

## Laparoscopic Fundoplication for Reflux Disease: Gap Between Efficacy and Effectiveness

Vikal N, Shaw M, Kirby R. *Clinical effectiveness of laparoscopic fundoplication in a U.S. community. Am J Med* 2003;114:1-5.

### Study Overview

**Objective.** To determine the outcome of laparoscopic fundoplication for gastroesophageal reflux disease (GERD) in patients who underwent this procedure in routine clinical practice.

**Design.** Cohort study.

**Setting and participants.** Patients who had undergone laparoscopic fundoplication in a managed care organization in Milwaukee between 1997 and 1999.

**Methods.** Patients were invited to complete a validated questionnaire to evaluate their postoperative symptoms. Demographic information, reason for surgery, postoperative medication use, and history of postoperative procedures were ascertained using a supplemental questionnaire. Details of all postoperative endoscopic and surgical procedures were obtained through direct patient interviews and chart review.

**Main results.** 151 patients were invited to participate, 87 agreed, and 80 were eligible. 51% of the eligible participants were men. Participants' mean  $\pm$  SD age was  $45 \pm 12$  years, and the mean duration after surgery was  $20 \pm 10$  months. 36 patients (45%) underwent the procedure because their physician recommended it, 22 (28%) because they thought it would cure their disease, and 12 (15%) because they did not wish to take medications for long term. 43 patients (61%) were satisfied with the outcome of the procedure, 26 patients (32%) were taking medications on a regular basis for treatment of heartburn, 9 patients (11%) required esophageal dilation for dysphagia, and 6 (7%) had repeat surgical procedures. Of the 54 patients (67%) who reported new symptoms after surgery, 38 reported excessive gas, 22 reported abdominal bloating, and 22 reported dysphagia. Health-related quality of life was significantly lower in patients with these symptoms.

**Conclusion.** New symptoms are common after laparoscopic fundoplication, and medical therapy is required for the control of heartburn in approximately one third of patients postoperatively. Patients need to be better informed about these surgical outcomes.

### Commentary

Since its description in 1991 [1], laparoscopic antireflux surgery has gained popularity for the treatment of severe uncontrolled GERD because of shorter recovery time [2]. Prior case series from referral centers have reported excellent results [3,4]; however, outcomes reported by referral centers may not be reflective of routine clinical practice, where selection criteria for patients and expertise of the surgical staff may vary [5]. Vakil et al highlight the gap between the theoretical efficacy and the clinical effectiveness of laparoscopic antireflux surgery.

Many of the patients (85%) surveyed by Vakil et al were at least somewhat satisfied with the results of the surgery. However, this relatively high rate of global satisfaction belies the high number of patients with new postoperative symptoms of excess gas, bloating, and dysphagia. Several of these symptoms persisted beyond the 12-month postoperative period, and those who experienced these symptoms had lower quality of life than those who did not.

As with most survey-based outcome studies, Vakil et al's conclusions have certain limitations. Patients' responses could have been biased by preferential recall. It is also unclear whether the cohort as a whole experienced any improvement in the quality of life after surgery. Furthermore, patients who agreed to participate in the survey may have been systematically different from those who did not. In spite of these limitations, this study has added further insights about the risks and benefits of surgical options for severe GERD. Primary care physicians, surgeons, and gastroenterologists alike should understand the potential long-term sequelae of this surgery and discuss them with their patients.

### Applications for Clinical Practice

While many patients are satisfied with the outcome of laparoscopic fundoplication for the treatment of severe uncontrolled

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GERD, it is not a panacea. Prior to surgery, patients should be informed about the significant likelihood of new postoperative symptoms, including bloating, dysphagia, and diarrhea. They also should be aware that a significant number of patients continue to require medical therapy.

*—Review by Eric G. Poon, MD*

### References

1. Dallemagne B, Weerts JM, Jehaes C, et al. Laparoscopic Nissen fundoplication: preliminary report. *Surg Laparosc Endosc* 1991;1:138–43.
2. Rattner DW, Brooks DC. Patient satisfaction following laparoscopic and open antireflux surgery. *Arch Surg* 1995;130:289–93.
3. Leggett PL, Churcham-Winn R, Ahn C. Reolving gastroesophageal reflux with laparoscopic fundoplication. Findings in 138 cases. *Surg Endosc* 1998;12:142–7.
4. Eubanks TR, Omelanczuk P, Richards C, et al. Outcomes of laparoscopic antireflux procedures. *Am J Surg* 2000;179:391–5.
5. Epstein RS, Sherwood LM. From outcomes research to disease management: a guide for the perplexed. *Ann Intern Med* 1996;124:832–7.

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