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Effectiveness of water pressure method in colorectal endoscopic submucosal dissection by novice endoscopists

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ABSTRACT

Background and study aims Colorectal endoscopic submucosal dissection (ESD) remains challenging for novice endoscopists. Not only the underwater conditions but also active use of water pressure with the water pressure method (WPM) can help widen the submucosal layer. This study aimed to clarify the usefulness of WPM in colorectal ESD, especially for novice endoscopists.

Methods This study was ex vivo and enrolled three novices. Each endoscopist performed conventional ESD (C-ESD) and ESD with WPM (WPM-ESD) 10 times on an excised bovine rectum. The treatment outcomes were compared between the two groups.

Results Median procedure time was significantly shorter in the WPM-ESD group than in the C-ESD group (54 minutes, interquartile range [IQR] 42–67 vs. 45 minutes, IQR 34–55, $P = 0.035$). Although no significant difference in the activation time of electrical surgical unit (ESU) during the procedure was noted, the interval time during the procedure at which the ESU was not activated was significantly shorter in the WPM-ESD group (52 minutes, IQR 40–65 vs. 42 minutes, IQR 32–52, $P = 0.030$) than in the C-ESD group. Moreover, the time required for the endoscope to enter the submucosa was significantly shorter in the WPM-ESD group than in the C-ESD group (8.0 minutes, IQR 6.0–10 vs. 5.0 minutes, IQR 3.0–6.0, $P < 0.001$).

Conclusions The present study reveals that the WPM method significantly shortens the procedure times for novices in colorectal ESD, especially the interval time, which refers to the time spent creating the field of view, and the time required for the endoscope to enter the submucosa.

Introduction

Endoscopic treatment is a minimally invasive and widely used modality for superficial colorectal lesions. The European Society of Gastrointestinal Endoscopy guidelines state that polypectomy or endoscopic mucosal resection is the strongly recommended treatment for most superficial colorectal tumors [1]. However, local recurrence is found in approximately 12% to 21% of cases in which resection, including piecemeal resection, is performed [2, 3]. Moreover, accurate pathological diagnosis

is unattainable in the specimens obtained by piecemeal resection, owing to the burning effect and inadequate orientation of multiple specimens. Endoscopic submucosal dissection (ESD) achieves secure en bloc resection regardless of specimen size and can overcome the abovementioned limitations of endoscopic resection [4]. However, performing ESD requires the expertise of an experienced endoscopist; therefore, it is not generally used in several countries, except Japan and other Asian countries [5, 6, 7, 8, 9]. We believe that if the technical hurdles of ESD are reduced, it would become more popular and benefit patients worldwide.

Recently, the effectiveness of underwater techniques for endoscopic procedures has been reported [10]. In colorectal ESD, usefulness of the underwater techniques has been described and it eliminates the gravity effect, utilizes buoyancy as a natural traction, and creates a magnified view owing to the difference in photorefraction between water and air [11, 12, 13]. In addition, we previously reported on the water pressure method (WPM), characterized by not only underwater conditions but also use of active water pressure via the water-jet function, which widens the submucosa more, helps the endoscope get beneath the lesion, and enables submucosal dissection in narrow spaces [14, 15, 16]. WPM has been reported to overcome difficult situations such as fibrosis in colorectal ESD [17]. Thus, we hypothesized that WPM would reduce technical difficulty and allow novice endoscopists to perform colorectal ESD. This study aimed to elucidate the usefulness of colorectal ESD with WPM by novices.

