Digestive Disease Week: EGS: TIF 'dramatically eliminates' GERD symptoms in most patients

By Amanda Pedersen

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CHICAGO — Gastroesophageal reflux disease (GERD) patients with incomplete symptom control even on the maximum dose of proton pump inhibitor (PPI) therapy have a new, less invasive option than surgery. **EndoGastric Solutions** (EGS; San Mateo, California) released new data at Digestive Disease Week (DDW) in Chicago that show most GERD patients who underwent the Transoral Incisionless Fundoplication (TIF) procedure with the EsophyX device continued to report complete elimination of all troublesome regurgitation and esophagitis for a full year after the procedure.

This new 12-month analysis of the prospective, randomized, multi-center clinical trial known as TEMPO also showed that all 21 patients in the original control arm who had received maximum-dose PPI therapy for the first six months of the trial crossed over to undergo the TIF procedure. This group achieved similar positive six-month results to the patients in the original treatment arm, according to EGS.

DDW is considered the largest gastroenterology meeting, and is jointly sponsored by the **American Gastroenterological Association** (AGA; Bethesda, Maryland) **Institute**, the **American Association for the Study of Liver Diseases**,(AASLD; Alexandria, Virginia), the **American Society for Gastrointestinal Endoscopy** (ASGE; Downers Grove, Illinois), and the **Society for Surgery of the Alimentary Tract**.(SSAT; Beverly, Massachusetts). The meeting kicked off Saturday and will run through Tuesday.

Karim Trad, MD, principal investigator of the TEMPO study, presented the new analysis as part of an AGA research forum on Monday at DDW.

"This study confirms that in well-selected GERD patients with incomplete symptom control on high-dose PPI therapy, the TIF procedure is capable of dramatically and durably eliminating GERD symptoms, healing esophagitis and improving quality of life," said Trad, a surgeon at **George Washington University School of Medicine and Health Sciences** (Washington). "This incisionless, endoluminal approach offers a subgroup of patients who are dissatisfied with PPIs a less invasive option than current surgical approaches, with minimal or no side-effects. We are planning to follow our study patients for up to three years."

According to the new analysis, 77% of patients in the original treatment arm (39 patients) reported a global elimination of daily troublesome regurgitation and atypical symptoms 12 months following the TIF procedure. Esophagatis, or inflammation of the esophagus, remained healed in 100% of the patients in the original treatment arm.

At the end of the first six months of the study, only 5% (one out of 21) of patients in the control group who received maximum-dose PPI therapy reported global elimination of regurgitation and

atypical symptoms; this proportion increased to 67% (14 out of 21) six months after these patients crossed over and had the TIF procedure. Additionally, 71% (15 out of 21) of the cross-over patients were completely off PPIs six months following the TIF procedure.

This is significant data for the patient population that have an absolute need for an answer to their symptoms, Trad told *Medical Device Daily*. "We had known for a long time that [TIF] worked," he added. What this data means, he explained is that for the first time "we can actually say it meets the level of evidence that is required to be an undisputed player. This is now a proven tool and should be used as one of the alternatives in managing those patients."

That doesn't mean the TIF procedure will replace current surgical and laparoscopic procedures or even PPI therapy, Trad said. "Those are modalities that have their role, but this is clearly a market that was under-served and now we're filling that gap. Therapy gap is a term used quite frequently in describing those patients who actually don't have a good solution to their problems, so we believe that TIF is now proven as a tool that can bridge that gap."

GERD is caused by anatomical changes where the muscle at the base of the esophagus relaxes between swallows, allowing corrosive stomach acid to wash back up into the esophagus. The stomach produces hydrochloric acid after a meal to aid in the digestion of food. The cells that line the stomach consist of protective mucus that protect it from erosion, but the lining of the esophagus does not share these resistant features and stomach acid can damage it.

This TEMPO data include results from 63 patients treated at seven U.S. centers, including three gastroenterology practices and four general surgery practices. The EsophyX was cleared by the FDA in 2007. The device is inserted transorally with visual guidance from an endoscope and used in the TIF procedure to reconstruct the gastroesophageal valve (GEV), restoring its competency and reestablishing the barrier to reflux.

The TIF procedure is based on traditional surgical principles and offers similar effectiveness to a surgical repair with the safety profile of an incision-free approach, EGS noted. Trad said that instead of rebuilding the valve from the outside like the traditional surgical approach, the TIF procedure rebuilds the GEV from the inside. But on the plus side, Trad said, "we don't see some of the annoying and bothersome side effects, like difficulty swallowing. This offers a solution but not facing any of these side effects."

Trad said the TIF procedure has been well received by physicians who have had the opportunity to see patients after they have undergone the procedure. "There is excitement there, referrals, and of course you have people who don't know much about the procedure and tend to lump it together with some of the earlier procedures that didn't fair that well so there is that bit of an incorrect, pre-conceived idea but physicians familiar with it are very enthusiastic."

The primary outcome of the 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.

"These results add to the growing body of tier-one clinical data supporting use of the TIF procedure as an important therapeutic option for many long-term GERD sufferers, particularly those who no longer respond to drug therapy, but aren't prepared for the risk and recovery time of traditional open or laparoscopic surgery," said Skip Baldino, president/CEO of EGS. "The presentation of the one-year outcomes from this important study represents one of the most important clinical milestones for EGS and the entire endoluminal procedure category to date."

EGS just announced Baldino as its new president/CEO last Thursday ahead of the DDW meeting. Baldino is no stranger to the gastrointestinal device and diagnostics space, however, he previously was president of the Americas for **Given Imaging** (Yokneam, Israel), which **Covidien** (Dublin, Ireland) bought for $860 million in March. Baldino also previously worked as a divisional VP for **Abbott Laboratories** (Abbott Park, Illinois).

Baldino told *MDD* this TEMPO analysis is one of many presentations and publications EGS expects during 2014. "I believe this evidence will have a substantial impact on the utilization of and reimbursement for endoluminal approaches for GERD, and is one of the key reasons why I wanted to join EGS at this time," he said.

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