Using Quality-of-Life Measurements to Predict Patient Satisfaction Outcomes for Antireflux Surgery

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Hypothesis: Preoperative quality-of-life measurement can predict which patients will be satisfied with surgical fundoplication in the treatment of gastroesophageal reflux disease (GERD).

Design: Review of a prospectively gathered database.

Setting: Tertiary referral center.

Patients: All patients underwent preoperative physiological testing by upper endoscopy, esophageal manometry, and 24-hour esophageal pH monitoring, and some had contrast radiography and gastric emptying scintigraphy. Patients were examined for symptoms and completed a symptom severity questionnaire (the GERD–Health-Related Quality of Life questionnaire) and a generic quality-of-life instrument (the 36-Item Short-Form Health Survey [SF-36]). Patients then underwent either open or laparoscopic fundoplication.

Main Outcome Measurements: Patients were contacted to assess satisfaction 2 months to 5 years postoperatively. They completed the GERD–Health-Related Quality of Life questionnaire and the SF-36. Patients were grouped into those satisfied and dissatisfied.

Results: Two hundred ninety patients were included. Median follow-up was 29 months. Thirty-four patients (12%) were dissatisfied with their surgical outcomes for any reason. The dissatisfied patients had statistically significantly worse scores preoperatively in 6 of the 8 domains of the SF-36 than satisfied patients. Dissatisfied patients had less symptomatic improvement. The satisfied patients had statistically significant improvement in 6 domains, whereas the dissatisfied patients had statistically significant worsening of scores in 2 domains.

Conclusions: Quality-of-life measurements are frequently used as an outcome end point. This study shows that a generic quality-of-life instrument can preoperatively identify patients with GERD who are likely to be dissatisfied with antireflux surgery. Use of quality-of-life instruments as a predictive tool for surgical outcomes deserves further study.

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There are several goals in the treatment of gastroesophageal reflux disease (GERD). These include symptomatic relief, healing of esophagitis and ulcers, inhibition of pathologic reflux, and, possibly, decreasing the risk of esophageal cancer. Among these goals is patient satisfaction.

There are many factors involved in patient satisfaction. These issues range from actual medical outcome to such nonmedical issues as staff-patient interaction.1,2 Research from this institution has shown that factors that are not related to the actual surgical procedure or its outcome can influence patient satisfaction for patients undergoing breast biopsy3 and laparoscopic cholecystectomy.4 Therefore, it seems reasonable to expect such influences in the management of GERD.

Determining who would be satisfied with antireflux surgery is of primary concern for surgeons. In fact, early in the history of antireflux surgery there was a high dissatisfaction rate. Development of physiological testing for GERD was a response to better determine who would have symptomatic relief from antireflux surgery.5 Currently, by means of a combination of symptoms, esophageal manometry, 24-hour esophageal pH monitoring, upper endoscopy, and upper gastrointestinal contrast series, GERD is diagnosed with a high degree of confidence.6

Nevertheless, despite accurately identifying which patients have pathologic gastroesophageal reflux, some patients still will not be satisfied with antireflux surgery.6,10 This dissatisfaction may be due to failure of the fundoplication to control reflux (ie, recurrent GERD), complications...
or side effects of the surgery, misdiagnosis of some other esophageal disorder as GERD (eg, an esophageal motility disorder or a functional esophageal disorder), or symptoms related to some nonesophageal disease (eg, cardiac). This being said, there will be a group of patients who will be dissatisfied with antireflux surgery for no physiologically demonstrable reason. The purpose of this study was to determine whether preoperative quality-of-life measurements can predict patient satisfaction after antireflux surgery.

