (GERD) by laparoscopic fundoplication and to evaluate surgical outcome, including quality of life and patient satisfaction. The second aim was to determine whether preoperative quality-of-life measurement can predict which patients will be satisfied with antireflux surgery.

Methods: The current prospective study evaluated the outcome of the quality-of-life data for 41 patients (13 men and 28 women) who underwent laparoscopic fundoplication in the author's department of surgery between 1 January 2002 and 31 May 2003. The mean age of the patients was 41 years. Quality of life was measured by using a new quality-of-life instrument (QOLARS) developed and validated by the author's study group. The patients completed the QOLARS questionnaire before surgery, then 6 weeks, 1 year, and 3 years after surgery.

Results: Before surgery, all the patients had a poor quality of life. The general quality-of-life and heartburn scores improved significantly within 6 weeks after surgery and showed further improvement by the end of the first postoperative year, then remained stable 3 years after surgery. The patients who became completely free of reflux-related symptoms were divided into two groups according to their satisfaction with the operative result. The patients dissatisfied with surgery had significantly worse median preoperative scores in four domains (physical functioning, emotional functioning, sleep disturbance, constipation) than the patients satisfied with the procedure.

Conclusions: The findings show that QOLARS is a sensitive tool for assessing surgical outcome after lapa-

roscopic antireflux surgery. The quality-of-life response closely follows the clinical outcome of surgical treatment, reflecting its side effects as well. This study suggests that a generic quality-of-life scale can preoperatively identify patients with GERD who are likely to be dissatisfied with antireflux surgery.

Key words: Gastroesophageal reflux disease — GERD — Laparoscopic antireflux surgery — Patient satisfaction — Quality of life — QOLARS

Gastroesophageal reflux disease (GERD) is a common disorder with a great impact on quality of life. Health-related quality of life (HRQL) is significantly affected by GERD, and its evaluation is emerging as a factor important in the selection of treatment options for GERD and in assessing the outcome of different treatment strategies [17]. In recent years, laparoscopic antireflux surgery (LARS) has become the standard procedure for treating severe GERD [8]. Quality-of-life data and patient satisfaction are important issues in estimating the outcome of LARS [11, 15].

Several studies have demonstrated that laparoscopic fundoplication can achieve an excellent surgical outcome including quality-of-life improvement for patients with GERD [3, 5, 12, 14]. This study prospectively evaluated the quality of life for 41 GERD patients during a 3-year follow-up period after laparoscopic fundoplication.

Patients and methods

This prospective study aimed first to report the midterm results for the surgical management of GERD by laparoscopic fundoplication and to evaluate surgical outcome, including quality of life and patient satisfaction. The second aim was to determine whether preoperative quality-of-life measurement can predict which patients will be satisfied with antireflux surgery.

Between 1 January 2002 and 31 May 2003, 41 consecutive patients underwent complete “floppy” Nissen ($n = 30$) or partial Toupet

($n = 11$) laparoscopic fundoplication for typical GERD at the author's institution. They were assigned to either the Nissen or Toupet group depending on their preexisting motility disorders. Laparoscopic Nissen fundoplication was performed for all patients with normal esophageal motility. The Toupet technique was used for the patients with poor esophageal motility (≤ 30 mmHg in the lower esophageal segments in response to wet swallows) or severely disordered peristalsis ($\geq 40\%$ simultaneous contractions during wet swallows). Patients with proven GERD were considered for surgery if the symptoms had recurred or persisted despite long-term adequate medical treatment with proton-pump inhibitors (PPIs). Only five patients were truly nonresponders to medical therapy. These patients had a history of GERD symptoms longer than 12 months.

The 41 study patients included 28 women and 13 men with a mean age of 41 years (range, 17–68 years). All the patients underwent preoperative physiologic testing by upper endoscopy, esophageal manometry, and 24-h esophageal pH monitoring, and some had contrast radiography and gastric emptying.

Quality of life was evaluated using the QOLARS, a newly developed, standardized, and validated quality-of-life questionnaire. Validation of the QOLARS was established with 116 patients, as described previously [20]. The purpose for constructing this questionnaire was to establish an instrument suitable for measuring the efficacy and success of surgery from the patient's viewpoint, and to determine the impact of surgery on the patient's quality of life. This questionnaire was developed to be more comprehensive than existing instruments.

