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A novel magnetic countertraction device for endoscopic submucosal dissection significantly reduces procedure time and minimizes technical difficulty

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Abstract

Background and study aims—In endoscopic submucosal dissection (ESD), effective countertraction may overcome the current drawbacks of longer procedure times and increased technical demands. The objective of this study was to compare the efficacy of ESD using a novel magnetic countertraction device with that of the traditional technique.

Methods—Each ESD was performed on simulated gastric lesions of 30mm diameter created at five different locations. In total, 10 ESDs were performed using this novel device and 10 were performed by the standard technique.

Results—The magnetic countertraction device allowed directional tissue manipulation and exposure of the submucosal space. The total procedure time was 605 ± 303.7 seconds in the countertraction group vs. 1082 ± 515.9 seconds in the control group ($P=0.021$).

Conclusions—This study demonstrated that using a novel magnetic countertraction device during ESD is technically feasible and enables the operator to dynamically manipulate countertraction such that the submucosal layer is visualized directly. Use of this device significantly reduced procedure time compared with conventional ESD techniques.

Introduction

Improvement in the diagnostic accuracy of screening endoscopy has resulted in higher detection rates of large, flat, neoplastic gastrointestinal lesions [1–4]. Early lesions within the mucosal layer rarely metastasize to peripheral regional lymph nodes, making them theoretically suitable for endoscopic resection without lymph node dissection. Endoscopic submucosal dissection (ESD) enables curative removal of larger lesions that cannot be removed by endoscopic mucosal resection in an en bloc fashion. Even though ESD is less invasive than traditional surgical resection, current ESD procedures are not used widely in the USA, partly because they are labor intensive.

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The goal of this study was to develop and assess a novel assistive device that provides dynamic, multidirectional countertraction during ESD, and to compare its efficacy with the conventional ESD technique.

Methods

Description of the magnetic countertraction device

The magnetic countertraction device consists of two rare-earth magnets—the smaller magnet is intraluminal and controlled by a larger extracorporeal magnet. The intraluminal magnet is a disc magnet (12×12×3mm) attached in equidistant fashion by 5-cm 2–0 silk sutures to two hemostatic clips (Resolution clips, Boston Scientific, Na-tick, Massachusetts, USA) (**Fig. 1a**). The larger magnet is 100×100×25mm (**Fig. 1b**). The rare-earth magnets are constructed from N42 grade, axially magnetized neodymium-iron-cobalt (K&J Magnetics Inc., Jamison, Pennsylvania, USA).

Preparation of the stomach model

A 5-cm incision was made at the greater curvature in the upper body of the resected porcine stomachs. The stomachs were then lavaged and inverted to expose the mucosal side. In each stomach, five simulated gastric lesions were created by marking dots around a standard circular template of 30mm in diameter (**Fig. 2**). Lesions were simulated at the anterior and posterior wall in the lower gastric body, the greater curvature in the middle gastric body, and the anterior and posterior wall in the proximal gastric body. Stomachs were then everted and fixed to a specialized experimental platform [5] after closure of the incision line with a running suture.

ESD procedure

In total, 10 ESDs were performed using the magnetic countertraction device (countertraction group) and 10 were performed using a standard technique (control group). A single endoscopist with extensive experience in ESD (H.A.) performed all procedures using standard ESD knives (Flex Knife and IT Knife; Olympus Medical Systems, Tokyo, Japan). Following the submucosal injection of saline, a round circumferential incision was made in all cases. Subsequently, in the control group, submucosal dissection was performed using the conventional technique. The endo-scope tip was used to visualize the submucosal dissection layer and saline was injected into the submucosal layer as necessary. In the countertraction group, the magnet was affixed near the tip of a double-channel upper endoscope (GIF-2TH-180, Olympus Medical Systems; **Fig. 3**), which was then introduced into the stomach. Using hemoclips with re-opening capability (Resolution clip; Boston Scientific), each clip was separately fixed to the edge of the incision. During submucosal dissection, an external high-power magnet was used to attract the internal magnet and to dynamically control the direction of countertraction. A single-channel upper endoscope was used to perform all ESDs in both study arms.

Time was recorded separately for circumferential incision and submucosal dissection, and maximum diameter of the specimen was determined following resection.

Results

The mean time for clip application was 140 ± 22.4 seconds (**Table 1**). Reliable external/internal magnet coupling as well as clip retention for the entire duration of the procedure was achieved in 100% of procedures (10/10). The two anchor points of the device provided the endoscopist with broad and direct visualization of the submucosal layer during submucosal dissection (**Fig.4a,b**). The traction angle could be precisely adjusted by the assistant in order to provide the endoscopist with the broadest view of the dissection line (**Fig.4a**). In the final stage of submucosal dissection for the lesion simulated at the anterior wall in the proximal body, the endoscope shaft was used as the pivot point for suture pulley (**Fig.4c**).

The total procedure time for the countertraction group was significantly lower than the control group (605 ± 303.7 vs. 1082 ± 515.9 seconds; $P=0.021$). When the total procedure time was subdivided into specific steps (**Table 1**), the mean time for submucosal dissection in the countertraction group was significantly shorter than that for the control group (296 ± 70.1 vs. 899 ± 146.2 seconds; $P<0.001$).