METHODS

PATIENTS

All patients referred for surgical management of GERD were examined with history, physical examination, esophageal manometry, 24-hour esophageal pH monitoring, and esophagogastroduodenoscopy. Patients were also selectively studied with upper gastrointestinal contrast series and gastric emptying scintigraphy. Preoperatively, patients also completed a symptom severity questionnaire, the GERD–Health Related Quality of Life (GERD-HRQL), and a generic quality-of-life instrument, the 36-Item Short-Form Health Survey (SF-36). The SF-36 measures 8 domains of quality of life: physical functioning (how patients perceive their ability to perform physical tasks), role-physical (how patients perceive their ability to fulfill their life role physically), role-emotional (how patients perceive their ability to fulfill their life role emotionally), bodily pain (how patients perceive their level of pain), vitality (how patients perceive their level of “energy”), mental health (how patients perceive their emotional and psychological well-being), social functioning (how patients perceive their ability to participate in social activities), and general health (how patients perceive their overall health and well-being). These instruments were chosen because they were previously assessed to be reliable, validated, responsive, and appropriate in the assessment of patients with GERD, chronic pain, and psychological issues addressed in this study. Patients who were considered candidates for antireflux surgery must have had either typical or atypical symptoms of GERD, pathologic acid reflux demonstrated by 24-hour esophageal pH monitoring, and esophageal manometry showing a hypotensive or low-normal lower esophageal sphincter pressure without significant esophageal motility disorders. Upper endoscopy had to rule out evidence of malignancy, and other studies, if obtained, could not contraindicate surgery.

SURGERY

Antireflux operations were performed with laparoscopic or open Nissen, Toupet, or Collis-Nissen fundoplications. The technique has been described in detail elsewhere. Briefly, laparoscopic Nissen fundoplications were completed with the patient in the low lithotomy position. Access was obtained with 5 trocars. Complete dissection of the esophageal hiatus was obtained to allow for at least 2 cm of intra-abdominal esophagus. The esophageal hiatus was closed posterior to the esophagus and to the crus to the right and left of the esophagus over a 54F to 58F dilator. Open Toupet fundoplications were done in the same manner, except that access was obtained through an upper, midline incision.

The Collis-Nissen fundoplication was reserved for the fore-shortened esophagus. This was determined intraoperatively if, after complete mobilization of the esophagus from the hiatus, the gastroesophageal junction would not stay within the abdominal cavity without tension. The Collis gastroplasty was performed by dividing the stomach from the angle of His caudad for 2 to 4 cm while a 56F to 60F dilator was in place. The hiatal defect was then repaired and 360° wrap completed as previously described.

FOLLOW-UP

Patients were routinely followed up for at least 6 weeks after the operation or until all postoperative complaints were resolved. All postoperative complications or untoward events were recorded. For the purpose of this study, patients were contacted by telephone or face-to-face interview. They were asked about their satisfaction with surgery and were allowed 2 choices: satisfied or dissatisfied. Patients were also asked to complete the GERD-HRQL and the SF-36 to determine symptom severity and quality of life.

STATISTICAL ANALYSIS

Nominal data were analyzed by means of the Fisher exact test or the χ2 test with continuity correction. The data from both the GERD-HRQL and SF-36 were analyzed by the Wilks-Shapiro test to determine whether the data followed a normal distribution. These data were found not to follow a normal distribution and, therefore, were analyzed by a nonparametric test, the Mann-Whitney test. P ≤ .05 was considered significant.

RESULTS

DEMOGRAPHICS

A total of 290 patients were included in this study. Of these, 34 (12%) were dissatisfied with their surgery. This dissatisfaction could be for any reason, not just whether, or to what extent, their reflux symptoms were controlled. Of the patients dissatisfied with antireflux surgery, 24 (71%) were female, compared with 105 (41%) of the satisfied patients. The mean ± SD age of the dissatisfied patients was 46 ± 13 years, compared with 50 ± 15 years for the satisfied patients.

OPERATIONS

Of the 290 operations done, 239 (82%) were Nissen fundoplications, 42 (14%) were Toupet fundoplications, and 9 (3%) were Collis-Nissen fundoplications. Of the pa-
Satisfaction with antireflux surgery, 82% had a Nissen fundoplication, 34% had a Toupet fundoplication, and 4% had a Collis-Nissen fundoplication. Of the patients dissatisfied with antireflux surgery, 29 (85%) had a Nissen fundoplication and 5 (15%) had a Toupet fundoplication. There was no statistically significant difference in the distribution of operations between the satisfied and dissatisfied patients.