Recently, more GERD-specific quality-of-life questionnaires have been reported. These questionnaires concentrate on GERD symptoms and include questions concerning only the reflux-related symptoms. However, they do not include items specific for the most frequent complications after surgery (e.g., swallowing difficulties, belching and vomiting inability, excessive gas bloating), which have a significant impact on the patients' postoperative quality of life. Most studies ignore these factors and complaints.

We classified the items concerning the most frequently occurring symptoms after surgical treatment to a scale. Five more questions eliciting the patient's subjective consideration of the operation's efficacy and the patient's satisfaction with his or her current status were added to our instrument.

In comparison, several other studies use disease-specific or generic questionnaires, but not both in combination. Generic instruments are comprehensive, designed to be applicable across disease, treatments, and populations. The disadvantage of these instruments is that they may not be sufficiently responsive. On the other hand, the disease-specific instrument is clinically more relevant, captures details about the disease activity and symptom patterns, and is likely to be more responsive to change than the generic instrument. Taking into consideration the complementary nature of these different kinds of instruments, we used them in tandem and combined the advantages of disease-specific and generic scales in our questionnaire.

As described previously [20], the resulting QOLARS instrument is a 50-item Likert-type questionnaire including both generic and disease-specific scales (Visick score, EORTC QLQ-C30, the modified GERD-HRQL, and questions focused on the new complaints appearing after antireflux surgery and overall satisfaction with the results of fundoplication) designed to measure patients' quality of life. The QOLARS is a practical, user-friendly instrument to which patients can easily respond. The excellent psychometric properties of QOLARS have been demonstrated by evaluations before surgery, then 6 weeks, 1 year, and 3 years after surgery.

Statistical analysis

The results are expressed as medians and ranges unless otherwise stated. Preoperative and postoperative data were compared with the use of the paired Student's *t*-test. All *p* values less than 0.05 were considered statistically significant. Statistical analysis was performed with SPSS version 11.0 using Windows.

Results

Before surgery, all 41 patients completed the questionnaire. Of the 41 patients, 28 (~68.29%) completed the

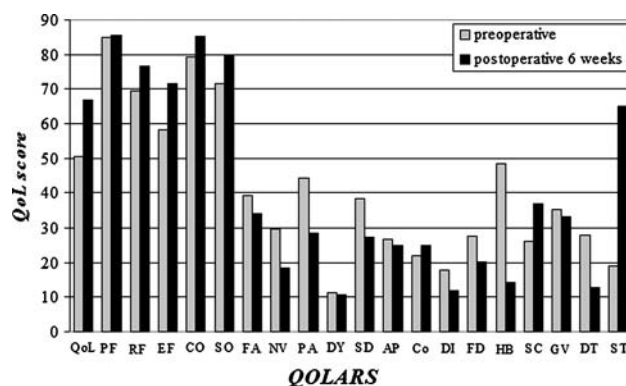


Fig. 1. Median preoperative and postoperative QOLARS scores. QoL, global quality of life; PF, physical functioning; RF, role functioning; EF, emotional functioning; CO, cognitive functioning; SO, social functioning; FA, fatigue; NV, nausea and vomiting; PA, pain; DY, dyspnea; SD, sleep disturbance; AP, appetite; Co, constipation; DI, diarrhea; FD, financial difficulty; HB, heartburn; SC, swallowing complaints; GV, gas bloat/vomit; DT, drug taking; ST, satisfaction with current status.

QOLARS questionnaire at the 6-week follow-up visit. The questionnaire was posted to each of the 41 operated patients 1 and 3 years after surgery for them to complete and return in an enclosed envelope. The patients who did not return questionnaire were contacted and asked to answer the questions by phone. A total of 32 patients (~78.04%) answered questionnaire 1 year after the operation, and 27 patients (~65.85%) did so at 3 years. Approximately 10 to 15 min were required to complete the questionnaire.

