

NEW PUBLICATION ON TIF 2.0 IN THERAPEUTIC ADVANCES IN GASTROENTEROLOGY PROVIDES A ROADMAP AS SURGEONS AND GASTROENTEROLOGISTS PARTNER TO USE THE PROCEDURE TO ACHIEVE OPTIMAL OUTCOMES FOR PATIENTS WITH GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Continued evolution of EndoGastric Solutions' EsophyX technology and concomitant use of TIF 2.0 with hiatal hernia repair brings long-term GERD relief to a broader spectrum of patients

REDMOND, WA –EndoGastric Solutions® announced the publication of a new review article in Therapeutic Advances in Gastroenterology¹ that describes the refinement of its EsophyX® technology and the evolution of Transoral Incisionless Fundoplication (TIF®) as a safe and effective treatment for patients with gastroesophageal reflux disease (GERD). The article, authored by Glenn Ihde, MD, a board-certified general surgeon at the Matagorda Medical Group in Bay City, Texas, provides an overview of current best practices with respect to TIF 2.0 as a stand-alone procedure as well as in conjunction with hiatal hernia (HH) repair. TIF was initially developed as an incisionless procedure, but as the EsophyX technology has become easier to use and yields more reproducible outcomes, a growing number of surgeons have combined it with laparoscopic hiatal hernia repair (LHHR) to provide durable relief of GERD symptoms to a broader patient population who may have anatomic defects that require correction beyond TIF.

“A robust and growing body of clinical data demonstrates that TIF as a stand-alone procedure or TIF performed with HH repair provides effective and durable relief of symptoms without many of the side effects associated with traditional anti-reflux procedures,” said Dr. Ihde. “Both straight TIF and TIF in conjunction with HH repair have been shown to improve quality of life and allow most patients to completely come off or significantly reduce their proton pump inhibitor (PPI) medications, which are not intended for long-term usage. The article published today is intended to provide gastroenterologists and surgeons with up-to-date information that they can use to support their clinical decision-making in the treatment of GERD.”

Key data highlighted in the publication includes the following:

- Refinements in technology and technique surrounding the TIF 2.0 procedure with EsophyX Z+ have led to improved ease of use, continued

exemplary safety profile and more reproducible outcomes

- With refinements to the TIF procedure, TIF 2.0 is identified as morphologically and physiologically similar to the gold standard Nissen fundoplication, without the common side effects such as postoperative dysphagia, bloat, gassiness and flatulence
- Patients with a HH of less than 2 cm can often be treated with the TIF 2.0 procedure alone
- The TIF 2.0 with HH repair can now be performed on a broader spectrum of patients, including those with a larger HH and more advanced disease

“In recent years, growing patient concerns about the long-term safety issues associated with chronic use of PPI medications have created the need for new treatment options,” said Jonathan Schneider, MD, a gastroenterologist at The Frist Clinic in Nashville, part of TriStar Medical Group. “This procedure allows gastroenterologists to offer an individualized patient care plan or partner with surgeons to treat a broader spectrum of patients suffering from GERD.”

On Wednesday, June 24, 2020, Dr. Ihde and Dr. Schneider participated in a live-streamed TIF Talk on Zoom, which further discussed the evolution of the TIF procedure and the importance of the collaboration between gastroenterologists and surgeons for the treatment of GERD.

“Dr. Ihde’s review provides important context to the evolution of both the EsophyX device and the TIF 2.0 procedure,” said Skip Baldino, President and CEO of EndoGastric Solutions. “With more than 20 percent of the U.S. population suffering from GERD, we are proud to be able to provide doctors with an effective, safe, and minimally invasive solution to address and treat a larger patient population.”