Of the 290 antireflux operations, 224 were completed laparoscopically, while 66 were either planned open operations or converted to open operations. Of the satisfied patients, 76% had laparoscopic antireflux surgery and the remainder open, compared with 28% (82%) of the dissatisfied patients (P = .4).

**Complications and Untoward Effects**

Of the 256 satisfied patients, 7 (3%) had some complication, side effect, or persistent symptom after antireflux surgery. This compares with 100% of the dissatisfied patients (P < .001). The table lists these complications and untoward effects. Of the 16 dissatisfied patients with persistent or recurrent symptoms, 8 agreed to be reexamined with upper gastrointestinal series, upper endoscopy, esophageal manometry, and 24-hour esophageal pH monitoring. Of these 8 patients, 4 had a physiologically demonstrable GIRD. These patients underwent repeat fundoplication. Sixteen of the dissatisfied patients were treated with antacid medications (usually a proton pump inhibitor); however, only 4 (25%) of these reported improvement in symptoms. Of the 3 patients with postoperative paraesophageal hernia and 1 patient with a perforation required operative intervention. Therefore, 8 (24%) of the 34 patients required another operation to relieve the complication of antireflux surgery.

**Symptom Severity and Quality of Life**

**Figure 1** shows the median total preoperative and postoperative GERD-HRQL scores for satisfied and dissatisfied patients. There was no statistically significant difference between the median preoperative scores of these groups. Postoperatively, both the satisfied and dissatisfied patients had statistically significant improvements; however, the dissatisfied patients had less improvement than the satisfied patients. In other words, the dissatisfied patients had more persistent or recurrent symptoms.

**Figure 2** shows the median preoperative and postoperative scores for the SF-36. Patients who were ultimately dissatisfied with surgery had statistically significantly worse median preoperative scores in 6 domains compared with patients who were ultimately satisfied with surgery. The dissatisfied patients had worse postoperative scores than the satisfied patients in all domains.
pared with the preoperative scores, satisfied patients showed statistically significantly better scores in 6 domains. However, the dissatisfied patients had statistically significantly worse scores in 2 domains.

Quality-of-life measurements have been used frequently to assess outcomes of antireflux surgery. Using a variety of symptom severity, disease-specific, and generic instruments, many authors have demonstrated quality-of-life improvements with antireflux surgery.36-38 Some in the medical community still question whether results from centers whose surgeons have expertise and interest in antireflux surgery are generally applicable to community surgeons who do the occasional operation.27 Nevertheless, quality of life is an important and accepted outcome measure for both medical and surgical treatment of GERD.

Quality-of-life instruments have uses beyond that of an outcome measure. These include uses as a discriminative index (to separate groups of patients on the basis of quality-of-life status) and as a predictive index (to predict an outcome).28,29 It is this use as a predictive index that was the basis of the hypothesis of this study.

Others have assessed a variety of physiological factors to predict outcomes of antireflux surgery. Campos et al30 performed a multivariate analysis of factors predicting the outcome after laparoscopic Nissen fundoplication. Of the factors they evaluated, they found that an abnormal 24-hour pH score, typical primary symptoms, and clinical response to acid suppression therapy predicted a successful outcome. However, a structurally defective lower esophageal sphincter as determined by esophageal manometry does not predict better symptomatic response.31 This same group reported that patients with normal lower esophageal sphincter pressures were at higher risk of postoperative dysphagia.32 The group from Washington University in St Louis, Mo, found that patients with daytime GERD while in the upright position tended to have worse symptomatic outcomes than did those with nighttime symptoms while in the supine position.33 Others have shown that whether the operation was done laparoscopically or open did not have a bearing on patient satisfaction.13,26 Nevertheless, despite all of these physiological factors predictive of symptomatic outcome, there will still be a group of patients who will not be satisfied with antireflux surgery even though there is physiological correction of the pathologic reflux.