All the quality-of-life scores except for constipation and swallowing were improved 6 weeks after the operation, as compared with the preoperative scores. The scores for the two exceptions worsened. The scores for physical functioning, dyspnea, appetite, and gas bloat/vomit 6 weeks after surgery did not differ from the preoperative scores. The current status scales for general quality of life, emotional functioning, pain, heartburn, drug taking, and satisfaction showed statistically significant improvement (Fig. 1).

The mean values of for the following nine subdimensions showed improvement 1 year postoperatively: role functioning, social functioning, appetite, pain, drug taking, general quality of life, nausea and vomiting, heartburn, and satisfaction. The scores for the last four had changed significantly. The mean scores for physical functioning, cognitive functioning, fatigue, sleep disturbance, constipation, diarrhea, financial difficulty, swallowing complaints, and gas bloat/vomit had not changed significantly by the end of the first postoperative year. The patients had worse postoperative scores for the emotional functioning and dyspnea domains 1 year after laparoscopic fundoplication (Fig. 2).

The current status scales showed statistically significant improvement 3 years after surgery for general quality of life, role functioning, cognitive functioning, social functioning, fatigue, nausea and vomiting, pain, appetite, heartburn, drug taking, and satisfaction. The mean scores for sleep disturbance, diarrhea, and gas bloat/vomit had not significantly changed. Physical

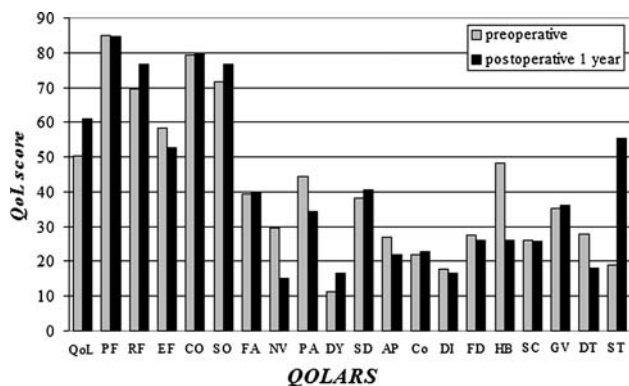


Fig. 2. Median preoperative and postoperative QOLARS scores. QoL, global quality of life; PF, physical functioning; RF, role functioning; EF, emotional functioning; CO, cognitive functioning; SO, social functioning; FA, fatigue; NV, nausea and vomiting; PA, pain; DY, dyspnea; SD, sleep disturbance; AP, appetite; CO, constipation; DI, diarrhea; FD, financial difficulty; HB, heartburn; SC, swallowing complaints; GV, gas bloat/vomit; DT, drug taking; ST, satisfaction with current status.

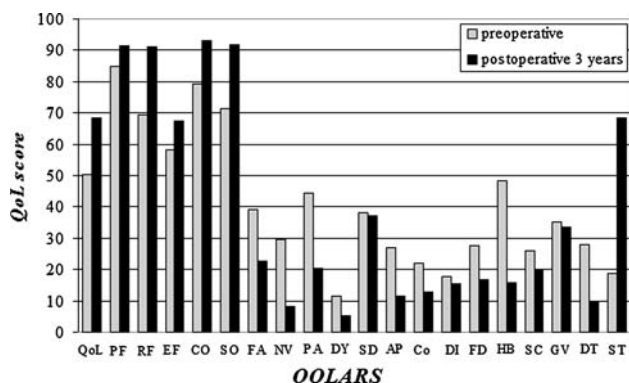


Fig. 3. Median preoperative and postoperative QOLARS scores. QoL, global quality of life; PF, physical functioning; RF, role functioning; EF, emotional functioning; CO, cognitive functioning; SO, social functioning; FA, fatigue; NV, nausea and vomiting; PA, pain; DY, dyspnea; SD, sleep disturbance; AP, appetite; CO, constipation; DI, diarrhea; FD, financial difficulty; HB, heartburn; SC, swallowing complaints; GV, gas bloat/vomit; DT, drug taking; ST, satisfaction with current status.

functioning, emotional functioning, dyspnea, constipation, financial difficulty, swallowing complaints had improved 3 years after surgery (Fig. 3).

Table 1 displays the operation 1 (op1) and op2 scores (subjective patient evaluations of operation efficacy) 6 weeks, 1 year, and 3 years after LARS. The op1 question asked: What degree do you consider the operation contributed to the relief of your GERD symptoms? The op2 asked: How do you consider your current health status compared with your preoperative status?

