

# ADVANCES IN GERD

Current Developments in the Management of Acid-Related GI Disorders

Section Editor: Joel E. Richter, MD

## The Esophageal Sphincter Device for Treatment of GERD



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### G&H When is nonmedical therapy indicated in patients with gastroesophageal reflux disease?

**RG** Treatment of gastroesophageal reflux disease (GERD) is easy when medical therapy (namely proton pump inhibitor therapy) works well and symptoms are completely controlled. However, although it is often thought that proton pump inhibitors are an excellent therapy for the vast majority of patients with GERD, this is true in only approximately 60% of patients; almost 40% of patients still have some degree of dissatisfaction while on proton pump inhibitor therapy and do not experience complete symptomatic relief. Some patients have intermittent GERD symptoms when they overeat or eat inappropriately, whereas others have frequent and severe heartburn and/or regurgitation, including nocturnal regurgitation (ie, choking or coughing while sleeping). In my opinion, surgery is absolutely indicated when patients with GERD have severe volume regurgitation with nocturnal choking, coughing, or aspiration, and surgery should be strongly considered in those with recurrent strictures, postprandial volume regurgitation, frequent breakthrough heartburn, or atypical symptoms, such as cough, hoarseness, or sore throat that cannot be controlled with proton pump inhibitor therapy. In addition, some patients with GERD may choose nonmedical therapy because they do not want to take long-term medication.

### G&H Is nonmedical therapy being used more commonly for GERD than in the past?

**RG** Medical therapy is still the preferred initial treatment option for GERD, although it does not cure the disease.

It merely treats symptoms and leaves the basic pathophysiology of the disease unchanged; the patient's acid is decreased, but his or her reflux continues. Thus, medical therapy is inherently unsatisfactory. The advantage of surgical treatment for GERD is that it treats the disease itself and stops reflux from occurring. It is commonly thought that surgery is bad—that undergoing surgery is considered a failure—but in many respects, surgery restores quality of life much better than medical therapy because surgery actually treats the disease.

### G&H What, specifically, is the pathophysiology of GERD?

**RG** GERD occurs when the lower esophageal sphincter opens when it should not. The reason for this incompetence of the sphincter is likely multifactorial and varies from person to person. Reasons can include low sphincter pressure or decreased functional sphincter length; an anatomic issue, such as a large hiatal hernia (particularly if it is nonreducible) or increased compliance and decreased gastric yield pressure; or transient lower esophageal sphincter relaxation (in which a normal-pressure or lower-pressure sphincter pops open inappropriately).

### G&H What types of nonmedical treatments are currently available for GERD?

**RG** There are currently 2 surgical therapies available for GERD: Nissen fundoplication and the recently developed esophageal sphincter device (LINX Reflux

Management System, Torax Medical). Endoscopic endoluminal therapies for GERD have not worked particularly well in the past. A randomized controlled trial of the Stretta procedure (Mederi Therapeutics) did not demonstrate good pH control, although patients did experience symptom relief. EndoGastric Solutions has recently developed an endoscopic incisionless fundoplication, which has potential; however, additional long-term and pH data are needed.

### G&H How does the esophageal sphincter device work?

**RG** The device is essentially a bracelet or ring of magnets, the magnetic attraction of which restores competency to the region of the gastroesophageal junction by making it less compliant (ie, harder to pop open). When a patient with the device eats, the food bolus forces the magnets apart so that eating can occur without difficulty (in most cases). When the patient finishes eating, the magnets reattract, restoring competency to the region of the gastroesophageal junction.

### G&H How effective is this device?

**RG** In a recent, prospective, controlled trial, patients with GERD who had failed proton pump inhibitor therapy demonstrated excellent symptom control and statistically significant pH control after receiving the device. This study, in which the patients served as their own controls, was published in the *New England Journal of Medicine* on February 21, 2013 and was the most robust study to date on the device. In this study, pH either normalized or was at least 50% reduced in at least 67% of patients. Almost every patient (92%) achieved a 50% reduction in reflux scores, and 93 of 100 patients had at least a 50% reduction in proton pump inhibitor therapy, which included complete discontinuation by 87% of patients. The most frequent adverse event, dysphagia, was found in 68% of patients postoperatively, in 11% at 1 year, and in 4% at 3 years, and the dysphagia was severe enough to warrant removal of the device in 6 patients.