There are issues that can affect patient-perceived outcomes of antireflux surgery that are not related to the pathophysiology of the disease or repair. Psychoemotional issues are both affected by and can affect how patients experience their disease.34-37 Issues such as chronic pain, psychiatric diseases, depression, anxiety, and personality issues all have been shown to result in patient-perceived problems with antireflux surgery.35-37 In fact, 1 study demonstrated that psychological intervention actually improves the symptomatic outcome of antireflux surgery in patients who believed that “stress” was a contributing factor to their GERD.38

Quality-of-life status has been shown to predict outcomes in other disease processes, including breast cancer,39 multiple sclerosis,40 cardiac disease,41 and chronic obstructive lung diseases.42 This study demonstrates that patients who are dissatisfied with surgery had lower preoperative quality-of-life scores compared with those who were satisfied. If their dissatisfaction stemmed solely from a poor operative outcome, then the preoperative scores would be similar in both groups. This difference in median SF-36 scores was present even though patients who truly had physiologically documented recurrent GERD or some other anatomic complication (eg, paraesophageal hernia, mechanical dysphagia, or perforation) were included in the dissatisfied group. It is also interesting that the perceived symptom severity, as measured by the GERD-HRQL, was similar in both groups. Therefore, even though reflux-related symptoms were similar, the dissatisfied patients still had lower preoperative generic quality-of-life scores. This implies that symptoms in the dissatisfied group of patients affect quality of life much more than in the satisfied group. This may explain why some studies of patients with postoperative GERD-like symptoms found only a minority of patients with pathologic reflux by objective physiological testing,43-46 and another showed that poor preoperative compliance with antireflux medications predicted poor symptomatic relief of GERD symptoms by antireflux surgery.47 Therefore, nonspecific postoperative problems may simply be magnified in this group of patients.

Some of the patients in this series had legitimate reasons not to be happy with their surgical outcome. Four patients had documented reflux recurrence, 3 had postoperative paraesophageal hernias, 3 had persistent dysphagia requiring dilation, and 1 had a perforation. These patients accounted for 11 (32%) of the 34 dissatisfied patients. These were true surgical failures. Nevertheless, 68% of dissatisfied patients did not have an objectively documented physiological or anatomic problem with their surgery. In fact, the median SF-36 scores for the dissatisfied patients with documented surgical failures were generally higher than those for the patients with unexplained dissatisfaction: physical functioning, 85 vs 80, respectively; role-physical, 87.5 vs 50; role-emotional, 100 vs 50; bodily pain, 67.5 vs 46; vitality, 75 vs 50; mental health, 90 vs 50; social functioning, 100 vs 62.5; and general health, 56 vs 42. This further strengthens the assertion that patients with lower preoperative quality of life will be more likely to be dissatisfied.

Nevertheless, using preoperative quality-of-life scores to reject a patient for surgery may be difficult. I use great caution in approaching patients with chronic pain syndromes, psychoemotional disorders, or low quality-of-life scores without complications related to GERD and frequently do not offer them antireflux surgery. Patients with complications of GERD such as esophageal ulceration (especially with signs of bleeding), Barrett...
esophagus, or esophageal strictures will be offered surgery. The ranges of scores, however, are such that a definitive cutoff level cannot be determined. Therefore, although preoperative lower quality-of-life scores can predict patient satisfaction, each patient needs to be approached as an individual.

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10. Velanovich V. Medication usage and additional esophageal procedures after antireflux surgery.


Raymond J. Joehl, MD, Hines, Ill: The author hypothesized that perception of preoperative quality of life (QOL) predicts satisfaction with an anti-reflux operation for severe GERD. They obtained pre-op and post-op perceptions of QOL using the standard SF-36 form and a GERD-specific symptom severity questionnaire. They found that the SF-36 preoperatively identified patients who were likely to be dissatisfied. This study involved a large amount of work treating and evaluating surgical results, as well as obtaining and evaluating patients’ perceived outcomes.

Functional outcome following surgical treatment for severe GERD and, for that matter, most surgically treated disorders and diseases should correlate with preoperative functional status. So, I am not surprised with the outcomes that Dr Velanovich reported today. I have these initial questions: (1) Did your QOL questionnaires merely identify patients with overt or occult depression or severe anxiety disorder? (2) Might a very thorough history and physical have detected these problems also? (3) How many of your post-op dissatisfied patients were being treated for depression or severe anxiety pre-op? (4) How many of your post-op dissatisfied patients have filed a malpractice complaint?