At 6 weeks after operation 2, 28 patients (7.14%) were taking medications and 3 patients (10.71%) had moderate dysphagia, which could not be perceived by the first postoperative year. Three patients (9.37%) experienced minimal GERD symptoms by the end of the first postoperative year and needed drug treatment because of occasional heartburn. Two patients (6.25%) were taking medications on a regular basis for treatment of heartburn. Of the eight patients (25%) who reported

Table 1. Subjective consideration of operation (op1 and op2) 6 weeks, 1 year, and 3 years after laparoscopic antireflux surgery (LARS)

	Mean postop score at 6 weeks (n = 28)	Mean postop score at 1 year (n = 32)	Mean postop at 3 years (n = 27)
Op1	66.96 ± 30.46	57.81 ± 36.71	65.00 ± 28.56
Op2	89.28 ± 21.97	78.12 ± 29.61	85.00 ± 26.15

postop, postoperative; Op1, subjective consideration of operation 1; Op2, subjective consideration of operation 2

new symptoms after surgery, three (9.37%) reported belching inability, and five reported excessive gas and abdominal bloating (15.62%). One patient (3.12%) experienced mild dysphagia not requiring dilation. Three patients (11.11%) were adequately maintained on short-term PPI therapy for reflux symptoms. Four patients (14.81%) had gas bloat, and two patients (7.40%) had belching inability 3 years after surgery. A minority of our patient population (15%) continued to use anti-secretory medication 3 years after fundoplication.

The surgical success rate, as defined by a Visick score of 1 to 2, was 86% in the 6 weeks after the operation, 84% by the end of the first postoperative year, and 85% 3 years after antireflux surgery. Regarding quality of life and complications after surgery, almost identical results were found preoperatively and at the follow-up assessment comparing the two groups that respectively underwent Nissen and Toupet fundoplication.

A total of 12 patients completely free of reflux-related symptoms after antireflux surgery, as evidenced by both objective measurements (pH monitoring, endoscopy) and their answers to questions concerning GERD symptoms on the questionnaire, were dissatisfied with the outcome and success of the operation.

The patients were divided into two groups according to their satisfaction with the operative results: group 1 (completely free of reflux-related symptoms and dissatisfied with the success of the operation) and group 2 (completely free of reflux-related symptoms and satisfied with the success of operation). The dissatisfied patients had significantly worse op1 and op2 scores than the satisfied patients. The postoperative reflux-related symptoms were similar in both groups. There was no difference in the distribution of operation types (Nissen or Toupet) between the satisfied and dissatisfied patients.

The two patient groups were similar in terms of their demographic data such as age, sex, and duration of GERD and medical treatment. All the patients had received PPI before surgery. None of the patients had undergone a previous antireflux procedure.

The patients dissatisfied with their surgery had significantly worse median preoperative scores than the satisfied patients in four domains: physical functioning (87.40 vs 92.82), emotional functioning (58.33 vs 66.67), sleep disturbance (25.92 vs 35.89), and constipation (22.22 vs 15.38). The dissatisfied patients also had worse postoperative scores than the satisfied patients in the following domains: general quality of life (61.11 vs 79.16), emotional functioning (54.86 vs 77.08), cognitive functioning (79.16 vs 93.05), fatigue (40.74 vs 20.37),

nausea and vomiting (15.27 vs 3.70), pain (33.33 vs 16.67), satisfaction with current status (43.75 vs 86.11), op1 (43.75 vs 92.36), and op2 (81.25 vs 99.30).

Most of the dissatisfied patients had worse preoperative heartburn and drug treatment scores, and they had not responded to medical treatment. Significant differences were not found in other domains.

Discussion and conclusions

In accordance with a number of previous studies, our results showed that laparoscopic fundoplication provides effective and durable relief of reflux for patients with GERD [2, 4, 6, 13]. The operation results in a high level of patient satisfaction, improved quality of life, and elimination of antisecretory medicines for the majority of patients.

