Antireflux surgery may be more effective than low-dose, but not high-dose, omeprazole for gastroesophageal reflux disease

Lundell L, Miettinen P, Myrvold HE, et al. **Continued (5-year) followup of a randomized clinical study comparing antireflux surgery and omeprazole in gastroesophageal reflux disease.** J Am Coll Surg. 2001 Feb;192:172-81.

QUESTION

Is antireflux surgery (ARS) more effective than omeprazole (OM) in patients treated for gastroesophageal reflux disease (GERD)?

DESIGN

Randomized (allocation concealed*), unblinded,* controlled trial with 5-year follow-up.

SETTING

Hospitals in Nordic countries.

PATIENTS

310 patients (76% men) with chronic GERD symptoms who had been successfully treated with OM (≤ 40 mg/d) to achieve complete symptom relief and had concomitant endoscopically confirmed esophagitis (healed with ≤ 4-mo treatment with OM, 20 or 40 mg) were included. Follow-up was 82%.

INTERVENTION

Patients were allocated to ARS (n = 155) or to a continuation of the run-in period dosage of OM (20 mg/d [n = 139] or 40 mg/d [n = 16]). Patients were given dose adjustments of OM to 40 mg or 60 mg in the event of symptom recurrence. The ARS procedures were chosen by the surgeon during surgery (total fundic wrap [n = 100], semifundoplication [n = 34], or a total or posterior partial fundoplication in addition to vagotomy [n = 10]). Endoscopies were done at 1, 3, and 5 years after ARS or beginning of therapy, and the findings were given an esophagitis grade ranging from 0 (normal esophageal mucosa) to 4 (frank, benign ulcer). Patients were assessed for GERD-related, general dyspeptic, and alleged postfundoplication symptoms and were rated from 0 (no symptoms) to 3 (severe, incapacitating symptoms).

MAIN OUTCOME MEASURE

Treatment failure, defined as ≥ 1 of the following: moderate or severe heartburn or acid regurgitation for ≥ 7 days before a follow-up visit; esophagitis ≥ grade 2; moderate or severe dysphagia or odynophagia symptoms with mild heartburn or regurgitation > 3 months after surgery; if allocated to surgery, requiring OM for > 8 weeks to control symptoms or having a reoperation; if allocated to OM, considered by the physician to require ARS or preferring ARS during the study.

MAIN RESULTS

Analysis was by intention to treat. Fewer patients in the ARS group than in the 20-mg OM group had treatment failure ($P < 0.001$) (Table). Of patients who received ARS, 14% had a symptom relapse, 13% had esophagitis > grade 2, 5% required > 8 weeks of OM, and 11% were otherwise censored from analysis. Of the patients receiving OM, 32% had a symptom relapse, 13% had esophagitis > grade 2, and 10% had ARS during the follow-up period. When OM was increased to 40 mg/d, treatments did not differ.

CONCLUSIONS

In patients treated for GERD, antireflux surgery was more effective than omeprazole (OM), 20 mg/d. When the dose of OM was increased, the treatments did not differ.

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*See Glossary.

Antireflux surgery (ARS) vs omeprazole for gastroesophageal reflux disease*

Outcome at 5 y	ARS	Omeprazole	RRR (95% CI)	NNT (CI)
Treatment failure	42%	58%	27% (8 to 42)	7 (4 to 25)

*Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.

COMMENTARY

The merits of surgical or medical therapy for GERD have been debated for the last 25 years. In 2 head-to-head studies (1, 2), surgery has been superior to medical treatment (antacids and H_2-blockers). On the surface one could argue that this study is strike three: Surgery wins! If we accept this simplistic conclusion, we ignore the real messages of this important study (1). Medical therapy is highly effective in relieving symptoms because only 10% of patients who were originally entered failed to achieve effective symptom relief on less than optimal therapy and could not be allocated (2).

No single therapy is 100% successful in long-term elimination of GERD symptoms; relapse should not be surprising, regardless of treatment (2). Surgery is not a cure and does not completely eliminate the need for medical therapy (3). Both methods provide effective long-term symptom relief with comparable quality of life despite the increased risk for dysphagia, inability to belch, and excess rectal flatus after surgery (4). Perhaps most important, a 20-mg dose of OM (or any proton-pump inhibitor [PPI]) is not sufficient therapy for all; however, effective dose titration (simple, safe, and good clinical practice) essentially equalizes the treatments.

This study should end any debate about surgical superiority. Surgery done by experienced surgeons in the most carefully selected candidates is at best equal to appropriately titrated medical therapy. Correctly dosed PPIs may produce long-term success (3) with minimal side effects in most patients.

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