Also, reports have shown that several pre-op factors help predict postoperative results after antireflux surgery. (1) How did your results/outcomes vary according to presenting primary symptom, eg, heartburn and regurgitation (which are very effectively controlled by antireflux surgery), vs cough, voice symptoms, asthma, and globus (which are less effectively controlled)? (2) How many of your dissatisfied patients had hiatal hernias greater than 2 cm? (3) Was there a disproportionate number of post-op dissatisfied patients who had significant medical comorbid diseases, eg, scleroderma with severe dysmotility, insulin-dependent diabetes, or obesity with body mass index greater than 40 to 45?

Finally, esophageal dysmotility disorders are sometimes difficult to detect and require sophisticated esophageal manometry, and even serial studies using, eg, 8- to 16-channel Dentsleeve catheters connected to a low-compliance pneumohydraulic perfusion apparatus and computerized polygraph. (1) How sophisticated was the manometry system used for evaluating your patients? (2) Were any of your dissatisfied patients later proved to have achalasia?

Dr Velanovich: I will just answer your questions in order here. Did the questionnaire merely identify patients with overt occult depression or severe anxiety disorders? Most likely. I haven’t exactly teased out these numbers, but I do believe that there is a correlation between the patients who do have chronic pain problems such as fibromyalgia, depression, anxiety, and these lower preoperative scores.

Might a thorough history and physical examination detect these problems? Yes. Again, I do all of the history and physicals myself, so when I see or hear about depression, anxiety, chronic fatigue syndrome, or fibromyalgia, or when I see on the medication list sertraline hydrochloride or paroxetine, a red flag goes up. I think that actually could be a very good surrogate compared with the SF-36 questionnaire.

How many of these postoperatively dissatisfied patients were being treated for depression and anxiety? I don’t have the exact numbers; I suspect most.

How many of these patients have filed a malpractice complaint? One, the one with the perforation. And he is the one whose case I would say is my one real disaster.

Did the outcomes vary according to primary symptoms? Again, I have not teased out those data specifically. I suspect they did. I suspect that the patients with the atypical symptoms were more likely to be in the satisfied group, because they probably perceived their symptoms a little more acutely than the patients who have the typical symptoms.

How many of my dissatisfied patients had hiatal hernias greater than 2 cm? A few; I don’t have the exact number, but some did.

Dr Joehl asked about associated medical conditions. I didn’t have any patients with scleroderma. With regard to dysmotility, I just had a paper recently accepted for publication looking specifically at that issue, and there is really no difference in satisfaction or symptom severity in that group of patients.

I live in Detroit, which is the second fattest city in the country. All of my patients are fat, so there is not much difference there.

Lastly, he asked about the manometry. I am sure we don’t have as sophisticated manometry as you have at Northwestern. We basically had a standard esophageal manometry probe, 16-channel Medtronic systems probe. And lastly you asked if any dissatisfied patients had achalasia. No.

David W. Easter, MD, La Jolla, Calif: I am going to push you a bit on your conclusions. Your presentation of median values on the subsets for the SF-36 doesn’t allow me to tease out a threshold for your dissatisfied patients. Are you willing to commit to which subset values matter and what is the lowest number or threshold where you say to your patients, “You’re going to be dissatisfied and I don’t want to offer you this operation”?

Dr Velanovich: That’s a good point. That is something to look at. I don’t have that number for you, but that would be a good number to know so that you can really identify preoperatively and have some threshold value, but I don’t have a figure.

Keith W. Millikan, MD, Chicago, Ill: I have a large experience with these patients and have not done the quality of life beforehand. I found a number of dissatisfied patients who have a normal workup afterward, and I place those patients on a calcium channel blocker because some of these patients when you wrap the esophagus have a spasm that cannot be picked up on manometry. It seems that in about 75% to 80% of these patients with no reason for symptoms, their symptoms go away after treatment with calcium channel blockers. Do you have any experience with that?

Dr Velanovich: I don’t have any experience with calcium channel blockers, but I do believe that a lot of these patients who do have postoperative symptoms have some type of functional esophageal disorder. Because of that, I have actually used a tricyclic antidepressant, usually amitriptyline hydrochloride or desipramine hydrochloride. About half of the people do respond to that in my experience.