

Surgery relieved symptoms but decreased survival more than medical treatment in gastroesophageal reflux disease

Spechler SJ, Lee E, Ahnen D, et al. Long-term outcome of medical and surgical therapies for gastroesophageal reflux disease. Follow-up of a randomized controlled trial. JAMA. 2001 May 9;285:2331-8.

QUESTION

In patients with complicated gastroesophageal reflux disease (GERD), how do the long-term outcomes of surgical therapy compare with those of medical therapies?

DESIGN

Randomized (allocation concealed*), blinded (unclear),* controlled trial with follow-up of a mean of 10 years.

SETTING

8 Veterans Affairs medical centers in the United States.

PATIENTS

247 patients (mean age 58 y) with complicated GERD. 129 of 160 surviving patients (mean age 67 y, 98% men) were included in the follow-up analysis.

INTERVENTION

Patients were allocated to receive surgical therapy ($n = 82$), continuous medical therapy ($n = 77$), or symptomatic medical therapy ($n = 88$). The method of surgical therapy was open Nissen fundoplication. Continuous medical therapy consisted of 2 antacid tablets, 1 and 3 hours after meals; ranitidine, 150 mg twice daily; and metoclopramide, 10 mg 4 times daily, and sucralfate, 1 g in 10 mL of warm water after meals, when necessary for persistent symptoms. Symptomatic medical therapy consisted of the above medications given only when necessary to control

symptoms. Treatments were given for 12 to 28 months. Patients were then managed by their physicians.

MAIN OUTCOME MEASURES

Survival, use of antireflux medications, and frequency of subsequent antireflux surgeries.

MAIN RESULTS

Analysis was by intention to treat. The 2 medical treatment groups (continuous and symptomatic) were combined for analysis purposes because baseline characteristics, study treatments, and outcomes were similar. Survival during a period of 140 months was lower in the surgical group than the medical group ($P = 0.047$) (Table). Surgical treatment decreased the use of antireflux medications after the treatment period more than did medical treatment ($P \leq 0.02$) (Table).

Surgical and medical treatments did not differ for use of prokinetics ($P = 0.39$) or subsequent antireflux surgeries ($P = 0.38$).

CONCLUSIONS

In patients with complicated gastroesophageal reflux disease, surgical treatment decreased survival and the use of antireflux medications more than did medical treatment. Surgical and medical treatments did not differ for subsequent antireflux surgeries.

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*See Glossary.

Surgical vs medical treatment for complicated gastroesophageal reflux disease†

Outcome during 140 mo	Surgical	Medical	RBR (95% CI)‡	NNH (CI)‡
Survival	60%	72%	20% (0.5 to 33)	7 (5 to 283)
Outcomes at mean 10 y	RRR (CI)			NNT (CI)
Any antireflux medication	62%	92%	33% (17 to 50)	4 (3 to 7)
Proton-pump inhibitor use	32%	64%	49% (21 to 70)	4 (3 to 9)
Histamine-2-receptor blocker use	41%	65%	37% (8.7 to 60)	5 (3 to 20)

†RBR = relative benefit reduction. Other abbreviations defined in Glossary; RBR, RRR, NNH, NNT, and CI calculated from data in article.

‡Calculated using Cox proportional-hazards data.

COMMENTARY

Despite the advent of laparoscopic techniques, antireflux surgery is still a difficult procedure with uncertain long-term outcomes. Antireflux surgery is a physiologic repair of the esophagogastric junction and involves 3 components: reduction of the hiatal hernia back into the abdomen, closure of the crura opening surrounding the esophagus, and reinforcement of the lower esophageal sphincter with fundoplication. Furthermore, even a successful repair can "wear out" over time because the esophagogastric junction continues to be exposed to repeated abdominal stressors, such as heavy isometric exercises or work-related activities, obesity, eating disorders, or recurrent vomiting and coughing.

The study by Spechler and colleagues is the first long-term study of antireflux surgery done outside a major esophageal surgical center in the United States. The results are probably similar to the experience in our general communities. Despite this study, which used traditional open Nissen fundoplication surgery, current laparoscopic results do not appear to be any better. This study may suggest that antireflux surgery

was a failure because 62% of patients returned to using medications for their GERD, and 32% returned to using proton-pump inhibitors. On the other hand, during the 9-year follow-up, 64% of patients treated with medications used proton-pump inhibitors, whereas only 32% of the surgical group needed this expensive class of drugs. As the authors suggested, future studies will need to prospectively address the lower survival rate in the surgical treatment group (60%) compared with that in the medical treatment group (72%).

This important study may help to better define the role of antireflux surgery in the future treatment of GERD. It is not a cure for all patients and may have other still-unknown disadvantages. However, some patients do well for a long time with minimal need for medication. Patients must understand the potentially beneficial and adverse effects of antireflux surgery and take part in this important treatment decision.

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