Late Outcomes After Laparoscopic Surgery for Gastroesophageal Reflux

Jean Y. Liu, MD, MS; Steven Woloshin, MD, MS; William S. Laycock, MD, MS; Lisa M. Schwartz, MD, MS

Hypothesis: Patients still have symptoms following laparoscopic antireflux surgery and require ongoing treatment.

Design: Mailed survey.

Setting: Academic tertiary care center.

Patients: Of 247 consecutive adults, 197 (80% response) who underwent laparoscopic fundoplication for gastroesophageal reflux disease in the prior 1 to 5 years.

Main Outcome Measures: Gastrointestinal symptoms (frequency and bother), actions taken to treat these symptoms (medications and dietary and lifestyle changes), and assessment of surgery.

Results: The mean age of the respondents was 51.1 years, and 52% were men. The median time since surgery was 2.6 years. Overall, 28% reported typical reflux symptoms (heartburn or regurgitation), but only 5% were bothered “a lot” or “terribly” by them. While 69% reported other gastrointestinal symptoms (bloating or dysphagia) that may be related to gastroesophageal reflux disease or to surgery, only 19% were bothered a lot or terribly by them. About half of the respondents reported taking at least 1 of the following actions for their symptoms: 6% take frequent over-the-counter medications, 13% take daily prescription acid-reducing medications, 41% make lifestyle changes (eg, eating smaller meals), and 44% avoid certain foods (eg, carbonated beverages). Nevertheless, 90% believed their surgery was working well.

Conclusions: In 1 to 5 years after laparoscopic antireflux surgery, many patients report gastrointestinal symptoms and take action to control these symptoms. Most, however, believe their surgical treatment is working well.

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SYMPTOMS attributable to gastroesophageal reflux disease (GERD) are extremely common: more than 25 million adults in the United States have daily heartburn. Patients with GERD have 2 basic treatment options: medical therapy (usually lifelong) aimed at gastric acid reduction and surgery. Because it corrects the underlying defect in the lower esophageal sphincter, many believe that antireflux surgery can effectively “cure” GERD. With the development of a laparoscopic antireflux procedure, enthusiasm for surgical treatment has grown. From 1997 to 1999, there was a 34% increase in the number of antireflux surgical procedures to 34,800 annually in the United States.

Recently, however, a well-publicized clinical trial cast doubt about the long-term effectiveness of antireflux surgery. After 10 years of follow-up, patients randomized to medical and surgical therapy had similar reflux symptom scores. Moreover, many surgical patients (62%) continued to require antireflux medications. Unfortunately, because the trial was largely restricted to male veterans, its results may not be generalizable. More important, the trial, which enrolled patients between July 1986 and October 1988, predated laparoscopic antireflux surgery, the surgical approach most commonly used today.

To describe outcomes after laparoscopic surgery, we surveyed patients from our institution 1 to 5 years after their operation. Because our goal was to help physicians and patients set realistic expectations about this surgery, we asked patients if they continued to have gastrointestinal symptoms, whether they continued to take actions to treat these symptoms (eg, acid-reducing medications and dietary or lifestyle modifications), and how they rated the results of their surgery.

RESULTS

PATIENTS

The Table shows that the patients were a mean of 51.1 years and had a high degree of formal education; most self-reported
PATIENTS AND METHODS

We mailed a survey to all patients who underwent laparoscopic surgery for GERD in the prior 1 to 3 years. This study was approved by the Institutional Review Board at Dartmouth-Hitchcock Medical Center.

DESIGN AND POPULATION

Using administrative records, we identified all patients who underwent primary laparoscopic fundoplication between November 13, 1993, and November 29, 1999. Based on medical record review, we excluded patients who underwent fundoplication for other diseases (achalasia or paraesophageal hernia [n = 36], spasmodic dysphonia [n = 1], and non-specific esophageal dysmotility disorder [n = 1]) and pediatric patients (those aged < 18 years [n = 5]). There were 248 adult patients who underwent surgery, but 1 subsequently died of unrelated causes, leaving 247 eligible patients for our study. During this period, all primary antireflux operations were performed laparoscopically.