Materials and methods

Study design

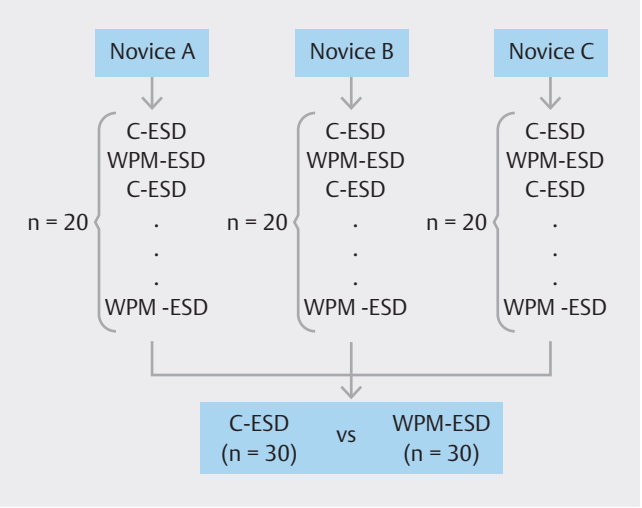
This was an ex vivo study using an excised bovine rectum in our institution. Three novices with no experience in clinical cases of colorectal ESD were enrolled. Each novice performed conventional ESD (C-ESD) and ESD with WPM (WPM-ESD) 10 times; they alternated between C-ESD and WPM-ESD to eliminate any bias introduced owing to the learning effect (▶ **Fig. 1**). Treatment outcomes were then compared between the two groups. This study used only excised bovine rectum; thus, Investigational Review Board approval and written consent were not required.

Animal training model and target lesions

A frozen bovine rectum was used for the experiment. The overtube was attached to the bovine anus, and the blind end was made by tying a string approximately 40 to 50 cm from the anus. Mesh copper was wrapped around the rectum and connected to an electrical surgical unit (ESU). The animal model was placed in a box and fixed to prevent it from moving. The lesion was created by marking a 2-cm diameter plastic disk placed on the gravitational side within 30 cm of the anus.

Conventional method

C-ESD was performed according to the following procedure: 1) initial mucosal incision of the proximal side; 2) creation of a mucosal flap by dissection of the proximal submucosa; 3) full circumferential incision; and 4) submucosal dissection of the residual area [18].



▶ **Fig. 1** Flowchart of this study.

Water pressure method

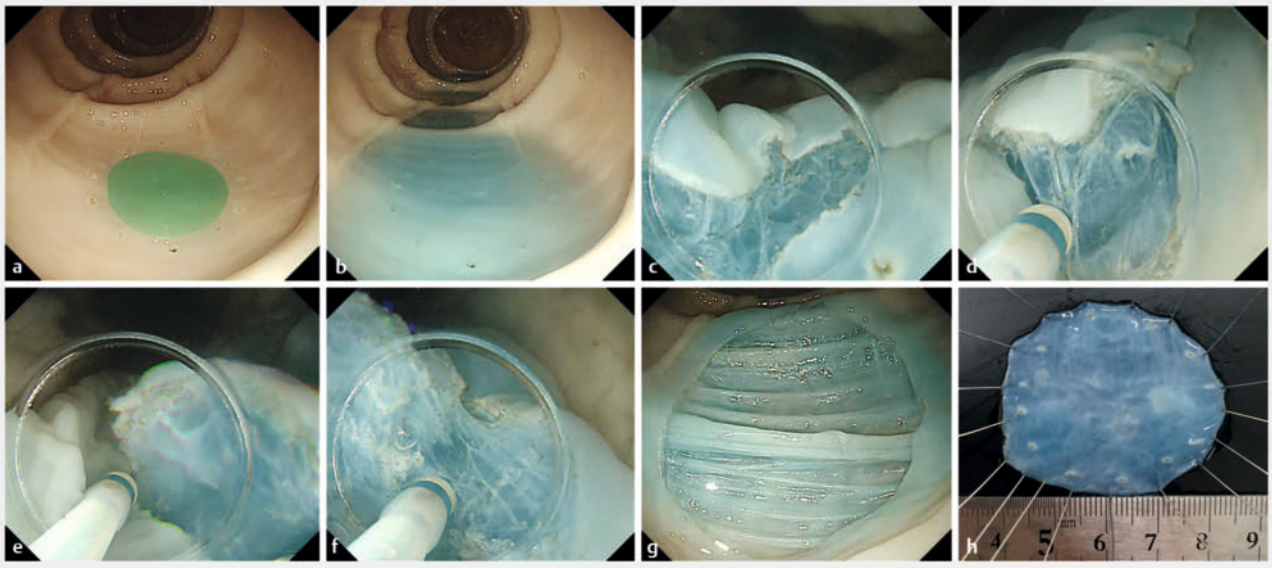
WPM was performed according to the following procedure: 1) aspiration of intraluminal air in the working space and irrigation of normal saline through the water-jet function (creating underwater conditions); 2) initial mucosal incision and trimming of the distal side to create an endpoint of submucosal dissection; 3) full circumferential incision; 4) creation of a mucosal flap by dissection of the proximal submucosa with application of active water pressure from the water-jet function to widen the submucosal layer; 5) dissection of both lateral edges of the submucosa using active water pressure; and 6) submucosal dissection of the central area (▶ **Fig. 2** and ▶ **Video 1**).

