

Updated Results from a Multi-center Post-marketing Surveillance Registry Study for Endoscopic Anterior Fundoplication

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Abstract

Endoscopic Anterior Fundoplasty (EAF) is a promising alternative to surgical fundoplication in treatment of patients with GERD. MUSE enables endoscopic incisionless stapling of the gastric fundus to the esophagus to restore the flap valve and create a partial anterior fundoplication. In addition; it can correct a small hiatal hernia and prevent the stomach from re-herniation.

Here we present data of post-marketing registry of patents underwent EAF in 13 international centers for management of GERD.

Background

This multi-center open label post-marketing registry collects data before and after EAF using MUSE™ in patients with GERD. Seventy-one patients with documented GERD on PPIs underwent EAF using MUSE in 13 international centers. 1 and 2 years post procedure data is available in 47 and 15 patients respectively. Patients were follow-up at 6 months, 1, 2 and 3 years post-procedure.

Aims of the study

Efficacy and safety assessment of endoscopic anterior fundoplication (EAF) using MUSE™ (Medigus Ultrasonic Surgical Endostapler) for GERD management

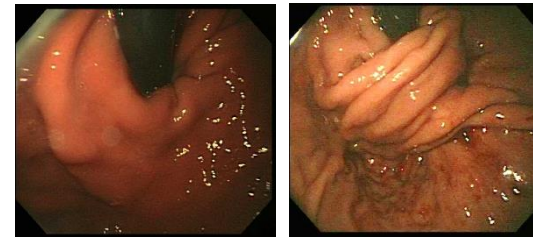
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Inclusion Criteria

- 18-70 years of age
- Symptomatic Gastroesophageal Reflux Disease
- Responsive to Proton Pump Inhibitors

Exclusion Criteria

- Endoscopic Hiatal hernia > 3 cm
- Normal acid exposure test on PH study
- Paraesophageal hiatal hernia
- Esophageal stricture causing dysphasia
- Barrett's Esophagus or grade IV esophagitis
- Esophageal or gastric varices
- Esophageal dysmotility on manometry
- Hill's classification Grade I
- BMI > 35 or <20.



Before and Endoscopic Anterior Fundoplasty using MUSE

Methods

- Baseline PPI GERD-Health Related Quality of Life Questionnaire (GERD-HRQL), treatment satisfaction and Gastroscopy was completed in all of the patients before and after EAF.
- In some patients baseline "off" medications GERD-HRQL, manometry and esophageal ambulatory pH testing off of medications are available.

Results

- GERD-HRQL improved from 24.0 to 10.0 at 1 year after EAF (CI, 7.4 – 12.6, $p < .00001$) and remained improved (10) at 2 years (CI, 4.0 – 16.0, $p < .00019$)
- Patient satisfaction was reported 74% satisfied at 1 year and 64% satisfied at 2 years.
- 70% (33/47) ($p < .00001$) of patients at 1 year and 69% (6/13) ($p < .0009$) at 2 years completely stopped PPI use or reduced PPI usage by $\geq 50\%$
- 87% of patients that responded favorably, stopped daily PPI intake.
- PH study results normalized in 16% (4/25) (%time $\text{pH} \leq 4$), and 68% (17/25) had a reduction of % time pH
- No new device or procedure related adverse events are reported

Conclusions

Data collected from this ongoing registry in patients with GERD after EAF using MUSE shows consistent improvement of symptoms based on GERD-HRQL index and sustained elimination or reduction of PPI usage..