From September 1, 2001, to October 31, 2001, we mailed a survey to the 247 eligible patients. To maximize the response rate, we mailed a second copy of the survey after 2 weeks and attempted to call those who had not responded after 6 weeks. There were 166 respondents to the mailed survey. We were unable to contact 35 patients (11 had no current address and 24 were unable to be contacted by telephone), 14 contacted by telephone declined to participate, and 1 returned the survey uncompleted.

Almost one third of the patients who underwent laparoscopic antireflux surgery at our institution in the past 1 to 5 years report at least some ongoing reflux symptoms. Two thirds report symptoms attributable to either

SURVEY AND ANALYSIS

The questionnaire covered 3 main domains: gastrointestinal symptoms, actions required to treat gastrointestinal symptoms, and satisfaction with surgery. The survey was pilot tested for understandability on 40 patients at Dartmouth-Hitchcock Medical Center. The exact wording of each question is provided where the results are reported. In the symptom section, we asked about the frequency and bother of typical (heartburn and regurgitation) and other gastrointestinal (cough, hoarseness, dysphagia, and bloating) symptoms. We also asked about the overall quality of life. The 31 patients who completed the survey by telephone were only asked the symptom-bother questions because the frequency and bother questions were so highly correlated (average Pearson r = 0.89) in the 166 who returned the mailed survey. Consequently, we only report the results of the bother questions, and because we found no systematic differences for the main outcome measures, we present data from the mail and telephone respondents together.

The treatment section included questions about GERD medication use (over-the-counter and prescription), dietary restrictions, lifestyle changes, and overall burden of treatment. To assess satisfaction with surgery, we asked patients how well they thought their surgery was working. We used computer software (Stata 6.0; Stata Corp, College Station, Tex) for all analyses.

TREATMENT

About half of the patients reported that they took some action (either used a medication or made diet or lifestyle changes) to manage their symptoms. Overall, 44% report making a dietary change. If they need to make a dietary change, on average they were making 4.0 changes. Similarly, 41% reported some lifestyle change. If they need to make a lifestyle change, on average they were making 1.8 changes.

Although many were taking actions, Figure, B, shows that most did not feel particularly bothered by these actions. No patients thought taking their reflux medications was a serious problem; 2% believed their dietary restrictions were a serious problem, and only 4% believed their lifestyle changes were a serious problem.

PATIENTS’ RATING OF SURGERY

The Figure, C, demonstrates that most people were satisfied with the results of their surgery: 90% believed their surgery was working well, and 50% reported that it was working “perfectly.” When asked about their eating and sleeping habits, 86% reported they were able to “eat what they want, when they want” and 81% reported that their “sleeping habits were back to normal.”

COMMENT

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GERD or the adverse effects of surgery (eg, bloating or dysphagia), and almost half take some actions to control these symptoms, such as daily antireflux medications, lifestyle changes, or dietary restrictions. Nevertheless, few patients find either their symptoms or their treatments to be bothersome, and almost all are satisfied with their surgical results. Only 14% of patients continue to take daily antireflux medications (over-the-counter or prescription) after laparoscopic surgery, considerably lower than the 62% reported in a recent trial of long-term outcomes after open surgery.\(^5\)

Our findings are generally consistent with those reported in previous case series. In one study, 97% of laparoscopic patients are heartburn free and have no daily medication requirements. This study,\(^4\) however, included only patients in the first year following surgery. In a recently published study\(^5\) that reported on the long-term outcomes (median, 6 years of follow-up) of 178 patients at a single institution, 90% of the patients were free of significant reflux symptoms (and satisfied with the outcomes of their surgery), but 11% were still taking antireflux medications regularly and 11% continued to avoid various foods because of dysphagia or food intolerance. Almost all patients were satisfied with surgery.