Within the control group, lesions in the proximal stomach required a significantly longer total procedure time compared with lesions in the middle or lower gastric body (1524 ± 331.0 vs. 641 ± 44.4 seconds; $P<0.001$) (**Table 2**). This was largely due to the time required for submucosal dissection (1286 ± 312.2 vs. 513 ± 72.6 seconds; $P<0.001$). However, in the countertraction group, there was no statistically significant difference between lesion locations in terms of the total procedure time or time for submucosal dissection (**Table 2**).

There was no significant difference in specimen diameter (37.7 vs. 38.6 mm; $P=0.109$), and there were no perforations or other adverse events in either group.

Discussion

ESD requires precise maneuvering of the endoscope. During circumferential incision, the ESD knife needs to accurately trace just outside the circular marking dots in order to avoid both incomplete resection of the lesion and excessive resection of normal tissue. The most critical and demanding phase of ESD is considered to be the initiation of submucosal dissection, in which the operator sometimes blindly dissects the submucosal tissue concealed underneath the mucosal layer. In addition, the tip of the endoscope must be inserted beneath the mucosal flap to ensure direct vision of the dissection layer and to avoid unintended bleeding or perforation. Conventionally, the flap elevation has been achieved by taking advantage of gravity or a transparent cap attached to the tip of the endoscope [6]. The process of submucosal tissue dissection has similarities to open or laparoscopic abdominal surgery, in which the operator incises the connective tissue between the target organ and supportive structures. In surgery, countertraction provided by an assistant surgeon is necessary to prevent inadvertent thermal injury to the surrounding normal organs. The traction force should be adjusted toward the most effective direction to complete each individual procedure. However, such countertraction is not currently available in conventional ESD and the lack of countertraction theoretically represents the main drawback

of ESD. In the current study, the magnetic force provided by the novel countertraction device effectively enabled the operator to gain direct vision of the submucosal connective tissue and thus provided straightforward identification of the dissection line.

The magnetic countertraction device used in this study employed two sutures attached to the smaller magnet. This feature facilitates countertraction anchoring from two traction points, resulting in ideal “triangulation.” This provides the operator with a direct line of sight to the dissection layer that is potentially broader than those provided using other traction procedures [7–13]. This is a simple and inexpensive device that consists of only two magnets, sutures, and standard endoscopic clips, and it is this simplicity that represents the greatest advantage of this device compared with the previously reported magnetic countertraction system [14].

Another significant advantage of this device is that by using magnetic force, the assistant can adjust the direction of countertraction in accordance with the operator's preference. The magnet can be freely manipulated within a three-dimensional hemisphere, thus potentially facilitating countertraction regardless of lesion location. In addition, we believe that this countertraction method can reduce the learning curve for trainees, as the assistant (expert) can provide the operator (trainee) with the most desirable view of the operative field, which is analogous to surgical training. This method could be utilized in ESD hands-on training. This study showed reduced procedure time for an operator who was experienced in ESD; however, this impact may be even greater for ESD trainees.

This study was ex vivo with procedures performed by a single experienced endoscopist and thus results may not be directly applicable to the clinical setting. However, we believe that in the in vivo setting, the direct vision of the submucosal layer will enable endoscopists to avoid inadvertent perforation and to identify submucosal thick vessels, which can be coagulated to prevent bleeding. These results have encouraged our group to pursue in vivo studies, which are currently under way. We intend to assess whether the external magnet has sufficient magnetic power for in vivo use, and whether this method is similarly effective in colorectal ESD. Additionally, we intend to assess whether large body habitus might affect feasibility.

In conclusion, we have developed and evaluated a simple magnetic countertraction device to enhance exposure of the dissection line during ESD. Regardless of lesion locations, the vector of countertraction could be dynamically adjusted over the course of the procedure in three dimensions according to endoscopist preference, and resulted in significantly reduced procedure times.

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Fig.1.
The magnetic countertraction device. **a** The smaller magnet (12×12×3mm) with two 2–0 silk sutures. **b** The larger magnet (100×100×25 mm), which enables extracorporeal control of the smaller magnet.

Fig.2. Inverted ex vivo stomach model. Initially, gastric lesions were simulated by marking dots around the 30-mm template.

Fig.3. Double-channel upper endoscope with the magnetic device. The two loop-shaped ends of the sutures were captured by hemoclips.

Fig.4. Endoscopic submucosal dissection using a magnetic countertraction device. **a** Simulated gastric lesion at the anterior wall in the upper body after circumferential dissection. **b** The outer magnet effectively attracted the inner magnet from the posterior wall side and the proximal edge of the isolated mucosa was effectively elevated. **c** In the final stage of submucosal dissection, the endoscope shaft could be used as the pivot point for suture pulley.

Table 1

Procedure time and specimen size.

	Magnetic device	Control	<i>P</i> value
Total procedure time, seconds	605 ± 303.7	1082 ± 515.9	0.021 *
Circumferential incision	168 ± 75.5	183 ± 73.2	0.657
Device deployment	140 ± 22.4	–	
Submucosal dissection	296 ± 70.1	899 ± 146.2	<0.001 *
Specimen size, mm	37.7	38.6	0.109

* Statistically significant (unpaired *t* test).

Table 2

Procedure time based on lesion location.

	Upper gastric body	Middle or lower gastric body	<i>P</i> value
Total procedure time, seconds			
Magnetic device	665 ± 336.6	545 ± 292.1	0.565
Control	1524 ± 331.0	641 ± 44.4	<0.001 *
Time for submucosal dissection, seconds			
Magnetic device	378 ± 242.4	215 ± 185.3	0.268
Control	1286 ± 312.2	513 ± 72.6	<0.001 *

* Statistically significant (unpaired *t* test).