Measuring the Effectiveness of Laparoscopic Antireflux Surgery

Long-term Results

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Objective: To evaluate long-term results and quality of life of patients undergoing laparoscopic antireflux surgery.

Design: A validated survey instrument, the Gastroesophageal Reflux Disease–Health-Related Quality-of-Life Scale (GERD-HRQL) was mailed to all patients who underwent laparoscopic fundoplications (LFs) from 1997 to 2006. Additional information was obtained regarding reintervention, satisfaction, and medication use.

Setting: Tertiary care referral center.

Patients: Four hundred five consecutive patients who underwent primary or redo LF from 1997 to 2006.

Main Outcome Measures: GERD-HRQL score, reoperation rate, and antireflux medication use.

Results: A 54% response rate was obtained. Median follow-up was 60 months (range, 4-75 months). In patients who underwent primary LF, the mean (SD) GERD-HRQL score was 5.71 (7.99) (range, 0-45, with 0 representing no symptoms). Seventy-one percent of patients were satisfied with long-term results. Forty-three percent of patients took antireflux medications at some point following surgery; half of these patients had no diagnostic testing to document GERD recurrence. Only 3 patients (1.2%) required reoperation. Patients undergoing redo LF had higher GERD-HRQL scores (mean [SD], 14.25 [10.33]), lower satisfaction (35%), and greater probability of requiring antireflux medication (78%). Patients with body mass indexes (BMIs) (calculated as weight in kilograms divided by height in meters squared) between 25 and 35 had lower GERD-HRQL scores than thin (BMI < 25) and morbidly obese (BMI ≥ 35) patients.

Conclusions: Contrary to the medical literature, our results demonstrate that patients undergoing primary LF by an experienced surgical team have near-normal GERD-HRQL scores at long-term follow-up and low reoperation rates and are satisfied with their decision to undergo surgery. Results following redo LF are not as good, highlighting the importance of proper patient selection and surgical technique when performing primary LF.

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LAPAROSCOPIC NISSEN FUNDOPPLICATION was first described in 1991.1 Many short-term studies2,3 have shown the effectiveness of laparoscopic Nissen fundoplication whereas longer-term studies have reported variable results.5,6 As surgeons rapidly adopted this technique, reports of its efficacy in the medical and surgical literature became widely divergent and debate has raged as to the long-term benefit of this procedure.3,8 The results of laparoscopic Nissen fundoplication performed at expert centers appear excellent,9 but the experience of low-volume providers may be different. Given the presence of effective medical therapy for many patients with gastroesophageal reflux disease (GERD), the need for reintervention, and the cost of resuming proton pump inhibitor (PPI) therapy, some have questioned whether the results of surgery merit the risks of surgical complications. Successful surgeons carefully screen their patients and establish a clear link between esophageal physiology and symptoms.8 The recommendation to proceed with surgery is often tempered by other considerations including body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared), psychiatric conditions, and patients’ willingness to accept potential postoperative adverse effects.

Several series claiming good results from laparoscopic Nissen fundoplication have relied on patient satisfaction as an outcome measure, but a validated survey instrument is more meaningful. A number of studies have used Short Form 36, a
generic quality-of-life tool that can be applied to many disease states, whereas the Gastroesophageal Reflux Disease–Health-Related Quality-of-Life Scale (GERD-HRQL) was specifically developed for patients with reflux disease. We therefore chose this as the primary tool for our study. The purpose of this study was to document the long-term outcomes of procedures performed by 1 high-volume surgeon at a tertiary medical center over a 9-year time frame to benchmark these results against published norms.

**METHODS**

This study was approved by the Partners Health Care System institutional review board. Between 1997 and 2006, a total of 405 consecutive patients underwent 412 operations (either primary laparoscopic fundoplication [LF] or redo LF) by a single surgeon at an academic tertiary care referral center. Criteria for surgery included abnormal 24-hour pH monitoring results, endoscopic evidence of erosive esophagitis, or significant improvement of reflux symptoms with antireflux medication. Patients with nutcracker esophagus or diffuse esophageal spasm were not considered surgical candidates. In addition, patients with severely impaired esophageal peristalsis were usually encouraged to pursue aggressive medical therapy rather than under LF.

