



Efficacy and safety of an internal magnet traction device for endoscopic submucosal dissection: ex vivo study in a porcine model (with video)

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Abstract

Background Appropriate traction allows for safer and easier endoscopic submucosal dissection (ESD). The aim of this study was to evaluate the efficacy and safety of an internal magnet traction device (MTD) for ESD in an ex vivo porcine model.

Methods The MTD consisted of a small neodymium magnet and a suture attached to a through-the-scope clip. A circumferential mucosal incision was completed around a 30-mm diameter template that served as the target lesion. The first MTD was deployed at the proximal edge of the lesion. A second MTD was deployed on the wall opposite the lesion. With both magnets connected, this created traction or lifting of the target lesion towards the opposing wall during submucosal dissection. Primary endpoint was comparison of submucosal dissection times between conventional ESD (C-ESD) and MTD-assisted ESD (MTD-ESD).

Results Twenty lesions along the anterior wall, posterior wall and greater curvature were resected using either C-ESD or MTD-ESD. The submucosal dissection time in MTD-ESD was significantly shorter than C-ESD (median: 6.4 [interquartile range {IQR} 4.6–8.7] min vs. 14.4 min [IQR 11.8–18.0], $p < 0.05$). There was a significant difference between MTD-ESD and C-ESD in total procedure times for lesions on the posterior gastric wall and greater curvature (median: 23.0 min [IQR 21.1–24.5] vs. 29.2 min [IQR 24.8–33.2], $p < 0.05$) with no difference for lesions on the anterior gastric wall (median: 18.8 min [IQR 15.5–20.5] vs. 17.1 min [IQR 13.1–20.0], $p = 0.5$). The number of muscularis propria injuries per lesion was significantly lower in MTD-ESD than C-ESD (median: 0 [IQR 0–0] vs. 1 [IQR 0–2], $p < 0.05$).

Conclusions MTD for ESD is effective and safe when compared to C-ESD. This approach significantly reduced submucosal dissection times with less injury to the muscularis propria. Furthermore, MTD-ESD was particularly beneficial for more challenging gastric lesions located on the posterior wall and greater curvature.

Keywords Endoscopic submucosal dissection · Traction · Internal · Magnet · Stomach · Porcine

Abbreviations

ESD Endoscopic submucosal resection
MTD Magnet traction device

MTD-ESD Magnet traction device-assisted endoscopic submucosal dissection
C-ESD Conventional ESD

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Endoscopic submucosal dissection (ESD) allows for *en bloc* resection and accurate histopathological diagnosis of targeted lesions [1]. One of the key benefits of ESD is a lower recurrence rate in early esophageal, gastric, and colorectal cancers compared to endoscopic mucosal resection [2–7].

ESD is facilitated by devices or methods that enable lesion traction during submucosal dissection, enhancing safety and efficiency of the procedure [8]. Several methods have been reported to provide appropriate traction during submucosal dissection, but most devices depend on the

endoscopic longitudinal direction, external magnets, lesion location, or thickness of the abdominal wall, with ineffective traction attained in the majority of cases [8–17]. Thus, we developed a unique internal magnetic traction device (MTD) that is unaffected by these factors. The aims of this study were to evaluate the efficacy and safety of the MTD for ESD in a porcine model *ex vivo*.

Materials and methods

This was a comparative *ex vivo* study that was exempt from approval by the Institutional Animal Care and Use Committee.

Experimental setting

All procedures were performed in explanted porcine stomachs. Each stomach was inverted from an incision along the greater curvature of the gastric body, and coagulation marks were made using argon plasma coagulation (Genii Inc., St Paul, MN) around a 30-mm diameter paper template at five different sites: anterior and posterior walls of the lower gastric body, anterior and posterior walls of the upper gastric body, and the greater curvature of the gastric body. The stomachs were then everted and the incision closed using 2–0 silk sutures. The stomachs were placed in a commercial *ex vivo* trainer (Endo-X-Trainer, Medical Innovations Inc., Rochester, MN) and an overtube (US Endoscopy Inc., Mentor, OH) inserted into the esophagus.

