PPI medications can't keep up in TEMPO, when compared to TIF

By Omar Ford
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Are Transoral Incisionless Fundoplication (TIF) procedures the go-to treatment for relief of GERD symptoms? While it might be a stretch to say that TIF procedures have reached that distinction, one-year results of EndoGastric Solutions'(EGS; San Mateo, California) TEMPO trial give credence to the procedure's effectiveness.

EGS makes the EsophyX, a device cleared by FDA in 2007, for use in TIF procedures to reconstruct the gastroesophageal valve. Inserted through the patient's mouth with visual guidance from an endoscope, the EsophyX device is used to reconstruct the gastroesophageal valve (GEV) in order to restore its function as a barrier to prevent stomach acids from washing back up into the esophagus.

Performed entirely through the mouth without the need for external incisions through the skin, the TIF procedure offers patients who require an anatomical change to correct the underlying cause of GERD, another treatment option beyond traditional surgery. Studies show that for up to three years after the TIF procedure esophageal inflammation (esophagitis) is eliminated and most patients are able to stop using daily PPI medications to control symptoms.

The TEMPO study found that the TIF procedure achieved sustained elimination of all GERD symptoms and healing of esophagitis.

"This a multi-center randomized trial, which took place at seven centers in the United States," Karim Trad, TEMPO principal investigator and a surgeon at **George Washington University School of Medicine and Health Sciences** (Washington), told *Medical Device Daily*. "We included patients with persistent symptoms of GERD, while on high-dose PPI. The study had a crossover structure, which means patients were placed for six months on high dose PPI. Then we studied them to see what the medications achieved. Then they got the procedure – at the end of that six months we also analyzed them."

The primary outcome of TIF Vs. Medical PPI Management of Refractory GERD symptoms (TEMPO) trial was elimination of daily troublesome regurgitation and atypical symptoms as evaluated by two validated instruments – Reflux Disease Questionnaire and Reflux Symptom Index; secondary outcomes included healing of esophagitis, normalization of esophageal acid exposure and PPI use in the TIF treated patients at six and 12 months.

"What we found is that in this patient population, the TIF procedure does offer a very clear therapeutic advantage," he said. "To put it in a nutshell, it has always been problematic to treat a certain category of patients even with medication."

In the patients randomized to the TIF treatment group (n=39), 93% achieved elimination of troublesome regurgitation; 77% achieved global elimination of all atypical symptoms and regurgitation. Reflux esophagitis was healed in all 19 patients who presented with the erosive

disease on PPI therapy before the TIF procedure. Ninety-seven percent of patients were off daily PPI therapy. All esophageal pH parameters were significantly reduced at 12-month follow-up, compared to baseline.

In the crossover (control) group (n=21), after six months of high-dose PPI therapy twice daily, only 5% (1/21) of patients reported global elimination of regurgitation and atypical symptoms; this proportion significantly increased to 65% (13/20) six months after these patients crossed over and had the TIF procedure. Additionally, 80% of the cross-over patients were off daily PPIs six months following the TIF procedure.

"We are thrilled that the results of this study have confirmed that the TIF procedure is significantly more effective than high-dose PPI therapy in relieving troublesome regurgitation and atypical GERD symptoms," said Skip Baldino, EGS president/CEO. "This is the only incisionless procedure currently available in the US that reconstructs a defective gastroesophageal valve with an endoscopic approach that is supported by safety and effectiveness data from randomized trials."

"The value of this particular study is that it its the first randomized controlled trial, offering level one evidence as to the efficacy as compared to the alternative treatment, which is medication," Trad said.

TEMPO is a post-market study. With the data that has been derived from it, Trad said that he is hoping it can overcome some of the potential barriers to adoption.

"The only barrier toward wider adoption at this stage is obtaining a CPT code designation and having insurance companies approve it across the board," he said. "That to me is the largest challenge. I have seven or eight patients, in the waiting, who know about the procedure and would clearly benefit from it; and who want it; but we're struggling with getting insurance coverage."

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