

Transoral fundoplication is an effective treatment for patients with GERD

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Transoral fundoplication is an effective treatment for patients with gastroesophageal reflux disease (GERD), especially for patients with persistent regurgitation despite proton pump inhibitor (PPI) therapy, according to a new study¹ published in *Gastroenterology*, the official journal of the American Gastroenterological Association.

"Despite therapy, patients with GERD often suffer from troublesome [regurgitation](#), which impairs their quality of life," said lead study author John G. Hunter, MD, from Oregon Health & Science University. "This study offers evidence that transoral fundoplication is effective in eliminating troublesome GERD symptoms, especially regurgitation, with a low failure rate and good safety profile for six months."

Researchers performed a prospective, sham-controlled trial to determine if transoral fundoplication provided GERD patients with better relief of troublesome regurgitation, or the sensation of acid backing up into a patient's throat or mouth, when compared to PPI therapy. The researchers randomly assigned 129 patients with troublesome regurgitation despite daily PPI use to transoral fundoplication using the EsophyX-2 device and six months of placebo, or a sham surgery and six months of once or twice daily omeprazole. Patients were then evaluated for six months.

The primary endpoint in this study, elimination of troublesome regurgitation, was achieved in a greater proportion of patients treated with transoral fundoplication than with omeprazole: 67 percent versus 45

percent. Further, a larger proportion of controls demonstrated no response at three months (36 percent) than patients who underwent transoral fundoplication (11 percent). Subjects from both groups who completed the protocol had similar reductions in GERD symptom scores. Severe complications were rare.

GERD remains one of the most common conditions for which Americans take daily medication, and PPI use has more than doubled in the last decade. Despite this, up to 40 percent of PPI-dependent GERD patients have troublesome symptoms of GERD. Transoral fundoplication—an incisionless procedure that allows physicians to reshape the anti-reflux valve that prevents stomach acid and contents from flowing up into the esophagus—may offer a new treatment option for these patients.

This study provides evidence of transoral fundoplication's efficacy, and will likely lead to more widespread use of the procedure in clinical practice.. To help health-care decision makers make informed decisions regarding this technology, the AGA Center for GI Innovation and Technology has partnered with EndoGastric Solutions® to establish the STAR Registry (Laparoscopic Nissen Fundoplication (LNF) Surgery Versus Transoral Incisionless Fundoplication (TIF®): Anti-Reflux Treatment Registry). The STAR Registry will provide the first real-world data observing patient outcomes following laparoscopic surgery and transoral fundoplication with the EsophyX® device. Learn more about this endeavor <http://www.gastro.org/corporate-relations/center-for-gi-innovation-and-technology/observational-research-device-registries>.

Provided by American Gastroenterological Association

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