Our findings should be interpreted in light of 4 limitations. First, our survey had an 80% response rate. While this is a good response rate for a detailed mailed survey,\(^6\) it is possible that nonrespondents differed systematically from respondents. In particular, nonrespondents may have been less satisfied with their surgical...
results. Our results are extreme enough, however, that even if all nonrespondents were dissatisfied and symptomatic, our findings would not change qualitatively. Second, because all study patients underwent laparoscopic surgery, we cannot compare surgical vs medical outcomes or outcomes for patients undergoing open vs laparoscopic surgery. Trials are needed to establish the relative efficacy of the various approaches to GERD. Nevertheless, our results are important because they add to the limited data available to inform physicians and patients about the likely results of laparoscopic antireflux surgery. Third, some may be concerned that our study only included patients at a single institution with considerable experience in laparoscopic antireflux surgery. Because physician factors (eg, procedure volume) may be related to outcomes after antireflux surgery, our results may not be broadly generalizable. Finally, follow-up times in our study were limited to 1 to 5 years. Although it is possible that symptom status may deteriorate over time, we did not find evidence of this trend in our analysis (data not shown).

In summary, patients undergoing laparoscopic antireflux surgery should not expect their surgery to be curative, ie, many will continue to experience some gastrointestinal symptoms or need to take some action to control these symptoms. Most patients, however, will experience significant improvement in their heartburn and regurgitation symptoms. Because medical and surgical therapy have improved considerably during the past decade, new clinical trials assessing current therapies are needed to further inform clinical decision making.

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Corresponding author: Jean Y. Liu, MD, MS, Department of Surgery (Mail Code 112), Department of Veterans Affairs Medical Center, 215 N Hartland Rd, White River Junction, VT 05009.

REFERENCES


DISCUSSION

David W. Rattner, MD, Boston, Mass: There are some additional details which Dr Liu did not have time to share with you. For example, they had an 80% response rate, which is one of the best reported in any publication that looked at outcomes from a patient’s perspective.

There are other confirmed reports by other large centers that most patients undergoing laparoscopic antireflux surgery are satisfied or pleased with their surgery.

Other investigators have measured outcomes with SF-36 [36-item Short-Form Health Survey]. GRSRS, as well as customized and often unvalidated instruments, and one of the criticisms of this study is that the instrument which Dr Liu et al used has not been validated. Irrespective of the instrument that was chosen, lap [laparoscopic] Nissen consistently leads to improved quality of life and the majority of patients who undergo this surgery when asked would have it performed again.

One index of how good this procedure can be is evidenced by the growing number of patients whose fundoplications have loosened and return asking their surgeons to redo the surgery. The fact is that they just feel better without reflux than they do on proton pump inhibitors.

Now when one employs more specific criteria than just satisfaction, the results of this operation appear a little less favorable. For example, in this particular group, 28% of the patients still had heartburn and 14% were taking medications for symptom control. I would like to know if the authors can provide any information on this subset in regard to pH probe testing. Dr Ron Hinder’s group has shown that the majority of patients who are put back on PPIs [proton pump inhibitors] do not in fact have recurrent pathology reflux.

Similarly, 42% of the patients with atypical symptoms in this study appear to have had an incomplete response to surgery. I wonder if the authors can provide specific information as to which atypical symptoms were the most difficult to treat and if there was objective evidence of abolition of pathologic reflux and yet persistence of symptoms.

Did the authors perform any subgroup analysis to look for correlations with obesity, irritable bowel syndrome, or other comorbidities and correlate that with satisfaction and other outcomes which they have presented?

As Dr Liu mentioned in her conclusion, while many patients report bloating, the authors point out that there really was no control group of medically managed patients and the bloating post-Nissen has in fact given the operation a little bit of a bad name when in fact this is a common symptom among patients with gastroesophageal reflux disease.