Device and equipment

ESD was performed using a therapeutic endoscope with water-jet function (GIF-H290T; Olympus Medical Systems, Tokyo, Japan). A short-type small-caliber transparent hood (DH-28GR; Fujifilm, Tokyo, Japan) was attached to the tip of the endoscope. We used a 1.5-mm DualKnife J (Olympus Medical Systems, Tokyo, Japan) and submucosal injection of 10% glycerin solution (Glycerol; Chugai Pharmaceutical Co., Ltd., Tokyo, Japan). We used VIO 300 D (ERBE Elektromedizin, Tübingen, Germany) with Endocut I (effect 2, cut interval 2, cut duration 2) for mucosal incision and swift coagulation (effect 3, 30 W) for submucosal dissection.

Measured outcomes

We collected data on the following characteristics of enrolled novices: age, years since graduation from a medical university, whether they were board-certified fellows of the Japan Gastroenterological Endoscopy Society (JGES), number of esophagogastroduodenoscopy (EGD) experiences, number of colonoscopy (CS) experiences, and number of ESD experiences. The primary endpoint of this study was procedure time. The secondary



▶ **Fig. 2** Water pressure method. **a** The target lesion was created by marking around a 2 cm diameter plastic disc. **b** The lesion was on the gravitational side where the water was pooling. **c** Initial mucosal incision and trimming of the distal side were performed to create endpoints. **d** A full circumferential incision was made and a mucosal flap was created using water pressure. **e** One-sided submucosal dissection was performed using active water pressure. **f** Submucosal dissection of the other side was performed using active water pressure. **g** Submucosal dissection of the residual central area was performed. **h** En bloc resection.

endpoints were as follows: activation time of ESU during the procedure, interval time during the procedure, time required for the endoscope to enter the submucosa, en bloc resection rate, perforation rate, whether the resected specimen had an incision inside the markings, and the area of the resected specimen (area [cm^2] = semi-major axis [cm] × semi-minor axis [cm] × π). Procedure time was defined as the time from initiation of mucosal incision to completion of lesion removal. Procedure time was divided into activation time of the ESU and interval time at which the ESU was not activated. Activation time of ESU was measured by VIO DOKU (ERBE Elektromedizin, Tübingen, DEU), which is a program for maintenance and inspection of the VIO 300 D. The time required for the endoscope to enter the submucosa was defined as the time from the end of the proximal mucosal incision to complete visualization of the submucosa by capturing the proximal edge of the lesion using the upper rim of the distal attachment.

Statistical analysis

Fisher's exact test was used to analyze categorical data. Quantitative data were compared using the Mann-Whitney U test. Statistical significance was set at P <0.05. All statistical analyses were performed using JMP software (version 16.0.0; SAS Institute, Cary, North Carolina, United States).

VIDEO

▶ **Video 1** Colorectal ESD with water pressure method.

