

Gastroenterology publishes landmark data from RESPECT study of Transoral Incisionless Fundoplication procedure

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Significantly More TIF/Placebo Patients Experienced Elimination of Troublesome Regurgitation as Compared to Sham/PPI Patients

EndoGastric Solutions (EGS) announces that *Gastroenterology*, the official journal of the American Gastroenterological Association (AGA) Institute and the most prominent journal in the field of gastrointestinal disease, has published landmark data from the first-ever blinded, randomized, sham- and placebo-controlled clinical study of the Transoral Incisionless Fundoplication (TIF[®]) procedure.

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Of the 87 patients who were randomly assigned to the group that underwent the TIF procedure and then received an ongoing course of placebo medication, after six months 67% reported elimination of troublesome regurgitation per Montreal consensus criteria. Meanwhile, of the 42 patients who were randomized to undergo sham surgery and then continued to take optimized doses of proton pump inhibitor (PPI) regiment (omeprazole), 45% reported elimination of the same symptom (p=0.023).

“Consistent with the Montreal definition, the RESPECT (Randomized EsophyX[®] vs. Sham/Placebo Controlled Trial) study enrolled patients with troublesome regurgitation and objectively confirmed gastroesophageal reflux disease (GERD). This is the first ever randomized blinded trial to focus exclusively on regurgitation,” said John Hunter, MD, Mackenzie Professor & Chairman of Surgery, Oregon Health & Science University and co-principal investigator.

“The data demonstrates 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,” continued Dr. Hunter.

In addition, 77% of the TIF patients had healed their reflux esophagitis. TIF procedure was also associated with a decrease in all acid exposure parameters while patients in the control group had no detectable improvements in pH control (p<0.001).

“In other studies, the therapeutic gain of PPI therapy over placebo for the control of regurgitation is modest. Data from this well designed study suggest that the TIF procedure provides an attractive option to manage troublesome GERD symptoms, especially considering a notable absence of troublesome dysphagia and bloating after the TIF procedure,” said Peter Kahrilas, MD, Professor of Medicine-Gastroenterology, Northwestern University and co-principal investigator.

“We are pleased to have the RESPECT data published in *Gastroenterology*,” said Skip Baldino, President and CEO of EndoGastric Solutions. “In a recent *New England Journal of Medicine*

editorial, the medical device industry was challenged to conduct more sham controlled trials in order to validate novel procedures and devices; we are thrilled that RESPECT has met this most rigorous scientific test.”

Both groups of patients enrolled in the RESPECT study, and their caregivers, were blinded to therapy during follow-up which occurred at two, 12 and 26 weeks. At the six month follow-up, all patients were un-blinded and the sham control patients were given the opportunity to have a TIF procedure.