Magnet traction device (MTD)

This prototype device consists of a commercially available small neodymium magnet ring ($3/16''$ od \times $1/16''$ id \times $1/16''$ thick; pull force: 0.7 lb; K&J Magnetics Inc., Plumsteadville, PA) attached to a through-the-scope clip (QuickClip; Olympus America Inc., Center Valley, PA or Resolution clip; Boston Scientific Inc., Marlborough, MA) using a 2–0 silk suture. The length of the suture between the clip and magnet was 2 cm (Fig. 1).

ESD procedure (Fig. 2, video)

A standard gastroscope (GIF-H180; Olympus America Inc.) with a transparent hood (D-201-11804; Olympus America Inc.) at its tip was used. All procedures were carried out by a single expert endoscopist (AD) with more than 300 clinical cases of ESD. A submucosal cushion was created using an injection of saline and methylene blue solution. A circumferential mucosal incision was made along the coagulation marks using an electro-surgical knife (Dual knife, Olympus America Inc.). In MTD-assisted ESD (MTD-ESD), the



Fig. 1 MTD. A magnet ($3/16''$ od \times $1/16''$ id \times $1/16''$ thick, pull force: 0.7 lb) attached to a through-the-scope clip (Resolution Clip, Boston Scientific, Marlborough, MA)

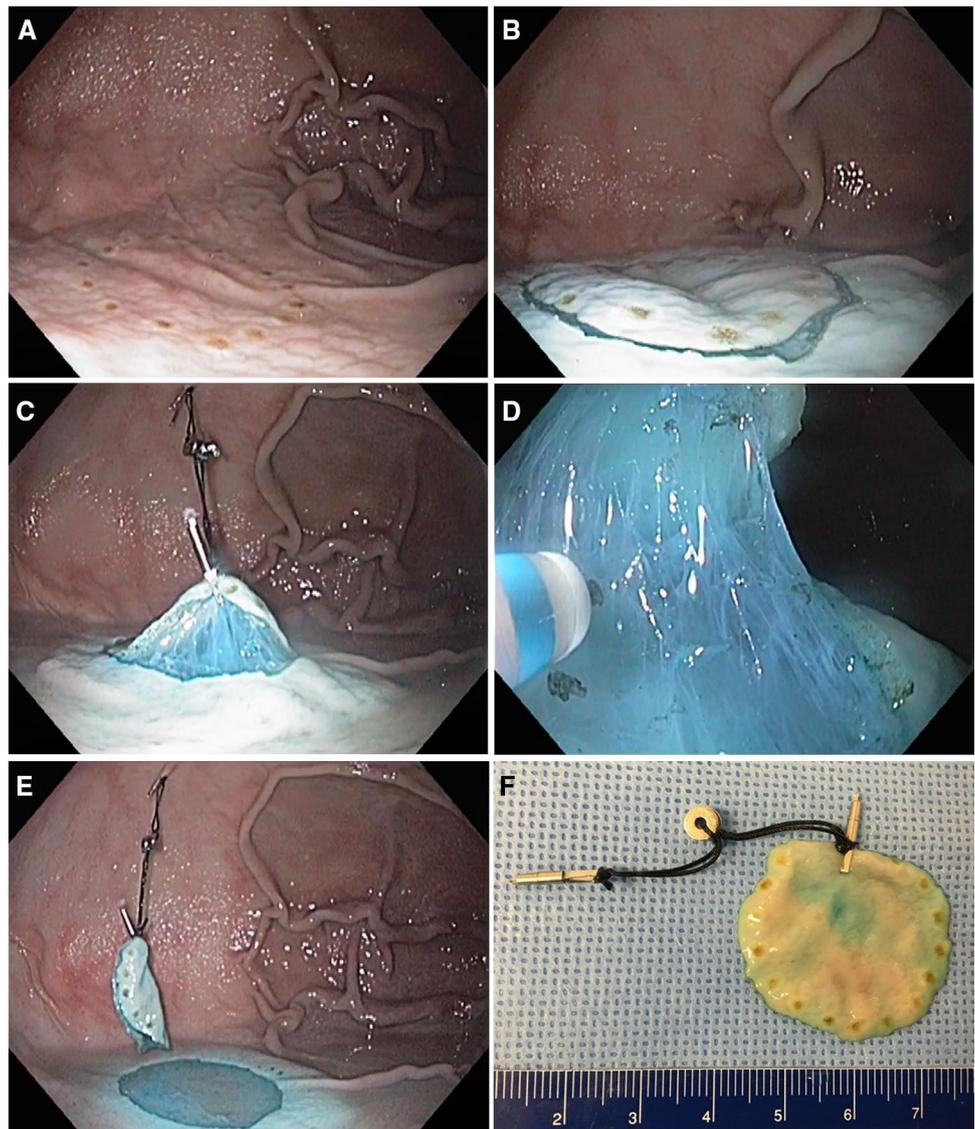
endoscope was withdrawn and the first MTD back-loaded through the working channel of the endoscope. The MTD was deployed at the proximal edge of the lesion. The endoscope was removed again and a second MTD back-loaded onto the endoscope. Once the two magnets of the MTDs had connected in the stomach, the placement and location of the second MTD on the opposing gastric wall was determined by the observed traction created between the connected devices. The degree of traction or lifting of the target lesion towards the opposing wall during submucosal dissection could be easily controlled by air insufflation. The total suture length when both MTDs are attached is 4 cm (each MTD has a fixed suture length of 2 cm). Both minimal and maximal distances between the lesion and the opposing wall can be controlled directly by the endoscopist using the degree of luminal distension.

