

# ADVANCES IN GERD

Current Developments in the Management of Acid-Related GI Disorders

Section Editor: Joel E. Richter, MD

## Transoral Incisionless Fundoplication for the Treatment of Gastroesophageal Reflux Disease



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### G&H Which endoluminal therapies are currently available for the treatment of gastroesophageal reflux disease?

**PK** The endoluminal therapies that are currently available for the treatment of gastroesophageal reflux disease (GERD) are transoral incisionless fundoplication (TIF; EsophyX, EndoGastric Solutions), which creates a fundoplication endoscopically; Stretta (Mederi Therapeutics), a radiofrequency therapy that aims to reduce heartburn by causing contraction or stricturing of the lower esophageal sphincter; the Medigus Ultrasonic Surgical Endostapler (Medigus); and LINX (Torax Medical), a device comprised of magnetic beads that are placed laparoscopically around the outside of the lower esophageal sphincter to augment the lower sphincter pressure. LINX is not an endoluminal therapy but is typically grouped with these other methods for treating GERD.

### G&H Why was TIF developed, and how is it performed?

**PK** TIF evolved out of the concept that an altered gastroesophageal junction anatomy could create a mechanical valve and prevent reflux. Initially, doctors examined the flap valve function of the gastroesophageal junction to determine methods to augment it via open surgery. The need to create some sort of plication device that would allow a clinician to place staples, sutures, or plastic stays led to the development of an endoluminal method that would approximate the benefit of a fundoplication without the associated morbidity.

The TIF procedure uses H-shaped stays (a flange on each side with a connector between the 2 flanges) that are placed transluminally inside the stomach for a stapling effect.

### G&H Is there a risk of bleeding during this procedure?

**PK** Yes, there is a risk of bleeding with any procedure that creates a hole through the wall of the stomach. However, bleeding caused by TIF is not very common, and when it does occur, it is usually controllable.

### G&H How does TIF compare with the use of proton pump inhibitors for the treatment of GERD?

**PK** In terms of controlling heartburn or healing esophagitis, proton pump inhibitors (PPIs) work extremely well. When it comes to managing regurgitation, PPIs can alter the acidity but will not stop symptoms of regurgitation completely. Therefore, my colleagues and I conducted a randomized, controlled trial that compared PPIs to the TIF procedure plus a placebo. Every study participant underwent TIF or a sham procedure and received either omeprazole or placebo (Figure). The primary outcome was the elimination of problematic regurgitation. Ours is the only trial that I am aware of that has used control of regurgitation rather than heartburn or esophagitis as a primary outcome measure. Statistically, the TIF procedure outperformed PPIs in this area (67% vs 45%;  $P=.023$ ), which is the first instance of any method showing superiority over a PPI.

### G&H How effective is TIF for treating GERD compared to standard fundoplication?

**PK** This is a difficult question to answer because it involves a lot of variables. Very few patients have undergone TIF in a controlled setting, and the consistency of the performance of the procedure among practitioners is unknown. What is known is that in a controlled setting by clinicians who were well trained in the procedure, patients with problematic regurgitation despite PPI therapy stand to benefit from undergoing TIF as opposed to continued PPI therapy.

### G&H Are there any patients in whom this procedure should be avoided?

**PK** In the trial my colleagues and I conducted, exclusion criteria included body mass index greater than 35, Barrett esophagus or hiatal hernia longer than 2 cm, presence of an esophageal ulcer or stricture, Los Angeles grade C or D esophagitis, esophageal dysmotility, previous esophageal or gastric surgery, peptic ulcer disease, gastric outlet obstruction, gastroparesis, pregnancy or plans for pregnancy in the next 12 months, immunosuppression, portal hypertension, and coagulopathy.

