Effective endoscopic treatment of Gastroesophageal Reflux Disease using a new endoscopic stapling system: Results of a prospective controlled multicenter trial

A. Roy-Shapira (Beer Sheva Israel), A. Bapaye (Pune, India), R. Kiesslich (Meinz, Germany), S. Horgan, San Diego, CA, USA, S.F. Schoppmann, Johannes Zacherl (AKV, Vienna, Austria), L. Bonavina (Milan, Italy), G.A. Lehman, Indianapolis, IN, USA

1. Study Aims

The study was designed to test the safety and efficacy of a new device for trans-oral treatment of GERD. The new device is a modified flexible video gastroscopy incorporating a surgical stapler and an ultrasonic sight/rangefinder. It enables a single operator, with skills in advanced endoscopic procedures, to staple the fundus of the stomach to the esophagus about 3 cm above the GE junction, using 2-3 quintuplets of standard B shaped titanium surgical staples. The end result is an anterior fundoplication which is similar to a surgically created Dor-Thal fundoplication.

2. Methods

- Multi center international prospective trial of otherwise healthy patients with moderate to severe GERD and hiatal hernia of up to 3 cm.
- No Barret, or other esophageal disorder, and up to grade III esophagitis.
- Procedure is performed under general anesthesia.
- PEEP of 5-10 mmHg is used to reduce hernia, if present.
- Strict compliance with ICH-GCP rules was enforced.
- 72 subjects were enrolled.
- 6 excluded for protocol violations. Followed only for safety.
- 66 patients were followed for intention to treat.

3. Safety: (72 subjects)

1. Occult perforation resulting in pneumothorax, empyema, treated by chest tube drainage and antibiotics.
2. Case of bleeding, requiring transfusion of 2 units of blood, unidentified source.
3. Case of asymptomatic pneumomediastinum, took a long time to resorb.
4. Additional procedure-related SAEs, considered mild, involved pain and fever.

All device-related SAEs occurred in the first 24 subjects. All resolved within 30 days. Following changes to the IFU and protocol, No further device-related SAEs were observed.

4. Efficacy: (66 subjects)

At six-month in comparison to baseline:

- 75.0% met primary success criterion of >50% reduction in OFF-PPI GERD-HRQL scores
- Median GERD HRQL score dropped from 29 to 6 (p<0.001)
- Mean Acid exposure dropped from 11.05 to 7.30 (p=0.002)
- PPI usage reduced by ≥50% in 85% (p<0.001)
- 77% of patients (46/60) demonstrated an improved flap valve angle.

5. Conclusions

- This study shows that endoscopic stapling using the Medigus SRS device is a safe and effective endoscopic treatment for GERD patients.
- The newly developed Medigus stapling device can endoscopically restore the gastroesophageal flap valve, functionally similar to anterior fundoplication.
- The procedure, done under general anesthesia, showed acceptable complications (9%), high efficacy rates (75%) and can be recommended for patients with small hernias (up to 3 cm).

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