Results

Characteristics of the novices

Characteristics of the three enrolled novices are presented in ▶ **Table 1**. Their ages were 30 to 33 years, and time since graduation from medical university ranged from 6 to 9 years. No endoscopists were board-certified fellows of the JGES. The number of CS experiences ranged from 750 to 2000. None of the participating endoscopists had any experience in performing colorectal ESD in humans, as mentioned in the inclusion criteria.

▶ **Table 1** Characteristics of the three enrolled novices.

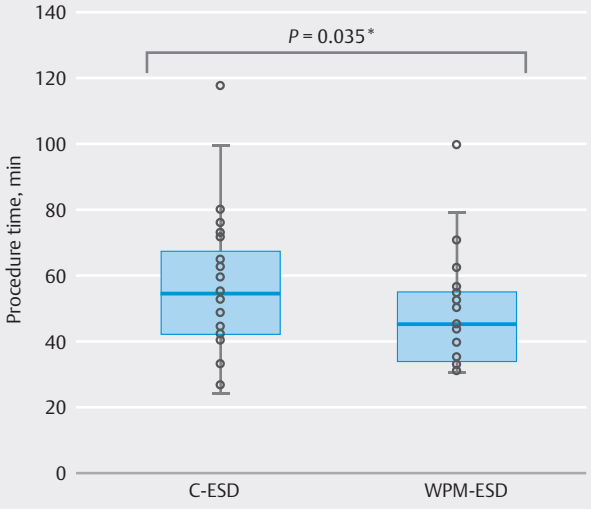
	Novice A	Novice B	Novice C
Age, years	31	33	30
Years since graduation	7	9	6
Board-certified Fellow	No	No	No
Number of EGD experiences	4000	2500	2300
Number of CS experiences	2000	1500	750
Number of esophageal ESD experiences	6	0	0
Number of gastric ESD experiences	35	17	0
Number of colorectal ESD experiences	0	0	0

EGD, esophagogastroduodenoscopy; CS, colonoscopy; ESD, endoscopic submucosal dissection.

Treatment outcomes

Each novice performed C-ESD and WPM-ESD (10 times each). The median procedure time was significantly shorter in the WPM-ESD group than in the C-ESD group (54 minutes; interquartile range [IQR] 42–67 vs. 45 minutes; IQR, 34–55, P= 0.035), and the WPM-ESD group showed a reduction of approximately 17% in the median procedure time (▶ **Fig. 3**). There was no significant difference in the ESU activation time during the procedure between the two groups (2.8 minutes; IQR, 2.2–3.1 vs. 3.0 minutes; IQR, 2.6–3.5, P=0.11). The interval time during the procedure was significantly shorter in the WPM-ESD group than in the C-ESD group (52 minutes; IQR, 40–65 vs. 42 minutes; IQR, 32–52, P=0.030). In addition, the time required for the endoscope to enter the submucosa was significantly shorter in the WPM-ESD group than in the C-ESD group (8.0 minutes; IQR, 6.0–10 vs. 5.0 minutes; IQR, 3.0–6.0, P <0.001) (▶ **Fig. 4**).

Comparisons of other treatment outcomes between the C-ESD and WPM-ESD groups are presented in ▶ **Table 2**. En bloc resection was performed in all cases. Although one perforation occurred in the C-ESD group, there were no perforations in the WPM-ESD group. In the C-ESD group, two resected specimens had an incision inside the markings, while in the WPM-ESD group, none of the resected specimens were cut inside the markings (▶ **Fig. 5**). The areas of the resected specimens did not differ between the two groups.