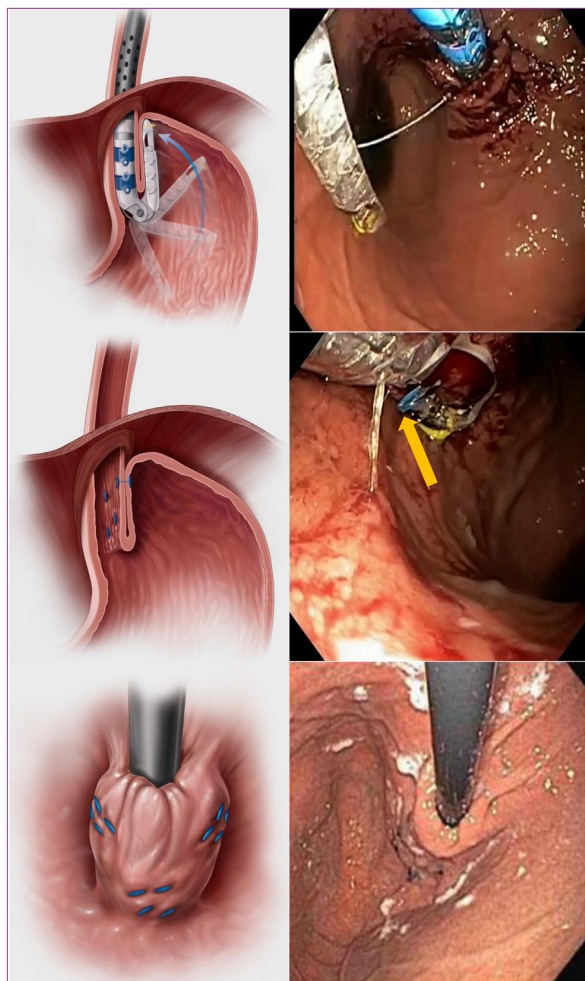
### G&H Is this procedure being performed in clinical practice?

**PK** Yes, it is. A number of institutions across the United States perform TIF, including my institution. One of the more challenging issues that arises from the procedure is insurance coverage, which is dependent on whether the carrier will reimburse the procedure and by how much it will be reimbursed.

### G&H Are repeat procedures or supplemental therapies needed with TIF, or with endoluminal therapies in general?

**PK** The durability of the stays used during TIF is largely unanswered because the available dataset is from the 6-month RESPECT (Randomized EsophyX vs Sham, Placebo-Controlled TIF) trial. The trial was carried out to 12 months, with a crossover occurring at 6 months. Thus, the control half of the trial has ended, and there are few data on the success or failure rates for repeat procedures.

LINX is a laparoscopic surgery; therefore, the practitioner can add to the implantation while simultaneously treating a hiatal hernia. That potential does not exist with TIF, and that is a significant difference. However, treating the hiatal hernia also presents a slight problem because no clear instructions exist on whether the hernia should



**Figure.** Transoral incisionless fundoplication was performed to create a 3-cm flap valve in a patient with gastroesophageal reflux disease.

Reproduced from Hunter JG, Kahrilas PJ, Bell RC, et al. Efficacy of transoral fundoplication vs omeprazole for treatment of regurgitation in a randomized controlled trial. *Gastroenterology*. 2015;148(2):324-333.e5.

be repaired always, sometimes, or never, or whether the LINX device should be placed below or above the diaphragm. Again, the procedure has not been performed in a large enough group of patients systematically enough, except in retrospective analyses, to address repeat or supplemental treatments.

### G&H Is symptom recurrence common with LINX?

**PK** A 5-year, follow-up study of a 100-patient cohort that was originally published in *The New England Journal of Medicine* was recently published in *Clinical Gastroenterology and Hepatology* and shows a good ability of preventing symptom recurrence. The median GERD–Health-Related Quality-of-Life scores at baseline were 27 in patients not

taking PPIs and 11 in patients on PPIs; after 5 years of device placement, this score was 4. Moderate or severe regurgitation occurred in 57% of patients at baseline and decreased to only 1.2% at the 5-year follow-up.

### G&H What do you believe are the next steps in research?

**PK** In general, more data are needed to show that TIF is effective. The dataset is just not at that stage yet. Clinicians are trying to create registries of the various endoluminal procedures to identify the barriers to implementation, but there just are not enough patients undergoing the procedures. Additionally, more studies are needed to address reimbursement issues and durability concerns.

*Dr Kahrilas has no relevant conflicts of interest to disclose.*

### Suggested Reading

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