About GERD

Gastroesophageal reflux disease (GERD) is a common gastrointestinal disease that affects nearly 20 percent of the U.S. population. It is a chronic condition in which the gastroesophageal valve (GEV) allows gastric contents to reflux (wash backwards) into the esophagus, causing heartburn and possible injury to the esophageal lining. In the United States (U.S.), GERD is the most common gastrointestinal-related diagnosis physicians make during clinical visits. Some patients may have mild or moderate symptoms of GERD, while others have more severe manifestations causing chronic

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heartburn, asthma, chronic cough, and hoarse voice or chest pain. Left untreated, GERD can develop into a pre-cancerous condition called Barrett's esophagus, which is a precursor for esophageal cancer. The first treatment recommendation for patients with GERD is to make lifestyle changes (e.g., diet, scheduled eating times and sleeping positions). Proton pump inhibitor (PPI) medications are commonly used to treat GERD, but there are a variety of health complications associated with long-term dependency on PPIs, and more than 10 million Americans are refractory to PPI therapy and may opt for surgery.

About Transoral Incisionless Fundoplication (TIF® 2.0 procedure) for Reflux

The TIF 2.0 procedure enables an incisionless approach to fundoplication in which a device is inserted through the mouth, down the esophagus and into the upper portion of the stomach. This approach offers patients looking for an alternative to traditional surgery an effective treatment option to correct the underlying cause of GERD. Based on clinical studies, most patients stopped using daily medications to control their symptoms and had their esophageal inflammation (esophagitis) eliminated up to five years after the TIF 2.0 procedure. Additionally, clinical results have demonstrated that concomitant laparoscopic hiatal hernia repair (LHHR) immediately followed by TIF 2.0 procedure is safe and effective in patients requiring repair of both anatomical defects.

Over 25,000 TIF procedures have been performed worldwide. More than 140 peer-reviewed papers have consistently documented the sustained improved clinical outcomes and exemplary safety profile the TIF procedure provides to patients suffering from GERD. For more information, please visit www.GERDHelp.com.

About Reimbursement

With the support of clinical societies, commercial and federal insurance providers, representing more than 130 million lives, have recognized the value of the TIF 2.0 procedure through recently expanded coverage policies. The TIF 2.0 procedure is a covered benefit for all Medicare beneficiaries across the country.

For the TIF 2.0 procedure, physicians and hospitals can reference CPT Code 43210 EGD esophagogastric fundoplasty. CPT is a registered trademark of the American Medical Association.

About EsophyX® Technology

The EsophyX technology is used to reconstruct the gastroesophageal valve (GEV) and restore its function

as a barrier, preventing stomach acids from refluxing back into the esophagus. The device is inserted through the patient's mouth with direct visual guidance from an endoscope, and enables creation of a 3 cm, 270° esophagogastric fundoplication. The U.S. Food and Drug Administration cleared the original EsophyX device in 2007. The evolving technology, including the latest iteration EsophyX Z+, launched in 2017, enables surgeons and gastroenterologists to use a wide selection of endoscopes to treat the underlying anatomical cause of GERD.

Indications

The EsophyX device, with SerosaFuse® fasteners and accessories, is indicated for use in transoral tissue approximation, full thickness plication and ligation in the gastrointestinal tract. It is indicated for the treatment of symptomatic chronic GERD in patients who require and respond to pharmacological therapy. The device is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia ≤ 2 cm in size in patients with symptomatic chronic GERD. Patients with hiatal hernias larger than 2 cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2 cm or less.

About EndoGastric Solutions®

Based in Redmond, Washington, EndoGastric Solutions, Inc. (www.endogastricsolutions.com), is a medical device company developing and commercializing innovative, evidence-based, incisionless surgical technology for the treatment of GERD. EGS has combined the most advanced concepts in gastroenterology and surgery to develop products and procedures to treat gastrointestinal diseases, including the TIF 2.0 procedure—a minimally invasive solution that addresses a significant unmet clinical need. Join the conversation on Twitter: @GERDHelp Facebook: GERDHelp and LinkedIn: EndoGastric Solutions.

Reference

1. Ihde GM. The evolution of TIF: transoral incisionless fundoplication. *Ther Adv Gastroenterol.* 2020;13:1-16.

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