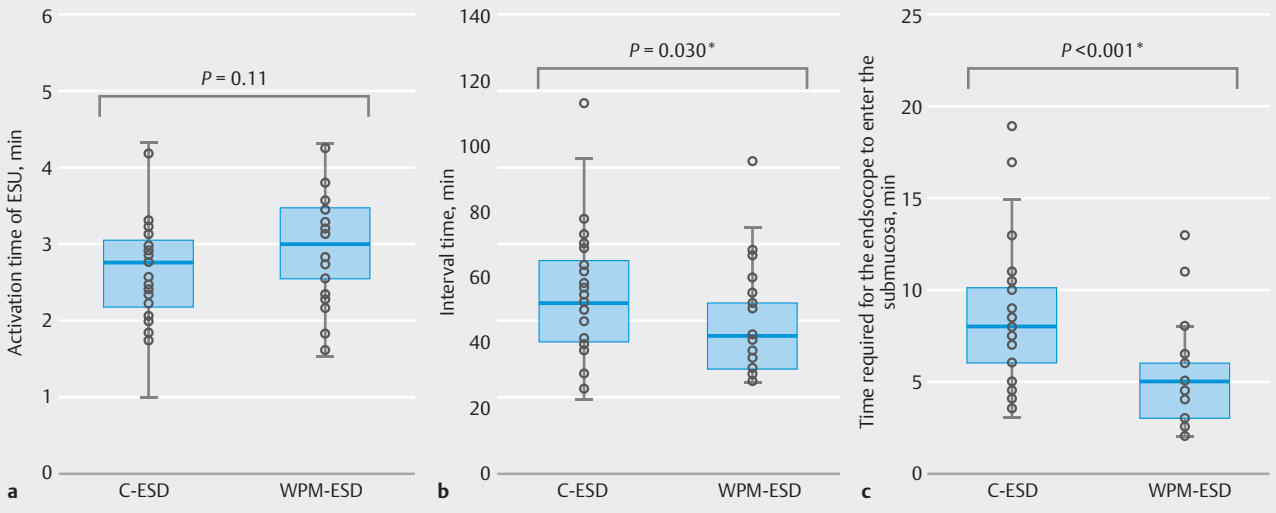
▶ **Fig. 3** Distribution of the procedure time between the C-ESD group (n = 30) and the WPM-ESD group (n = 30). The median procedure time was significantly shorter in the WPM-ESD group than in the C-ESD group (54 IQR, 42–67 vs. 45 IQR, 34–55 minutes, P=0.035). ESD, endoscopic submucosal dissection; WPM, water pressure method; IQR, interquartile range.

Discussion

This study successfully revealed that WPM-ESD significantly reduced procedure time by 17% compared to that of the conventional method when performed by endoscopists with no experience in colorectal ESD. To the best of our knowledge, this is the first study to illustrate the usefulness of WPM-ESD for colorectal ESD, especially for novices.

Colorectal ESD is difficult for novice endoscopists because of several factors. First, the colorectal wall is very thin, and careless passive energization can easily lead to perforation. Second, the anatomical characteristics of the long luminal organs often result in poor scope maneuverability [6, 19]. Third, the development of this strategy is complex. Although an efficient procedure needs to be considered by changing the patient's position to control the direction of gravity for good traction, the maneuverability of the scope, approachability to the lesion, and scope angle with the muscle layer can easily worsen depending on the patient's body position [20]. The key to successful colorectal ESD is controlling these factors and performing rapid and precise dissection.

Several useful methods have been proposed for successful colorectal ESD, such as the mechanical traction method and the pocket-creation method (PCM) [18, 21, 22, 23, 24, 25, 26]. However, these methods still have certain issues that need to



▶ **Fig. 4** Distribution of the activation time of ESU, interval time, and time required for the endoscope to enter the submucosa between the C-ESD group (n = 30) and the WPM-ESD group (n = 30). **a** There was no significant difference in the ESU activation time during the procedure between the two groups (2.8 IQR, 2.2–3.1 vs. 3.0 IQR, 2.6–3.5 minutes, *P* = 0.11). **b** The interval time during the procedure was significantly shorter in the WPM-ESD group than in the C-ESD group (52 IQR, 40–65 vs. 42 IQR, 32–52 minutes, *P* = 0.030). **c** The time required for the endoscope to enter the submucosa was significantly shorter in the WPM-ESD group than in the C-ESD group (8.0 IQR, 6.0–10 vs. 5.0 IQR, 3.0–6.0 minutes, *P* <0.001). ESD, endoscopic submucosal dissection; WPM, water pressure method; IQR, interquartile range.