### G&H What is the longest that patients have been followed after receiving the esophageal sphincter device?

**RG** The aforementioned study presented 3-year findings. To date, other studies have followed patients up to 5 years after device insertion, with similar efficacy. The device should hold up well, as magnetic power lasts for perpetuity, and studies have not reported any device migrations or erosions.

### G&H How does this device compare with Nissen fundoplication for treatment of GERD?

**RG** The esophageal sphincter device is much easier to insert and has fewer adverse events than Nissen fundoplication. In addition, the device is associated with many fewer side effects and is not associated with gas bloat syndrome. After receiving an esophageal sphincter device, patients can still belch and vomit, unlike with a Nissen fundoplication. This is important because the inability to belch and vomit is the most common reason that patients turn down a Nissen fundoplication.

In terms of controlling GERD symptoms, the esophageal sphincter device appears to work as well as Nissen fundoplication for a select cohort of patients (ie, those with GERD who have small hiatal hernias). Patients with large hiatal hernias have not yet been studied.

### G&H Is the esophageal sphincter device contraindicated in any patient populations with GERD?

**RG** There are several relative contraindications. For example, the device cannot be used in patients with preoperative dysphagia or patients who need to undergo magnetic resonance scans.

### G&H Following insertion of the device, do patients need to take supplemental therapies or make any lifestyle modifications?

**RG** No, in fact, patients can resume their regular diet immediately after the procedure, and no antibiotics are needed. Device insertion is a same-day, outpatient procedure. Patients discontinue proton pump inhibitor therapy immediately after surgery.

### G&H How has patient satisfaction and tolerability been with the device thus far?

**RG** In the *New England Journal of Medicine* study, patients' satisfaction with their condition substantially improved following insertion of the esophageal sphincter device. At 3 years, 94% of patients were completely satisfied with how their reflux was treated; prior to surgery, only 13% of patients were satisfied.

### G&H How has the device been received by gastroenterologists?

**RG** Most gastroenterologists are taking a wait-and-see approach, but the ones who have used the device have been satisfied with it. As more and longer-term data become available, the device will certainly be used more frequently in the future.

**G&H** Do you foresee use of the esophageal sphincter device as a first-line treatment option for GERD in the future?

**RG** Right now, the indication of the device is failure or dissatisfaction with proton pump inhibitor therapy. However, use of the device as a first-line therapy may someday be a possibility.

**G&H** Does the esophageal sphincter device have potential applications in other diseases?

**RG** The device has been used for treatment of fecal incontinence, with good anecdotal and study results. It is also possible that the device can be used for obesity control, similar to a laparoscopic band.

**G&H** What are the next steps in research in this area?

**RG** The next steps are to conduct a postimplant follow-up study, reduce the dysphagia associated with the device, modify the device so that it allows use of magnetic resonance scans, and investigate the device in patients with large hiatal hernias.

**G&H** Are there any other promising treatments for GERD currently under development?

**RG** Yes. EndoStim is examining whether the sphincter can be paced to treat GERD. Medigus is developing an endoscopic fundoplication procedure similar to the transoral incisionless fundoplication procedure developed by EndoGastric Solutions. Hopefully, there will be many other new endoscopic approaches, since a large number of patients with GERD remain dissatisfied with proton pump inhibitor therapy.

*Dr Ganz has no conflicts of interest to disclose.*

### Suggested Reading

Ganz RA, Peters JH, Horgan S, et al. Esophageal sphincter device for gastroesophageal reflux disease. *N Engl J Med.* 2013;368(8):719-727.

Bonavina L, DeMeester T, Fockens P, et al. Laparoscopic sphincter augmentation device eliminates reflux symptoms and normalizes esophageal acid exposure: one- and 2-year results of a feasibility trial. *Ann Surg.* 2010;252(5):857-862.

Lipham JC, DeMeester TR, Ganz RA, et al. The LINX reflux management system: confirmed safety and efficacy now at 4 years. *Surg Endosc.* 2012;26(10):2944-2949.

Ganz RA, Gostout CJ, Grudem J, Swanson W, Berg T, DeMeester TR. Use of a magnetic sphincter for the treatment of GERD: a feasibility study. *Gastrointest Endosc.* 2008;67(2):287-294.