

Endoscopic Anterior Fundoplication with the Medigus Ultrasonic Surgical Endostapler (MUSE™): Results from an Ex-vivo Simulation Trial to Assess the Efficacy of the Procedure by Comparing Stapling Position and Gastric Yield Pressures

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BACKGROUND & AIMS

- Gastroesophageal reflux disease (GERD) is the result of lower esophageal sphincter (LES) dysfunction caused by inappropriate transient LES relaxation or diminution of resting basal pressure. Recently, the Medigus Ultrasonic Surgical Endostapler (MUSE™, Medigus, Omer, Israel), a combined video- and ultrasound-guided transoral surgical stapler, has been FDA-approved for endoscopic anterior fundoplication. Aim of this study is to determine the ideal position of the staples in relation to the gastroesophageal junction (GEJ) in a validated simulation model.

METHODS

- MUSE procedures were performed in the EASIE-R simulator (Endosim LLC, Hudson, MA) using fresh ex-vivo porcine stomachs (Figure 1). As a surrogate for LES function, the gastric yield pressure (GYP) was determined by inserting an 18-Gauge cannula into the stomach lumen, which was connected to a pressure transducer (Figure 2). The stomach was gradually filled with methylene-dyed normal saline using a roller pump. The GYP was determined by detection of reflux of the methylene-dyed water in the esophagus with a gastroscope positioned above the GEJ. We also compared the aimed staple location with the actual measured stapler location following the procedure.

Figure 1. Endoscopic stapling with MUSE in the EASIE-R simulator



RESULTS

- We performed eight MUSE procedures in eight ex-vivo porcine stomachs. Figure 3 shows the ex-vivo procedure setup. After the MUSE procedure, GYP pressure and stapling distance from GEJ was measured (Figure 4). We observed a discrepancy of 5-10mm between targeted distance and actual measured distance between stapling location and GEJ.

Figure 3. Measurement of GYP pressure

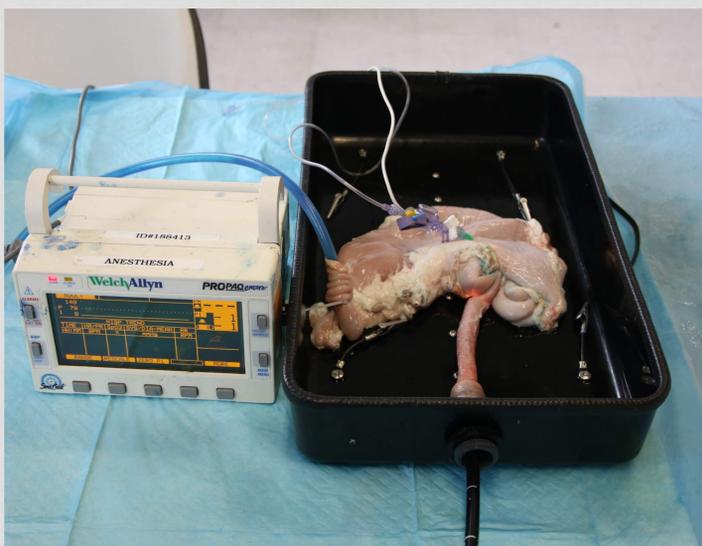


Figure 4. Ex-vivo stomach after the Medigus procedure



Figure 4. Measurement of stapling distance from GEJ



- Results of GYP pressure and distance between stapling position and GEJ was shown in Table 1. Baseline GYP was 0 mm Hg in all stomachs. Mean GYP increase after the Medigus procedure was 10.0 ± 10.2 mmHg. We observed a gradual increase in GYP with the distance of stapling position and GEJ. Procedures with a distance of at least 30mm between GEJ and stapler location resulted in an improved LES valve mechanism with an increase in GYP in comparison to baseline. If the distance was less than 30mm the LES valve was insufficient (GYP less than 6 mm Hg).

Table 1. Results of endoscopic stapling with MUSE in the EASIE-R simulator

	Measured 1st Stapling Position (anterior)	Measured 2nd Stapling Position (posterolat.)	Post-treatment GYP in mmHg
Procedure 1	5	15	0
Procedure 2	20	15	1
Procedure 3	25	20	3
Procedure 4	25	25	6
Procedure 5	35	35	10
Procedure 6	25	25	25
Procedure 7	40	40	9
Procedure 8	45	45	26

CONCLUSIONS

- Based on our experiments, there should be a minimal distance of 30 mm between each stapler location and the GEJ to create an efficient valve with the MUSE procedures. Limitations of this study are the small sample size and the use of an ex-vivo model with lack of intrinsic LES pressure.