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EndoGastric skips toward positive study review for GERD device

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EndoGastric Solutions is trumpeting promising study data for its device for gastroesophageal reflux disease (GERD), weeks after the company picked up a reimbursement code for its procedure to treat the condition.

The EsophyX2 device--Courtesy of EndoGastric Solutions

A review of data from EndoGastric's two multicenter, randomized studies found that the company's transoral incisionless fundoplication (TIF) procedure is more effective than proton pump inhibitor (PPI) drugs at eliminating regurgitation in a subgroup of GERD patients. TIF is also capable of "dramatically eliminating" symptoms with minimal or no side effects, healing esophagitis and improving individuals' quality of life, Dr. Karim Trad, principal investigator of one of the studies, said in a statement.

Trad reviewed the results during a presentation at the annual meeting of the Society of American Gastrointestinal and Endoscopic Surgeons in Nashville, TN.

The company is touting positive numbers for both studies, showing TIF's effectiveness in reducing symptoms for patients with GERD. EndoGastric's EsophyX device is inserted through the patient's mouth with visual help from an endoscope and reconstructs the gastroesophageal valve through the TIF procedure to prevent stomach acids from washing back up into the esophagus. In January, the company released data from a blinded study which showed that more than two-thirds of patients who underwent the procedure had no regurgitation after 6 months. In a sham-controlled arm of the study with 42 patients, 45% of individuals reported elimination of the same symptom.

The study also showed that more than three-quarters of patients had healed their reflux esophagitis after the TIF procedure, a potentially fruitful number as the company looks to expand the reach for its device.

EndoGastric CEO Skip Baldino

Promising findings come at a critical moment for San Mateo, CA-based EndoGastric, as the company eyes more widespread adoption for its EsophyX device and TIF procedure. Last year, the company snagged $30 million in a Series G financing round to help fuel commercialization of its FDA-cleared GERD device. In March, the company picked up a CPT code for its TIF procedure. If all goes according to plan, broader payer reimbursement should take effect in January 2016, president and CEO Skip Baldino told *FierceMedicalDevices* earlier this year.

- read the release