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New data shows TIF benefits go the distance for GERD

By Amanda Pedersen, Senior Staff Writer

At first glance, three-year data supporting a commercialized technology already backed by a body of strong clinical evidence might not seem like a huge leap for the company selling the device. But for Endogastric Solutions Inc. (EGS), that's exactly what the company and — more importantly — payers have been waiting for.

The Redmond, Wash.-based company reported three-year results from its TEMPO study at the American Gastrointestinal and Endoscopic Surgeons (SAGES) meeting that wrapped up Saturday in Boston. The latest data demonstrated that the initial clinical benefits of the transoral incisionless fundoplication (TIF) procedure using EGS' Esophyx device in patients with chronic gastroesophageal reflux disease (GERD) is actually maintained for up to three years in most patients.

The FDA cleared the original Esophyx device in 2007 and EGS launched the third generation Esophyx, dubbed the Esophyx Z, just last year. The technology is designed to provide a wider selection of endoscopes, including low profile and larger high-definition models, to treat the underlying anatomical cause of GERD. The Esophyx technology is used to reconstruct the gastroesophageal valve and restore its function as a barrier, preventing stomach acids refluxing back into the esophagus. The device is inserted through the patient's mouth with direct visual guidance from an endoscope.

Principal investigator Karim Trad of the George Washington University School of Medicine and Health Sciences reported elimination of troublesome regurgitation among 91 percent of TEMPO patients at three years, while 71 percent were able to completely stop proton pump inhibitor (PPI) therapy and reflux esophagitis healed in 87 percent of patients in the study. TEMPO enrolled 63 patients randomized to either the TIF procedure group (40 patients) or the PPI therapy control group (23 patients). All PPI patients crossed over and received TIF procedures six months after the study began.

OVERCOMING HISTORICAL BIAS

To truly appreciate the significance of this long-term data, Trad told Medical Device Daily it's important to look at the reflux device space in a historical context.

"The TIF is only the latest of a series of endoscopic procedures that have attempted to cure reflux in this patient population and the previous companies have failed precisely because they had not been able to show sustained results long term," Trad said. Even companies that had strong data at 12 months were never able to carry the clinical benefits of the respective techniques beyond a year, he said.

"This is the first time we have been able to say those benefits we demonstrated at 12 months out are actually maintained as long as three years," Trad said.

Also, he noted, compared to the one-year, two-year and now three-year data available from this study the results are a flat line without any sign of deterioration down the road. That's a big deal to payers that have previously been burned by covering technology that had promising early results and later bombed. But, Trad said, that is the legacy EGS inherited when it entered the space and the company is finally able to prove its approach is "a different ball game" from other endoscopic devices that have come and gone for GERD treatment. It also shows it is a durable alternative to PPIs and more invasive operations, he said.

"Payers have been waiting for long term results," he said. In meetings with medical payers to seek reimbursement coverage for the TIF procedure, Trad said the payers were complimentary about what TIF can achieve but they still didn't want to pay for it without longterm data. EGS initially planned to conclude the study at three years but the company now plans to expand TEMPO to four or five years.

Last year SAGEs, along with three other primary GI societies jointly sponsored an application to the American Medical Association for a new category I current procedural terminology (CPT) code, which became effective Jan. 1. The new CPT code

allows patients to more easily receive access to treatment for GERD, EGS said, and doctors and hospitals can reference the code for TIF procedures. It's a step in the right direction, Trad explained, but a CPT code itself doesn't guarantee that payers will reimburse providers for the cost of the procedure. The CPT code plus the recent durability data is a good combination though. "It's a good place to begin to look forward to better coverage," he said.

SCOPE OF THE PROBLEM

EGS said acid reflux impacts more than 80 million U.S. patients at least once a month. The standard treatment for symptomatic GERD includes lifestyle changes and escalating doses of prescription drugs for prolonged periods of time, the company noted. The problem with that is long-term, maximum-dose usage of those medications has been linked to a variety of other complications, according to EGS.

The patients in the TEMPO study were medically refractory

to PPI treatment for more than 11 years, with no other option left for them, Adrian Lobontiu, medical director at EGS, told MDD. Traditionally, surgery has been an option for GERD patients failing medical therapy and surgery has been shown to keep most patients off medication for up to 10 years. But even though surgery cures the patient's regurgitation, they often have trouble with gas and bloating and sometimes difficulty swallowing, which makes many patients reluctant to have surgery. The TIF procedure is performed endoscopically without any actual incisions. Currently patients who have TIF are taken to the operating room and kept overnight in the hospital but one physician previously told MDD that she thinks the technique could eventually be simplified enough to be done in the endoscopy suite. One limitation of TIF is that patients with a large hernia (3 centimeters or more) are ineligible for the procedure unless they first have surgery to reduce their hernia..