Fifty-four cases were excluded from the study because of an international address or an incomplete domestic US address. A validated survey instrument, the GERD-HRQL, was mailed to the remaining 351 patients (Figure 1). This is a disease-specific instrument consisting of 10 questions with a resultant score of 0 to 45, with 0 representing no symptoms. The survey also contained questions regarding the use of postoperative antireflux medication, the need for postoperative reintervention (reintervention was defined as any therapeutic procedure ranging from endoscopic dilation to reoperation targeted at the gastroesophageal junction or diaphragmatic hiatus), and patient willingness to have the operation again (Figure 2). Additional data were retrieved both from a prospectively created database as well as retrospective review of the patients’ records.

Laparoscopic fundoplications consisted of primarily Nissen and Toupet procedures. Laparoscopic Nissen fundoplication was performed by creating a loose 2-cm wrap around a 56 F bougie and secured with 3 pledgeted nonabsorbable sutures. The short gastric vessels were routinely divided and the diaphragmatic crura were reapproximated with an average of 2 to 3 pledgeted nonabsorbable sutures. Laparoscopic Toupet fundoplication was performed by creating a 270° posterior wrap and secured with a total of 8 nonabsorbable sutures: 3 on each side of the esophagus and 2 posterior anchors to the crural repair. Again, the diaphragmatic crura were reapproximated with an average of 2 to 3 pledgeted nonabsorbable sutures. Significant portions of each operation were performed by a surgical resident or fellow.

All statistical analyses were performed using the Primer of Biostatistics Statistical Software Program, version 4.0. Continuous variables were compared using analysis of variance. Nominal data were analyzed using the χ² test. A P value ≤ .05 was considered statistically significant.

A total of 193 surveys were returned. Two of these questionnaires were filled out incompletely, resulting in 191 evaluable surveys for an overall 54% response rate (Figure 1).

The median duration of follow-up was 60 months (range, 4-75 months). The study population was 60% female and 40% male, with a mean age of 52 years. The overall demographics of the survey respondents in the study population were compared with the survey nonresponder population. The 2 groups were comparable with respect to duration of follow-up, male-female ratio, and presenting symptoms. However, the mean age was slightly...
older in the nonresponder group (52 years vs 47 years; \( P = .01 \)).

One hundred seventy-three patients had primary LF and 18 patients had redo LF. Preoperatively, 56% of patients had typical symptoms (ie, heartburn, regurgitation), 41% had atypical symptoms (ie, cough, hoarseness, upper respiratory symptoms), and 3% of patients primarily complained of dysphagia. The patients who complained of dysphagia all had either paraesophageal hernias (PEHs) or underwent redo LF. There was no significant difference between GERD-HRQL score or need for postoperative medications between these 3 groups of patients.

Forty-one patients who underwent primary LF had PEH: 15 underwent Nissen fundoplication, 24 were treated with Toupet fundoplication, and 2 were treated with gastropexy alone. Only 4 patients (10%) with PEH presented primarily with typical reflux symptoms. The remainder presented with anemia, gastrointestinal bleeding, dyspnea, and chest pain. Given that the GERD-HRQL questionnaire was designed for patients with predominantly reflux-related symptoms, and the unexpected finding of equivalency in GERD-HRQL scores among patients with typical symptoms, atypical symptoms, and PEH, we chose to perform a subset analysis of patients whose chief complaint was GERD related. Patients who presented with PEH were excluded from this portion of the analysis. Thus, 132 patients who underwent primary LF (non-PEH) were evaluated; all of these patients underwent a Nissen fundoplication. Seventeen patients who underwent redo LF (non-PEH) were evaluated; of these, 13 patients underwent Nissen fundoplication and 4 patients underwent Toupet fundoplication (Figure 1). The mean (SD) GERD-HRQL score for patients who underwent primary LF (non-PEH) was significantly lower than patients who underwent redo LF (non-PEH) (5.71 [7.99] vs 14.25 [10.33], respectively; \( P < .001 \)). Furthermore, patients who underwent primary LF (non-PEH) had a satisfaction rate of 71% while only 35% of patients who underwent redo LF (non-PEH) reported satisfaction (\( P = .005 \)). The overwhelming majority of patients in both groups, however, stated they would have the surgery again: 88% (primary LF, non-PEH) and 76% (redo LF, non-PEH).

The non-PEH study population was then divided into 4 groups based on the World Health Organization classification of BMI. Body mass index had a significant impact on long-term outcomes. Patients with normal (<25) and morbidly obese (≥35) BMIs had higher mean (SD) GERD-HRQL scores (6.84 [9.36] and 11.36 [11.78], respectively) compared with patients classified as overweight (BMI 25–29.9) or obese (BMI 30–34.9) (3.48 [5.26] and 5.21 [6.27], respectively). Specifically, morbidly obese patients had a significantly higher GERD-HRQL score when compared with overweight (\( P = .001 \)) and obese (\( P = .02 \)) patients (Figure 3).

