Study supports TIF procedure for treating GERD symptoms

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An independent study seems to support the growing efficacy of transoral incisionless fundoplication procedures in the treatment of GERD symptoms. The results could be a boon to **EndoGastric Solutions** (EGS; San Mateo, California), which has developed the EsophyX, a device that is used in TIF procedures.

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.

The study showed that TIF provides dramatic symptom resolution, similar to that achieved after laparoscopic Nissen or Toupet fundoplication. Results were published in the September issue of the *American Surgeon*, the official journal of the **Southeastern Surgical Congress** (Cumming, Georgia) and the **Southern California Chapter of the American College of Surgeons** (El Segundo, California).

"The intent of the study is to show efficacy of different approaches," Alexander Rosemurgy, a physician at **Florida Hospital Tampa**, and an investigator for the study, told *Medical Device Daily*. "There are many different ways in which reflux can be cared for. Physicians and the caregivers have options and the patients or consumers have options. The options vary by how invasive they are; the intent and what their scope is. The problem is that while on one level the degree of invasiveness is pretty obvious to observe, efficacy is not."

This data is from a case controlled study of three cohorts, each with 20 patients — TIF procedure, laparoscopic Nissen and Toupet fundoplication — that were controlled for age, BMI and pH scores.

In each of the treatment arms, most patients experienced GERD symptoms less than once per month. Operative times were significantly shorter with the TIF procedures averaging 71 minutes vs. 119 minutes for Toupet and 85 minutes for Nissen. In addition, length of postoperative hospital stay was significantly shorter after the TIF procedure.

"I presumed that the laparoscopic approach would provide better symptom relief, when in fact that didn't turn out to be the case," he said.

The authors concluded, "Patient satisfaction and effective palliation of symptoms prove that the TIF procedure is safe and efficacious in comparison to laparoscopic Nissen and Toupet fundoplication surgeries, and we offer strong support for its continued application and evaluation."

"Having new data published independently comparing our TIF procedure to the current standard of care is another important milestone for EGS, and adds to the growing body of clinical evidence surrounding our technology," said Skip Baldino, EGS president/CEO. "It is significant for GERD patients needing a less invasive option, that the TIF procedure outcomes have been clinically validated to be similar to traditional surgery."

GERD is the most common gastrointestinal-related diagnosis made by physicians during clinical visits in the U.S. It is estimated that pain and discomfort from acid reflux impacts more than 23 million people two or more times per week in the U.S. The standard recommendations for symptomatic GERD patients include lifestyle changes (e.g. diet, scheduled eating times, and sleeping positions) and escalating doses of prescription medications for prolonged periods of time. Long-term, maximum dose usage of prescription medications have been linked to a variety of other health complications which has led to physicians looking for other treatment methods.

This also paved the way for EGS to develop the EsophyX device. It was cleared by the FDA in 2007. Inserted transorally with visual guidance from an endoscope, the EsophyX device is used in the TIF procedure to reconstruct the gastroesophageal valve (GEV), restoring its competency and reestablishing the barrier to reflux. The device with SerosaFuse fasteners is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia less than 2 cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

"We've worked through these 60 people in the study and we have accumulated a significant number of patients with pH data and that will be in the next report," Rosemurgy said. "If we're going to get the pH data to show that these procedures have effectively and durably taken care of the acid reflux [then we'll need another study]. It's not just their symptoms we want to fix. We also want their reflux to go away."

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