Evaluation of the Medigus SRS Endoscopic Stapling System for the Treatment of Gastro-Esophageal Reflux Disease (GERD): Preliminary 6 month Report.

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BACKGROUND: Recently, several endoscopic methods for treating GERD have been introduced to clinical practice. Newly designed SRS Endoscopic Stapling System (Medigus Ltd, Omer, Israel) can be used to rebuild the antireflux valve between the esophagus and the stomach. The SRS System is a specially designed gastroscope which contains a stapler and ultrasonic transducer to measure the thickness of tissue to be stapled. This enables stapling of the fundus of the stomach to the esophagus in two or three locations which are 1-3 cm above the GE junction, and separated by at least 90 degrees. This creates a partial anterior fundoplication and helps restore the angle of His. The purpose of this study was to assess the safety and efficacy of this new method.

METHODS: Patients with an established diagnosis of GERD, who used daily PPI treatment for at least 6 months with at least partial relief of symptoms, were enrolled in the study. Other inclusion criteria were abnormal esophageal pH study and hiatal hernia ≤3 cm, which was reducible with PEEP. Exclusion criteria included esophageal motility disorder, coagulopathy and Barrett's mucosa. GERD symptom was assessed using GERD Health Related Quality of Life (GERD-HRQL) questionnaire. Acid exposure was measured using 24-48 hour Bravo pH testing. Esophageal manometry was performed using Sandhill water perfused equipment. Each test was performed at baseline and 6 months after procedure at least 7 days after discontinuation of PPI treatment.

RESULTS: Twenty two patients were enrolled from Nov. 18 2008 and 19 patients (M:11, F:8) have at least 6 months follow up. Patients' mean age was 44.6 year (23-68). The endoscopic procedure was performed successfully in all enrolled patients with placement of 15 staples (3 staple sets of 5 staples each) per patient. The mean GERD-HRQL was 32.6±5.9 at baseline and 9.5±10.1 at 6 month follow-up ($p<0.001$). Fifteen (79%) patients showed improved GERD-HRQL from baseline of >50% at 6 months. The mean total acid exposure was 10.3±5.7% at baseline and 8.2±3.9% at 6 months. Four (27%) patients had normal acid exposure (pH≤4.5% of time) at 6 months. Twelve (63%) patients showed improved acid exposure after stapling. The mean lower esophageal sphincter pressure (LESP) was 12.6±5.9 mmHg at baseline and 9.7±4.6 at 6 months. Seven (37%) patients showed increased LESP after the procedure. Follow-up endoscopy at 6 month showed intact staple sites in all patients. Hill's grade of the cardia at the end of procedure was Ⅰ or Ⅱ in all patients. At six months, 13 (68%) patients showed improved Hill grade from baseline and 12 patients (63%) were Hill's grade Ⅰ or Ⅱ. All patients reduced or stopped their acid reducing medication at 6 months. Four (27%) patients totally stopped all medication. Fifteen (79%) patients reduced daily PPI dose greater than 50%. There was one (5.3%) major complication of bleeding probably from the staple site with transfusion required.

SUMMARY: SRS System improved GERD-HRQL by at least 50% in 79% of patients, improved Bravo pH in score 63% of patients, reduced PPI use in all patients, but didn't increase the LESP.

CONCLUSIONS: SRS Endoscopic Stapling System is a relatively safe and partially effective endoscopic method to control GERD. Further studies will be needed to define the optimal number and location of stapling treatment.