Submucosal dissection was completed using the Dual knife. Once the targeted lesion was resected, the through-the-scope clip on the opposing wall and the resected tissue were removed using a snare (Olympus America Inc.). In conventional ESD (C-ESD), submucosal dissection was performed using only the Dual knife after completion of the circumferential mucosal incision.

Outcome measurements

The primary outcome measure was comparison of submucosal dissection times between MTD-ESD and C-ESD. Secondary outcomes measured included the rate of *en bloc* resection, time for MTD deployment, volume of submucosal injection, total procedure time, specimen size, visualization of the submucosal layer during dissection, iatrogenic injury of the muscularis propria, and ease of use for MTD-ESD. Total procedure time was defined as time from circumferential incision to retrieval of the resected specimen. Muscularis propria injury was defined as any defect caused by the

Fig. 2 ESD using the MTD. **A** Lesion located on the posterior wall of the upper gastric body. **B** Circumferential mucosal incision was completed. **C** Two MTDs were deployed to connect the lesion to the opposing gastric wall. **D** Clear visualization was obtained during submucosal dissection. **E** The lesion was removed without trauma to the underlying muscle layer. **F** Resected specimen with attached MTDs



Dual knife that was confined to the muscularis propria layer without perforation. Ease of use was evaluated using a visual analog scale ranging from 0 (poor) to 5 (excellent). Visualization of the submucosal layer was evaluated by using the proportion of time that the submucosa was clearly visualized during submucosal dissection (SM ratio) according to a previous report [18]. Two independent assessors (ACS, ER) reviewed the 20 recorded videos on C-ESD and MTD-ESD and the mean value of the SM ratio was calculated.

Statistical analysis

Quantitative parameters were compared using Student's *t* test or the Mann–Whitney U test and qualitative parameters with Pearson's χ^2 test. $p < 0.05$ was considered statistically significant. Statistical analysis was performed using Stata 12.0 software (Stata Corp., College Station, TX).

Results

Twenty target lesions were created in five porcine stomachs (three to five lesions per stomach) along the anterior and posterior walls, and greater curvature. Ten lesions each were resected using either MTD-ESD or C-ESD (Table 1). *En bloc* resection was successfully completed without perforation in all cases. Traction was easily controlled by insufflation of the lumen with air in MTD-ESD group. The median time for deployment of both MTDs was 3.4 min (IQR [interquartile range] 2.7–3.5). All MTDs and through-the-scope clips were successfully retrieved. The submucosal dissection time for MTD-ESD was significantly shorter than in C-ESD (median: 6.4 min [IQR 4.6–8.7] vs. 14.4 min [IQR 11.8–18.0], $p < 0.05$). The SM ratio was significantly higher in the MTD-ESD group compared to C-ESD [93.0% (IQR 88.4–94.8) vs. 35.2% (IQR 24.6–63.0), $p < 0.05$].

