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GERD transoral surgical startup releases sham-controlled data as it awaits reimbursement code

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EndoGastric Solutions is awaiting the outcome of a CPT code meeting to enable payer reimbursement for its transoral gastroesophageal reflux disease (GERD) surgical device within the next few weeks. In the meantime, the startup has released data on the transoral incisionless fundoplication (TIF) procedure in the latest issue of the journal *Gastroenterology*.

The EsophyX2 device--Courtesy of EndoGastric Solutions

The sham-controlled and randomized study evaluated 87 GERD patients that underwent the TIF procedure with EGS' EsophyX device. After 6 months, 67% percent reported the elimination of troublesome regurgitation. In the sham arm of 42 patients, 45% reported elimination of the same symptom while taking optimized doses of the proton pump inhibitor (PPI) omeprazole.

"This is the first ever randomized blinded trial to focus exclusively on regurgitation," Dr. John Hunter, Mackenzie Professor & Chairman of Surgery at Oregon Health & Science University and co-principal investigator said in a statement.

He continued, "The data demonstrate that the TIF procedure is more effective than optimized PPI drugs at eliminating troublesome regurgitation in selected chronic GERD patients with hiatal hernia less than 2 cm."

The study also found that 77% of the TIF patients had healed reflux esophagitis. At six months, data results were unblinded and participants in the sham arm were given the option of the TIF procedure.

EsophyX is inserted through a patient's mouth and down the esophagus in a manner similar to an endoscope. The device provides a visualization of the procedure as it uses tissue manipulation and 12 or more full-thickness polypropylene fasteners to reconstruct the gastroesophageal valve

and restore its function as a barrier to prevent stomach acids from washing back up into the esophagus.

The startup expects that its target market is the roughly 8 million people in the U.S. who suffer from GERD but aren't sufficiently aided by PPIs and don't want traditional surgery.

The EsophyX was cleared by the FDA in 2007 and has been used on more than 16,000 patients. It has amassed $75 million in U.S. revenues thus far.

EndoGastric CEO Skip Baldino

Up next for the EGS, it hopes to hear back on its application for a CPT code for reimbursement. This is a coding system maintained by the American Medical Association (AMA) that eases the reimbursement process with payers such as Medicare. That event should happen in the next few weeks, the company's president and CEO, Skip Baldino, told *FierceMedicalDevices* in an interview at last week's JP Morgan Healthcare conference.

He said if they get a CPT code approved then broader payer reimbursement should take effect in January 2016. This is a binary event for investors, Baldino said. EGS hopes to fundraise later this year after it gains a CPT code. Those funds would go to accelerate commercialization.

Baldino said current usage of the device is about 85% by surgeons and 15% by GI specialists, a ratio that he expects will shift after reimbursement and usage become more widespread.

- here is the release on the study