When the study population was analyzed for sex differences, no significant difference in GERD-HRQL scores was identified. When the sex comparison was subjected to a subset analysis based on BMI, however, a paradoxical trend was seen: females tended to have higher GERD-HRQL scores as BMI increased (\( P = .04 \)) and males tended to have lower GERD-HRQL scores as BMI increased (\( P = .17 \)) (Figure 4).

Further analysis was also done to determine whether basal lower esophageal sphincter pressures (LESPs) were different between the 4 groups. The majority of patients with a BMI less than 25 had normal LESP in contrast to the other 3 groups (BMI >25), which all had a predominance of low LESP (\( P = .04 \)) (Figure 5). Despite the relationship between GERD-HRQL score and BMI, there was no correlation between BMI and need for postoperative medications or reintervention (Table).

Postoperatively, 43% of patients undergoing primary LF took antireflux medications at some point compared with 78% of patients undergoing redo LF. Patients taking medications postoperatively in the primary LF group and the redo LF group typically were given medication without radiographic or physiologic documentation of recurrent reflux (50% vs 62%, respectively). For ex-
ample, only 20 of the patients who were given medications postoperatively in the primary LF group had follow-up testing performed at our institution. Six of 20 (30%) had completely normal study results but nonetheless restarted medication use either by themselves or on the advice of their medical physicians. Patients with Barrett esophagus preoperatively who were found to have persisting Barrett esophagus after fundoplication also routinely were given PPIs again. Only 5 patients (25%) had 24-hour pH probe study and/or barium study results demonstrating recurrent reflux.

In this series, 5 patients (2.9%) who underwent primary LF required an upper endoscopy and dilation at some point postoperatively and only 2 patients (1.2%) required reoperation. Of the patients who underwent redo LF, 3 (16.7%) required upper endoscopy and dilation postoperatively and 1 of these patients eventually required a laparoscopic partial takedown of his fundoplication.

Many short-term studies have demonstrated the effectiveness of laparoscopic Nissen fundoplication in controlling GERD. Compared with open Nissen fundoplication, laparoscopic Nissen fundoplication is associated with a shorter hospital stay, less postoperative pain and morbidity, and equivalent functional results, with claims that 85% to 90% of patients have resolution of their reflux symptoms. There are fewer long-term studies, however, and those have shown less impressive results. Furthermore, with increasingly potent PPIs, the enthusiasm for laparoscopic Nissen fundoplication has waned in recent years.

Contrary to many other studies that only relied on patients’ reported satisfaction, we used a validated disease-specific instrument (the GERD-HRQL) to determine long-term outcomes. We found that patients undergoing primary LF had excellent results 5 years after surgery, as reflected in their low GERD-HRQL scores. Unfortunately, the results were not as good in patients undergoing a redo LF. These findings are similar to those of previously published studies. Even so, the overwhelming majority of patients in both groups stated that, in retrospect, they would choose to have the surgery again. This suggests that LF (whether primary or redo), when performed by an experienced surgeon, improves patient symptoms and quality of life.

When looking at primary symptoms, the majority of our study patients presented with typical symptoms, such as heartburn and regurgitation. However, no significant outcome differences were found between patients with typical and atypical symptoms—at least as measured by the GERD-HRQL. These results suggest that presenting symptoms alone are not the primary determinant of long-term outcomes. It has been our experience that documentation of pathological gastroesophageal reflux that is correlated with the patient’s symptoms is a sine qua non for patient selection. We rely heavily on the data obtained from preoperative 24-hour pH probe studies and the patient’s symptomatic response to acid-suppressive medication, as suggested by Campos et al, in deciding whether to recommend surgery to our patients.

Preoperative BMI is also a significant factor in the long-term outcome of antireflux surgery. Given the epidemic rise in obesity, the majority of patients presenting for antireflux surgery are, in fact, overweight. For example, in our series, less than 30% of patients had a BMI less than 25. Therefore, even though these patients had a “normal” BMI as defined by the National Institutes of Health, we consider them “thin” relative to the population of patients we see in our practice who are candidates for LF.

