GASTROENTEROLOGY

GERD: Two Options Offer Similar Long-Term Relief

Gastroesophageal reflux disease (GERD) is a chronic relapsing disease, so patients usually choose long-term medication, such as a proton pump inhibitor (PPI), or surgery. Whereas studies have compared open antireflux surgery and laparoscopic antireflux surgery (LARS), or open antireflux surgery and drug treatment, researchers from the LOTUS (Long-Term Usage of Esomeprazole vs Surgery for Treatment of Chronic GERD) trial said few have compared LARS and pharmaceutical treatment. Such studies were often small, added the researchers, or had other drawbacks.

By contrast, the LOTUS trial followed 554 patients for 5 years. It compared maintenance therapy with dose-adjusted esomeprazole with standardized LARS in patients who responded well to acid-suppressive therapy.

The LOTUS trial was an exploratory, randomized, open, parallel-group study conducted in academic hospitals in 11 European countries. All patients were aged 18 to 70 years and had chronic symptomatic GERD. Of the 554 patients initially enrolled, 372 completed the follow-up: 192 in the esomeprazole group and 180 in the LARS group. The main outcome measure was the time to treatment failure—for LARS, this was defined as the need for acid suppressive therapy; for esomeprazole, it was inadequate control of symptoms after dose adjustment.

At 5 years, the 2 groups had similar results: 85% remission in the LARS group, and 94% in the esomeprazole group.

The LARS group had 33 treatment failures: 29 patients needed another treatment to control symptoms; 1 needed more than 1 dilation; and 3 had postfundoplication adverse events. In the esomeprazole group, there were 19 treatment failures with a complete inability to resolve symptoms.

The LARS group showed slight deterioration (from 90% to 85%) in symptom control between 3 and 5 years. The better long-term control in the esomeprazole group may have been the result of dose escalation, the researchers say. In their study, patients, whose reflux symptoms were not adequately controlled by a standard maintenance regimen (20 mg/d), were allowed to increase the dose to 40 mg/d, then to 20 mg twice a day. The researchers say splitting the dose can improve breakthrough nocturnal symptoms for some patients. The percentages of patients who needed an increased dose of esomeprazole were similar for each year during the study. At 5 years, 23% of patients were receiving a higher dose.

Both treatments were well tolerated, with no surgery-related deaths and similar safety profiles. The LARS patients were more likely to have dysphagia, bloating, and flatulence, while the esomeprazole patients were more likely to have regurgitation. During the 5-year period, 29% of the LARS patients, and 24% of the esomeprazole patients, reported serious adverse events. However, the investigators judged that no specific, serious adverse events were attributable to acid-suppressive therapy alone. In fact, the few hip fractures they observed "suggest that fractures are rare with PPI, and that previous observational studies might have overestimated the risk of these events."

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