Table 1 Magnetic traction-assisted ESD vs. conventional ESD

	MTD-ESD (n = 10)	Conventional ESD (n = 10)	P value
Total procedure time (min), median (IQR)	21.0 (20.2–23.2)	24.2 (17.4–32.2)	0.2
Circumferential incision	10.2 (8.4–12.2)	9.7 (6.9–13.2)	0.9
MTDs deployment	3.4 (2.7–3.5)	N/A	-
Submucosal dissection	6.4 (4.6–8.7)	14.4 (11.8–18.0)	<0.05
Total volume of submucosal injection (ml), median (IQR)	25 (23–28)	28 (20–31)	0.3
Injection during the circumferential incision	20 (16–21)	17 (14–19)	0.2
Injection during submucosal dissection	4 (3–5)	12 (6–13)	<0.05
Specimen size (mm), median (IQR)	38 (36–40)	39 (36–40)	0.9
SM ratio (%), median (IQR)	93.0 (88.4–94.8)	35.2 (24.6–63.0)	<0.05
Number of muscular injuries per lesion; median (IQR)	0 (0–0)	1 (0–2)	<0.05
Ease-of-use score for MTD, median (IQR)*	5 (5–5)	N/A	-

ESD endoscopic submucosal dissection, MTD magnet traction device, IQR interquartile range

*Score based on a visual analog scale (0 = poor, 5 = excellent); SM ratio = proportion of time that the submucosa was clearly visualized during submucosal dissection

Furthermore, the number of muscularis propria injuries per lesion was significantly lower in MTD-ESD than C-ESD (median: 0 [IQR 0–0] vs. 1 [IQR 0–2], $p < 0.05$). The ease-of-use score for MTD-ESD was excellent (median: 5 [IQR 5–5]). The volume of submucosal injection used in MTD-ESD was significantly lower than in C-ESD (median: 4 ml [IQR: 3–5] vs. 12 ml [IQR 6–13], $p < 0.05$). There was no difference in specimen size between the two groups (median: 38 mm [IQR 36–40] vs. 39 mm [IQR 36–40], $p = 0.9$).

There was no significant difference in overall total procedure time for all lesions, including MTD deployment and removal, compared to C-ESD (median: 21.0 min [IQR 20.2–23.2] vs. 24.2 min [IQR 17.4–32.2], $p = 0.2$). However,

with subgroup analysis, there was a significant difference between MTD-ESD and C-ESD in total procedure time for lesions on the posterior gastric wall and greater curvature (median: 23.0 min [IQR 21.1–24.5] vs. 29.2 min [IQR 24.8–33.2], $p < 0.05$) but not with lesions located on the anterior gastric wall (median: 18.8 min [IQR 15.5–20.5] vs. 17.1 min [IQR 13.1–20.0], $p = 0.5$) (Table 2). In addition, there were significant differences between MTD-ESD and C-ESD in submucosal dissection times, SM ratio, and muscularis propria injuries for lesions on the posterior gastric wall and greater curvature. In contrast, there was no difference in these assessed parameters for lesions on the anterior gastric wall (Table 2).

Table 2 Subgroup analysis based on location of lesions

	MTD-ESD	Conventional ESD	p value
Total procedure time (min), median (IQR)			
Anterior gastric wall	18.8 (15.5–20.5)	17.1 (13.1–20.0)	0.5
Posterior gastric wall and greater curvature	23.0 (21.1–24.5)	29.2 (24.8–33.2)	<0.05
Submucosal dissection time (min); median (IQR)			
Anterior gastric wall	5.3 (4.2–6.3)	11.2 (6.7–13.4)	0.2
Posterior gastric wall and greater curvature	8.7 (6.3–11.9)	17.0 (14.1–19.8)	<0.05
SM ratio (%), median (IQR)			
Anterior gastric wall	91.2 (88.4–100)	54.4 (33.8–98.1)	0.1
Posterior gastric wall and greater curvature	93.6 (88.3–94.8)	29.5 (22.1–36.1)	<0.05
Number of muscular injuries per lesion; median (IQR)			
Anterior gastric wall	0 (0–0)	0 (0–1)	0.3
Posterior gastric wall and greater curvature	0 (0–1)	2 (1–2)	<0.05