The results of this study suggest that BMI clearly correlates with a successful functional outcome of surgery. Patients with a BMI considered normal (<25) or morbidly obese (≥35) tended to have higher GERD-HRQL scores on long-term follow-up when compared with those with an overweight or obese BMI (25-34.9). In other words, patients at both ends of the BMI spectrum had worse results compared with those in the middle of the BMI curve. Our group has previously reported a high failure rate of both transabdominal and transthoracic anti-reflux surgery in obese patients. Subsequently, other groups have reported both confirmatory and contradictory findings. A recent study showed that BMI not only has an effect on GERD severity but that the physiology of GERD in obese patients may be different from non-obese patients, thus questioning the wisdom of performing a fundoplication in this patient population. When measured by GERD-HRQL score, it seems not only that antireflux surgery is less successful in morbidly obese patients, but that patient satisfaction seems lower (though not reaching statistical significance) in thin patients as well. This finding was previously noted in a study by Fraser et al. The explanation may lie in the fact that more than 60% of patients with erosive reflux disease have abnormal LESP. Given that the LESP was normal in significantly more patients with a BMI less than 25 than their obese counterparts, it is possible that these patients either had primarily nonerosive reflux disease or a functional component to their symptoms (ie, visceral hypersensitivity). While more ill-defined functional upper gastrointestinal tract disorders can often
mimic GERD, these patients tend to respond poorly to treatment for reflux alone. In addition, there is a body of literature that suggests that normal LESP may increase the risk of postoperative dysphagia. All of these factors may explain the higher GERD-HRQL scores and lower satisfaction in patients with a BMI less than 25.

Despite the possible difference in pathophysiology of disease between the 4 groups, there remained no difference in their need for postoperative medications or postoperative procedures. Postoperatively, 43% of patients who underwent primary LF and 78% of patients who underwent redo LF required medications. These findings are similar to recent studies evaluating long-term results of laparoscopic Nissen fundoplication. While other studies have reported lower rates of medication use, some of these series do not include the use of H₂ receptor antagonists. Furthermore, our study includes all self-reported cases of medication use regardless of short- vs long-term duration or medications taken on an “as needed” basis.

While the need for postoperative acid-suppression therapy may initially raise the concern of a failed operation, closer evaluation of the data proves otherwise. In fact, it is difficult to assess whether any of these patients’ fundoplications truly “failed” since many did not have postoperative testing to determine the presence of reflux. For example, analysis of the subset of patients who underwent primary LF who had testing performed at our institution revealed that 30% of these patients were given medications without any evidence of recurrent reflux. Other studies have shown an even higher percentage of such patients. Many of these patients may restart medications on their own or be restarted empirically by their physicians without proven need. However, studies have shown that the sole presence of symptoms is actually a poor indicator of recurrent reflux disease, as documented by studies such as 24-hour pH monitoring.

Even a successful antireflux operation (as evidenced by results of pH studies, esophageal function tests, or endoscopy) may not completely abolish all reflux-related symptoms. Previous reports have demonstrated a lack of correlation between reflux-related symptoms and esophageal acid exposure. One recent study found that patients whose symptoms improved while taking PPIs continued to have excess levels of acid reflux; conversely, patients who still had reflux symptoms after surgery had no objective evidence of persistent reflux. This further supports the notion that quality of life measured by a validated survey instrument is perhaps as important a measure of success after antireflux surgery as 24-hour pH probe data.

The evaluation of long-term outcomes in a single-surgeon series has the advantage of consistency in preoperative evaluation, surgical technique, and postoperative management of patients. As such, attention to these factors, along with high surgical volume, may help to explain our reoperative rate of 1.2%, which is lower than previously published reports. This figure, however, must be viewed with caution since this is a retrospective study and the follow-up was incomplete. A weakness of the current study is the absence of preoperative GERD-HRQL scores that would have allowed comparison with the postoperative scores. Furthermore, while it would have been ideal if all patients underwent objective functional testing postoperatively, this is not feasible in our socioeconomic environment. It is often difficult to convince patients and providers to undergo or order these tests when both pH monitoring and upper endoscopy are invasive, and somewhat uncomfortable, examinations. Compared with the ease of empirically restarting medical therapy, the choice by nonsurgeon providers is all too often the latter.

CONCLUSIONS

In contrast to reports in the medical literature, the results of this study demonstrate that most patients undergoing primary LF by an experienced surgical team have near normal GERD-HRQL scores at long-term follow up and low reoperation rates and are satisfied with their decision to undergo surgery. In addition, BMI appears to be an important factor when predicting long-term outcomes. Although patients may be prescribed acid-suppression therapy again after surgery, there is often no physiologic evidence of recurrent postoperative reflux. The results following redo LF are not as good, highlighting the importance of proper patient selection and careful surgical technique when performing primary LF.

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