▶ **Table 2** Comparison of treatment outcomes between the C-ESD and WPM-ESD groups.

Variables		C-ESD n = 30	WPM-ESD n = 30	*P* value
En bloc resection	Yes, N (%)	30 (100)	30 (100)	>0.99
Perforation	Yes, N (%)	1 (3)	0 (0)	>0.99
Cutting inside the markings	Yes, N (%)	2 (7)	0 (0)	0.49
Area of resected specimen	Median [IQR], cm^2	12 [9.7–14]	13 [11]–[16]	0.14

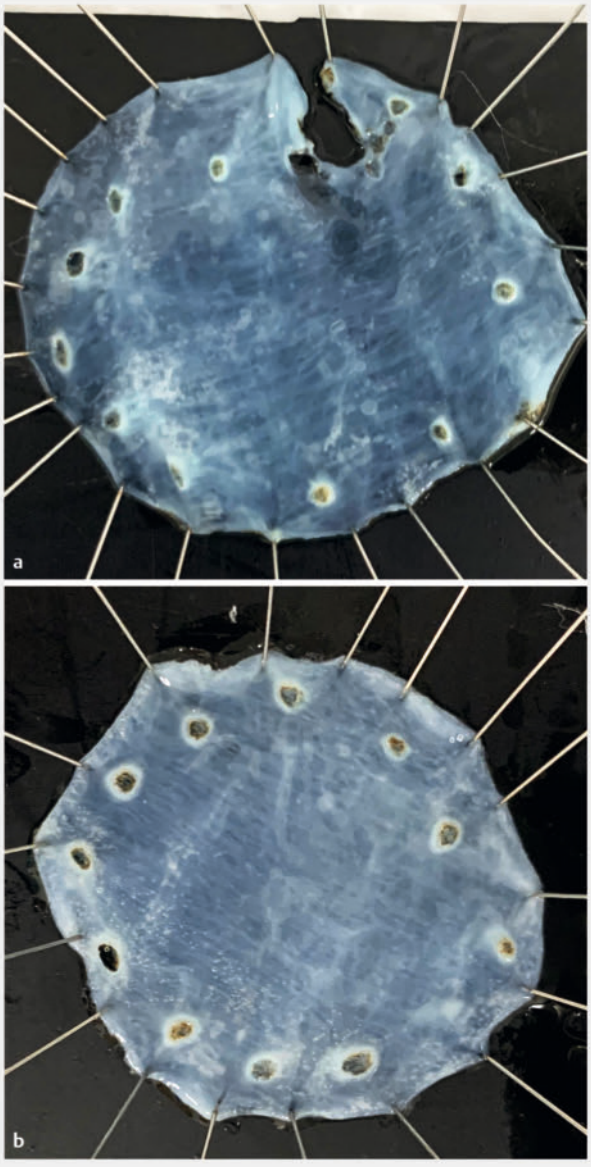
IQR; interquartile range.

be resolved. Endoscopist experience is required to choose the position of deployment of the traction device, and if the position is inappropriate, the situation does not improve. In PCM, it is difficult to create the first pocket and remove the edges in the last pocket-opening phase. Inexperienced endoscopists sometimes lose orientation in the pocket and are unsure of how much submucosal dissection to perform and in which direction [27].

In this study, we evaluated not only the total procedure time but also the time of the various other phases to provide a detailed and objective evaluation of the WPM-ESD. We divided the procedure time into the activation time of ESU and interval time and found that WPM-ESD significantly reduced the median interval time by 10 minutes. This degree of reduction in the interval time was almost the same as the degree of reduction in the total procedure time, indicating that WPM-ESD was mainly effective in the interval phase. The interval time (incision and dissection was not performed in this period) refers to the time spent creating the field of view and preparing it for incision and dissection. It was objectively shown that WPM-ESD helps create a good field of view.

