SAGES 36mo Tempo Trial.

Transoral Fundoplication offers durable symptomatic control for chronic GERD: 3-year final report from the TEMPO randomized trial with a crossover arm

Background: Three previously published randomized controlled studies have demonstrated the short-term (up to 12 months) efficacy and safety of transoral esophagogastric fundoplication (TF) performed with the EsophyX device in eliminating troublesome gastroesophageal reflux symptoms and improving quality of life (QOL) in a sub-set of patients with chronic GERD. The aim of this study was to assess the durability of these outcomes at 36 months follow-up.

Methods: The TEMPO trial (TIF EsophyX vs Medical PPI Open Label Trial) was conducted in 7 US sites. Between June and August 2012, chronic GERD patients with small (<2cm) or absent hiatal hernias and who suffered from troublesome symptoms while on PPI therapy for at least six months and with abnormal esophageal acid exposure (≥5.3%, 48-hour pH-metry) were randomized either to TF group (n=40) or to PPI group (n=23). Following evaluation at six month, all remaining PPI patients (n=21) elected to undergo crossover to TF. During the course of the study, 11 patients (6 TF, 2 PPI and 3 PPI-crossover patients) were lost to follow-up. Therefore, for the purpose of this work, the patient population comprised of the original TF patients (n=34) at 3 year follow-up and the crossover patients (n=18) at 30-month follow-up. GERD symptoms were assessed with 3 validated instruments; GERD Health-related Quality of Life (GERD-HRQL), Reflux Symptom Index (RSI) and Reflux Disease Questionnaire (RDQ). EGD (esophagogastroduodenoscopy) and 48-hour pH-metry was used for objective assessment. Two patients who underwent revisional laparoscopic procedures (1 Nissen, 1 Dor) were included in this analysis.

Results: At the end of study, 38/54 (70%) patients were off daily PPIs. Elimination of troublesome regurgitation was reported by 39/43 (91%) of patients. Atypical symptom control was supported by improvement in the mean RSI score from 21.9±9.0 on PPIs before TIF to 4.2±7.3, $p<0.001$. The RSI score was normalized (≤13) in 40/46 (87%) of patients. The GERD-HRQL score improved from 26.3±9.3 on PPIs before TF to 5.4±8.4, $p<0.001$, indicating control of typical symptoms and improvement in QOL. The total GERD-HRQL and RSI scores

between 12-month and the end of study remained stable ($p>0.05$). The number of reflux episodes was reduced from 172±84 to 107±72, $p<0.001$. Mean total % time pH <4 was improved from 10.2 to 7.8, $p=0.017$. Esophagitis was healed in 20/23 (87%) of patients.

Conclusion: This study demonstrates that TF can be used to achieve long-term control of chronic GERD symptoms, healing esophagitis and improvement in esophageal acid exposure.