

ADVANCES IN GERD

Current Developments in the Management of Acid-Related GI Disorders

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An Overview of Transoral Incisionless Fundoplication and Magnetic Sphincter Augmentation for GERD



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G&H How is transoral incisionless fundoplication performed?

RF Transoral incisionless fundoplication (TIF) is an endoscopic technique performed with the EsoPhyX (EndoGastric Solutions) device to create a full-thickness serosa-serosa plication. The procedure, performed under general anesthesia in an endoscopy room, constructs a valve 3 to 5 cm in length and 200 to 300 degrees in circumference. The valve is intended to improve the barrier between the esophagus and the stomach and significantly reduce gastroesophageal reflux.

G&H How does magnetic sphincter augmentation work?

RF In contrast with TIF, the magnetic sphincter augmentation device LINX (Torax Medical) is a surgical technique that is performed in the operating room by surgeons only. The LINX device is a miniature ring of interlinked titanium beads with a magnetic core that is placed around the gastroesophageal junction using a standardized laparoscopic procedure that does not alter the anatomy of the esophagogastric junction. The magnetic bond between adjacent beads augments the sphincter competence. The beads can temporarily separate to accommodate a swallowed bolus, can allow belching or vomiting, and can close to augment the lower esophageal sphincter to prevent gastroesophageal reflux.

G&H What are the main advantages associated with these therapies compared with other available treatment options?

RF The main advantage of the TIF procedure is that it provides an alternative option for patients who are not interested in medical therapy (due to lack of efficacy, development of side effects, poor compliance, concerns about the emergence of proton pump inhibitor–related side effects over time, or cost) and at the same time are not interested in surgical therapy for gastroesophageal reflux disease (GERD). Additionally, TIF is an outpatient procedure, can be performed by a gastroenterologist or a surgeon in an endoscopy room, and should not take more than 45 to 60 minutes to complete.

One of the main advantages of the LINX device is that it provides an alternative therapy for the different types of surgical fundoplication and the need for long-term medical therapy. Insertion of the magnetic ring does not alter the anatomy of the esophagogastric junction, whereas Nissen fundoplication requires anatomic alteration of the proximal stomach, which is responsible for the development of many of the adverse events postsurgery. Furthermore, the procedure is easy to perform, is highly efficacious, and the device is removable.

G&H What disadvantages are associated with these procedures?

RF TIF requires highly skilled gastroenterologists or surgeons, as the outcome of the technique is related to the expertise of the physician performing it. Similarly, there is a learning curve until surgeons become proficient in performing the LINX procedure. There have been concerns regarding the LINX device in relation to having a foreign body placed around the esophagus long term. Both procedures are still lacking long-term data about their

efficacy and durability. There are various side effects that may develop following TIF or the LINX procedure in the short term (immediately after the procedure) or the long term. The LINX device cannot be placed in patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous material. Magnetic resonance imaging should be avoided in patients with LINX. TIF should not be performed in patients with a hiatal hernia larger than 2 cm, and the LINX device should be avoided in patients with a hiatal hernia larger than 3 cm.

G&H What are the most common adverse events associated with TIF and magnetic sphincter augmentation?

RF Studies have shown that approximately 3% to 10% of patients who undergo TIF will experience some type of adverse event. Some of the more concerning side effects of TIF include mucosal tear, perforation, bleeding, pneumothorax, and mediastinal abscess. The most common adverse event related to the LINX device is dysphagia. However, patients may develop immediate adverse events post-LINX placement related to surgery and anesthesia. Patients may develop side effects such as odynophagia, achalasia-like picture, bleeding, cough, device failure, or device migration. Other adverse events may include device erosion and the ring eroding into the esophageal lumen.

G&H How can these complications be managed? Are there any preventive measures that can be used?

RF The primary approach to preventing complications is to have well-trained physicians in centers that perform the procedures regularly, as complications are more likely to arise when gastroenterologists or surgeons do not have enough experience to perform these procedures. In addition, it is important to select the proper patients for these procedures.

G&H Which patients would benefit the most from these therapies? In which patients are they contraindicated?

RF Both of the procedures are performed predominantly in patients with typical GERD-related symptoms. TIF is indicated in patients who have nonerosive reflux disease or low-grade erosive esophagitis (grades A and B). Patients should have small (<2 cm) hiatal hernias. Similarly, the LINX procedure is indicated in patients with nonerosive reflux disease or low-grade erosive esophagitis (grades A and B) with hiatal hernias smaller than 3 cm.

Both techniques should be avoided in patients with advanced erosive esophagitis, Barrett esophagus, atypical

and extraesophageal manifestations of GERD, scleroderma, history of esophageal or esophagogastric surgery, major esophageal motor disorder, history of unresolved dysphagia, esophageal stricture or other gross esophageal anatomic abnormalities, esophageal or gastric varices, and lactating or pregnant women. LINX should be avoided in patients with a body mass index greater than 35 and in patients with an allergy to titanium or stainless steel. LINX should also be avoided in patients with electrical implants, such as pacemakers or defibrillators.

G&H Are repeat interventions common with either approach?

RF A small subset of patients may require conversion of TIF to surgical fundoplication; likewise, a small number of patients may undergo removal of the LINX device (explant) or conversion to surgical fundoplication.

G&H Are there any data reporting on the effectiveness of these procedures in the long term?

RF There are cohort studies reporting 7 years' follow-up with the LINX procedure and 6 years with TIF. For both procedures, the studies show maintenance of symptoms and health-related quality-of-life improvement, reduction in proton pump inhibitor utilization, and reduction in esophageal acid exposure. There are also 5 randomized, controlled trials that describe the efficacy of TIF in patient populations with classic symptoms of GERD, such as heartburn and regurgitation. However, a recent systematic review and meta-analysis that was published in *Surgical Endoscopy* and assessed 18 studies; 5 randomized, controlled trials; and 13 prospective trials claimed that there was an increase in proton pump inhibitor utilization over time (albeit in a reduced dose), that the satisfaction rate was 69.2% at 6 months, and that there were no significant improvements in esophageal acid exposure or acid reflux episodes.

G&H Is there any reluctance to use TIF on the part of providers or patients?

RF In general, most patients with GERD are looking for medical options. They are less interested in surgical or endoscopic techniques (although they prefer endoscopic techniques over surgical intervention). However, there is now a growing interest among patients in nonmedical therapeutic strategies for GERD. This interest is driven primarily by the growing number of publications suggesting that chronic treatment with proton pump inhibitors may be associated with a variety of adverse events, including some that are devastating. Thus, patients are

looking for nonmedical options, bringing into attention techniques like TIF and magnetic sphincter augmentation (LINX).

From providers' point of view, I think that gastroenterologists are hesitant to refer patients for TIF because of the concern about the durability of this procedure. Furthermore, some providers may be concerned about endoscopic therapy for GERD due to the failure of the first generation of endoscopic therapies for GERD.

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

RF It would be beneficial to assess the durability of both techniques as well as long-term efficacy. In the case of LINX, long-term safety assessment is necessary, especially in relation to ring erosion or migration. More research is needed regarding the value of these techniques in different clinical scenarios (for example, the role of TIF in patients post–sleeve gastrectomy who report severe GERD-related symptoms).

Dr Fass is a consultant for Torax Medical and Ethicon.

Suggested Reading

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