There was no significant difference in the activation time of the ESU. In a previous report, the use of a bipolar knife was recommended in saline immersion because saline solution is more conductive than tissue, and the use of a monopolar knife in saline solution would dissipate the electrical energy [12]. The results of this study indicated that the DualKnife J did not worsen the efficiency of the dissection to the extent that would lead to a problem. The short and thin DualKnife J may create sufficient current density to the tissue even in saline solution and allow for sharp dissection.

We also measured the time required for the scope to enter the submucosa, which is the most difficult phase of colorectal ESD, and found that the WPM-ESD group was significantly faster than the C-ESD group. Until a mucosal flap is created and the dive under the submucosa has been performed, the visibility of the submucosa is poor, often making it difficult for a parallel approach to the muscular layer.



▶ **Fig. 5** Resected specimens. **a** One C-ESD case with an incision inside the marking.**b** No WPM-ESD cases had incisions inside the marking. C-ESD, conventional endoscopic submucosal dissection; WPM, water pressure method.

Occasionally, blind dissection is crucial, and only experienced endoscopists can perform this technique [28, 29]. The results of this study suggest that WPM-ESD may facilitate this difficult phase, owing to its buoyancy and the submucosal widening effect, particularly for novice endoscopists.

In this ex vivo study, the lesion was intentionally created on the gravitational side. As mentioned above, gravity is a factor associated with colorectal ESD. Underwater conditions can eliminate the effects of gravity, and hence, it is partly responsible for the shorter procedure time resulting in the simplification of colorectal ESD, which may allow novice endoscopists to perform the steps shown in ▶**Fig. 2**. In this procedure, the edges are dissected preferentially; therefore, the field of view expands rapidly, and the orientation can be easily understood by novice endoscopists. Furthermore, there were no perforations during WPM-ESD. This might have been due to the effect of buoyancy, widening of the submucosa, and magnified view in the WPM, which allows for precise, high-quality dissection. In addition, there were no cases of resected specimen cuts inside the markings. This may be because of the precise edge processing of the WPM, which makes it possible to safely obtain high-quality resected specimens that allow for an accurate pathological diagnosis.

WPM-ESD has certain disadvantages in clinical settings. First, visibility can be reduced by major bleeding or intestinal content. Second, WPM-ESD has a potential risk of causing abdominal pollution due to the leakage of intestinal contents and tumor cells into the abdominal cavity. Therefore, the intestinal tract should be sufficiently cleaned before the procedure, and if perforation occurs, it should be closed as soon as possible [20].

Despite these concerns, the results of this study revealed that WPM-ESD is a useful technique that creates a good field of view and allows for precise dissection, even by novice endoscopists; in addition, the gravity factor does not need to be considered. It is also available at any location and time; thus, it can complement a combination of other useful methods, such as PCM and mechanical traction [30, 31, 32, 33, 34, 35]. In the future, WPM-ESD may reduce the technical difficulties of colorectal cases and foster popularization of this technique worldwide.

This study had several limitations. First, it was ex vivo. These results did not consider the various factors present in clinical ESD, such as bleeding, fibrosis, heartbeat, peristalsis, respiratory fluctuation, maneuverability, and stool. Second, the sample size was very small. This study includes only three novice endoscopists, which may not be representative of the larger population of novice endoscopists. It was unclear whether the results could be generalizable to other novice endoscopists or experienced endoscopists. Third, a bias was introduced because the endoscopists were not blinded to the method of the procedure. The endoscopists may have consciously or unconsciously modified their technique or performance based on their knowledge of whether they were performing C-ESD or WPM-ESD. Owing to these limitations, the results of our study should be interpreted with caution. Further prospective studies in clinical settings are needed.

Conclusions

In conclusion, WPM contributed to the creation of a good field of view and aided in rapid, safe, and precise dissection, even for endoscopists with no experience in colorectal ESD. WPM may reduce the technical hurdles of colorectal cases for novice endoscopists.

Conflict of Interest

The authors declare that they have no conflict of interest.

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