Finally, the authors are to be commended for a postoperative dilation rate of only 1%, that is, only 1% of the patients in the study needed postop [postoperative] dilation for dysphagia. This is extraordinarily low. Could you tell me and perhaps some of the rest of the people what we are doing wrong if we are still dilating 3% to 10% of our patients?

Dr Liu: Our dilation rate was 1%, and the reoperation rate was actually 4%. The dilation rate that I was able to get was actually based on patient response to the questionnaire as well as doing chart reviews for our patients. We do a standard Nissen fundoplication over a 60-F bougie with a 3-stitch repair that is 2.5 cm long. We close the diaphragm over pledgets, and we take down all the short gastric vessels to create a floppy Nissen.

In answer to your fourth question, we did do a subgroup analysis. Our first instinct was to wonder if there was a difference between the Toupet and the Nissen fundoplication patients, but we actually found that they had exactly the same rate as those who were back on PPIs and exactly the same rate complained of heartburn, so there was no difference in that group.
We did not specifically look at inflammatory bowel disease or obesity but we did ask them questions to generate a Charlson Comorbidity score, which, for those who are unfamiliar with that score, is something that they initially used for chart review, but they have since modified it to include patient questionnaire data. Our patients were generally young and healthy; as you know, the people who come in for fundoplication in general are pretty young and pretty healthy. The average Charlson score for our respondents was 0.3, and basically any time you have a comorbidity, you get 1 point for it, just to give you an indication of how healthy our patients were.

In answer to your second question about atypical symptoms, we did not have data on the preoperative complaints so we actually do not know how many really had cough and hoarseness before the operation but what I found when I did the chart review was patients do not always complain of just one symptom from their reflux. They complain of heartburn as well as hoarseness, or regurgitation and a cough. They usually go together, so it is a little hard for me to subdivide the groups and do a specific analysis for just atypical symptoms.

And in answer to your first question, this was a study designed really about patient perception and although a pH probe would make us feel better that they did not physiologically have reflux, we cannot ignore the fact that patients say “I have heartburn” and “This is my typical heartburn.” When they go to their primary care physician or come back to us and say “This is my typical heartburn” and they feel better when they are on their proton pump inhibitor, it is hard to tell them “You do not have heartburn and you should not take your proton pump inhibitor.”

ARCHIVES OF INTERNAL MEDICINE

Epidemiologic Review of the Calcium Channel Blocker Drugs: An Up-to-date Perspective on the Proposed Hazards

Jorge R. Kizer, MD, MSc; Stephen E. Kimmel, MD, MSCE

In the setting of soaring popularity, postmarketing studies of calcium channel blockers came to suggest an increase in a variety of major adverse end points. The evidence, however, was largely observational, and large-scale trials capable of addressing the concerns were wanting. Clinical trials now support the safety and efficacy of the long-acting dihydropyridines for patients with both uncomplicated and diabetic hypertension, although conventional therapies and, in the latter case, angiotensin-converting enzyme inhibitors have superior proof of benefit. By contrast, short-acting dihydropyridines should be avoided. In the acute coronary syndromes, β-blockers remain the treatment of choice; the evidence for nondihydropyridines remains inconclusive. Stable angina calls for β-blockers as first-line therapy and nondihydropyridines as second-line therapy, whereas in ventricular dysfunction, safety data for nondihydropyridines are lacking. Initial reports of cancer, bleeding, and suicide have been contradicted by subsequent data, making the associations uncertain or unlikely. Remaining questions await completion of ongoing trials to better define the indications for these agents. (2001;161:1145-1158)

Corresponding author: Stephen E. Kimmel, MD, MSCE, University of Pennsylvania School of Medicine, 717 Blockley Hall, 423 Guardian Dr, Philadelphia, PA 19104-6021 (e-mail: skimmel@cccb.med.upenn.edu).

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