MTD-ESD Magnet traction device-assisted endoscopic submucosal dissection, ESD endoscopic submucosal dissection, IQR interquartile range, SM ratio proportion of time that the submucosa was clearly visualized during submucosal dissection

Discussion

This is the first report of ESD assisted by internal MTDs. This *ex vivo* study assessed the efficacy and safety of gastric MTD-ESD when compared to C-ESD. The innovative device was easily deployed, and the resultant traction allowed for a clear view of the submucosal layer, resulting in shorter dissection times. Lesions on the posterior gastric wall and greater curvature especially benefitted from the MTDs with improved procedure times and reduced muscle injuries, while lesions located on the anterior gastric wall had adequate exposure of the submucosal layer just from the inherent traction of gravity [9]. In our study, the devices were all placed in the gastric body. However, it is likely that the pre-pyloric region may be challenging due to the limited working space. MTDs should be selectively used based on lesion location.

Magnetic anchor-guided ESD was reported with both an external magnet and an internal magnet [8–11]. The disadvantages of using an external magnet include the need for a strong magnetic field as magnetic attraction becomes weaker with increasing distance between the internal and external magnets, which is often caused by a thicker abdominal wall. In addition, the direction of traction is limited within a three-dimensional hemisphere [9]. Matsuzaki et al. reported that 14% (7/50) of internal magnets detached from the lesion due to strong magnetic forces exerted by the external magnets [11]. Our internal dual MTD system is not influenced by the thickness of the abdominal wall or the location of the lesion, and exerts a relatively weaker magnetic force. The second MTD, which is an alternative to the external magnet, can be placed anywhere within the stomach with appropriate tension obtained. An appealing and key feature of this device was the degree of traction that could be easily controlled by increasing or decreasing distention of the lumen.

Several methods have been previously reported to provide appropriate traction during submucosal dissection; however, the majority of these devices depend on the endoscopic longitudinal direction, with ineffective traction attained [15–17]. S–O clip has been described clinically as a traction device for colon and gastric ESD [13, 14]. The S–O clip is classified as an internal traction method [12] and the fundamental concept is similar to our MTD system. The internal traction method can determine the direction of the traction, which is important for ESD. However, the S–O clip has some limitations, including challenges in grasping and re-positioning the clip, and fracture of the spring of the clip if over-stretched [14]. With the MTD, the immediate magnetic connection eliminates the difficulties described with grasping the S–O clip and, if over distension occurs, the magnets disconnect and

tissue injury averted. In addition, the second MTD can be removed and re-positioned as required to change the direction of traction. Other techniques and options available for ESD include submucosal tunneling [19], underwater technique [20], and dedicated traction devices such as the EndoLifter (Olympus America Inc.) [18] and LumenR (Boston Scientific Inc.) [21], which is a new endoscopic platform. However, our device is easy to use in contrast to these options that require advanced training.

Our study limitations include the *ex vivo* setting and performance of all procedures by a single expert endoscopist. The risk of bleeding, especially with removal of the second MTD, could not be assessed using this model. In the present iteration, this system cannot be passed through the working channel of an endoscope. Thus, overtube placement was necessary for safer and multiple esophageal intubations. Future iterations would include a through-the-scope device. The length of the suture is also fixed at 2 cm but innovative configurations will allow for adjustable suture lengths. Development of a commercial product for clinical use is currently underway. The use of this device will likely be feasible in the colon but potentially challenging in the esophagus due to the limited working space.

In conclusion, this novel internal MTD for ESD appears to be both effective and safe particularly for lesions on the posterior gastric wall and greater curvature. Furthermore, this approach significantly improved submucosal dissection times and visualization of the submucosal layer with reduced muscle injuries.

Author contributions Endoscopic procedure, manuscript writing: AD. Preparation for *ex vivo* experiment: JL, CAM, and MAK. Data analysis and manuscript editing: ACS, LMWKS, CJG, and ER.

Compliance with ethical standards

Disclosures Akira Dobashi and Elizabeth Rajan have intellectual property with Medtronic. Christopher Gostout is Chief Medical Officer for Apollo Endosurgery and a consultant for Olympus Medical Systems. Andrew C. Storm, Louis M. Wong Kee Song, Jodie L. Deters, Charles A. Miller and Mary A. Knipschild have no conflict of interest or financial ties to disclose.

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