

Endoluminal fundoplication by a transoral device for the treatment of GERD: A feasibility study.

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BACKGROUND: A new endoluminal fundoplication (ELF) technique performed transorally using the EsophyXtrade mark device was evaluated for the treatment of gastroesophageal reflux disease (GERD) in a prospective, feasibility clinical trial. **METHODS:** Nineteen patients were enrolled into the study. Inclusion criteria were chronic and symptomatic GERD, proton pump inhibitor (PPI) dependence, and the absence of esophageal motility disorder. Two patients were excluded due to esophageal stricture and a 6 cm hiatal hernia. The median duration of GERD symptoms and PPI use in the remaining 17 patients was 10 and 6 years, respectively. The ELF procedure was designed to partially reconstruct the antireflux barrier through the creation of a valve at the gastroesophageal junction. **RESULTS:** The ELF-created valves had a median length of 4 cm (range 3-5 cm) and circumference of 210 degrees (180-270 degrees). Adherence of the valves to the endoscope was tight (n = 14) or moderate (n = 3). Hiatal hernias present in 13 patients (76%) were all reduced. Adverse events were limited to mild or moderate pharyngeal irritation and epigastric pain, which resolved spontaneously. After 12 months, the ELF valves (n = 16) had a median length of 3 cm (1-4 cm) and a circumference of 200 degrees (150-210 degrees). Eighty-one percent of valves retained their tightness. The hiatal hernias present at the baseline remained reduced in 62% of patients. The median GERD-HRQL scores improved by 67% (17-6), and nine patients (53%) improved their scores by $\geq 50\%$. Eighty-two percent of patients were satisfied with the outcome of the procedure, 82% remained completely off PPIs, and 63% had normal pH. **CONCLUSION:** The study demonstrated technical feasibility and safety of the ELF procedure using the EsophyXtrade mark device. The study also demonstrated maintenance of the anatomical integrity of the ELF valves for 12 months and provided preliminary data on ELF efficacy in reducing the symptoms and medication use associated with GERD.