Significant improvement was observed in quality of life after surgery. Before surgery, all the patients had a poor quality of life. The scores for general quality-of-life, heartburn, and satisfaction with current status showed statistically significant improvement 6 weeks after the operation, and further improvement by the end of the first postoperative year. It remained stable 3 years after LARS.

In most cases, evaluation of HRQL could replace the objective postoperative testing. The quality-of-life response closely follows the clinical outcome of surgical treatment, reflecting its side effects as well. The QOLARS instrument is a sensitive tool for assessing surgical outcomes after fundoplication.

We acknowledge the limitations of our study. First, our follow-up rate was a bit poor: 78.04% for the first postoperative year and 65.85% 3 years after surgery. If those who failed to return completed questionnaires also were patients dissatisfied with the results of the procedure, their data would have made our results dramatically less favorable. The low follow-up rate can be explained by the poor compliance of our patients because only 68.29% presented themselves at the scheduled 6-week control visit. Another explanation can possibly be found in the method of follow-up assessment, which involved questionnaires sent by post. Some patients had changed their addresses, so the questionnaires could not be delivered. A group of patients requested to answer by phone changed their phone numbers or refused participation in the study. Furthermore, patients could choose not to respond to all the questions, and these questionnaires were excluded from the study.

Despite the significant postoperative improvement in quality of life, patient satisfaction and the effectiveness of fundoplication fell behind other reports of outcomes 1 year or more after laparoscopic fundoplication [1, 7, 9, 16]. We observed that despite accurate identification of patients with pathologic gastroesophageal reflux, some patients still are not satisfied with antireflux surgery. A possible explanation is that laparoscopic fundoplication is associated with an increased risk of some complications as well as the occurrence of new complications specific to the procedure: gas bloating, swallowing and belching difficulties, and vomiting inability.

In our opinion, patient satisfaction seems mainly to depend on the disappearance of GERD's clinical symptoms. However complaints appearing as a consequence of the operation (e.g., swallowing and belching difficulties, vomiting inability, or excessive gas bloating) can have a significant negative impact on patients' quality of life and satisfaction with surgical treatment. Such complaints appear more frequently among dissatisfied patients.

Nevertheless, patients with proven GERD should be informed before the operation that some symptoms related to dyspepsia are likely to persist after surgery. We believe that the greater the spectrum of preoperative functional symptoms, the more the improvement in quality of life after surgery is questionable, but further investigations of this are needed. The findings show that among dissatisfied patients, there were more nonresponders to medical therapy. Such patients also have worse preoperative heartburn and drug treatment scores. Our data demonstrate that the patients dissatisfied with surgery, no matter how their reflux symptoms were controlled, had lower preoperative generic quality-of-life scores in some domains (physical functioning, emotional functioning, sleep disturbance, constipation) than the satisfied patients. Nevertheless, the dissatisfied patients did not have an objectively documented postoperative physiologic or morphologic problem. Moreover, there are many factors involved in patient satisfaction. It is known that several comorbidities such as psychoemotional factors, chronic pain, psychiatric disease, and personality will affect subjective outcome after LARS even when there are no corresponding differences in the physiologic data [10, 18, 19].

The data obtained suggest that these patients generally should not be excluded from LARS, but should be selected more carefully. This study suggests that a generic quality-of-life scale can preoperatively identify patients with GERD who are likely to be dissatisfied with antireflux surgery even if they are free of objectively documented postoperative physiologic or morphologic problems and their reflux-related symptoms are controlled. Our results show that patient satisfaction is more complex than simply relief of GERD symptoms, and that patients who may ultimately be dissatisfied with their symptoms outcome and success of surgery may preoperatively be identified. Thus, we consider the combined application of disease-specific and generic questionnaires important. We hope that QOLARS will identify patients who would benefit from antireflux surgery, and that the questionnaire will be able to predict less improvement and success after surgical treatment from the patient's viewpoint.

Our questionnaire (QOLARS) presumably will be administered as a part of clinical trials with GERD patients who have undergone laparoscopic fundoplication. It is our aim that it can contribute to determination of indications for surgery, better patient selection, plans for individual treatment strategy, and therefore the success of antireflux surgery. Quality-of-life instruments used as predictive tools for surgical outcomes, additional long-term follow-up studies that include quality-

of-life data, and patient satisfaction reports after LARS still are required.

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