Effectiveness of multi-loop traction device for colorectal endoscopic submucosal dissection in trainees: a pilot study

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Abstract

Colorectal endoscopic submucosal dissection (ESD) is a difficult procedure, and its introduction in trainees have been debated. Although the criteria for starting colorectal ESD vary among institutions, it is often initiated after gaining experience in animal and upper gastrointestinal ESD. This pilot study aimed to compare the treatment outcomes of the trainees using the multi-loop traction device (MLTD group) and the experts' conventional-ESD (control group), and determine whether MLTD can be used for safe introduction of colorectal ESD in trainees. We included 26 colorectal ESD patients (13 in the MLTD group and 13 in the control group) treated at our hospital from October to December 2021 in the analysis. There were no significant differences in procedure time (50 min vs. 30 min), dissection speed (19.9 mm²/min vs. 28.7 mm²/min), and intraoperative perforation (0 % vs. 0 %) between the two groups. Furthermore, the proportion of ESD self-completion in the MLTD group was 100%. Thus, MLTD was used for safe introduction of colorectal ESD even among endoscopists with no experience in colorectal ESD. Subsequently, MLTD may replace animal and upper gastrointestinal ESD in the introduction of colorectal ESD in trainees. Further studies using larger sample sizes need to be conducted.

Introduction

Colorectal cancer (CRC) is a common fatal disease. Approximately 150,000 new cases of colorectal cancer are diagnosed annually, and approximately 50,000 people in the United States are expected to die from colorectal cancer each year^[1]. In recent years, the importance of endoscopic submucosal dissection (ESD) for early-stage colorectal cancer has increased; however, colorectal ESD remains a challenging procedure. Colorectal ESD has a high rate of intraoperative perforation (2.6%) compared to other organs, rendering it difficult to introduce to trainees^[2]. The introduction and training for colorectal ESD in trainees is still under discussion^[3]. In addition, the criteria for starting colorectal ESD vary among institutions and have not yet been established; however, colorectal ESD is often initiated after gaining experience in animal and upper gastrointestinal ESD^[4]. In recent years, gastrointestinal ESD using a traction device has been applied to colorectal ESD because it improves the visual field of the submucosa, which shortens procedure time, increases dissection speed, and decreases intraoperative perforations^[5, 6]. Although there have been reports on colorectal ESD using traction devices for those who have gained a certain level of experience with ESD in animals and the upper gastrointestinal tract, as described above^[5], to the best of our knowledge, no reports on colorectal ESD using traction devices for those who have never been trained in colorectal ESD exist. The purpose of this study was to compare the treatment outcomes of the trainee group using a multi-loop traction device (MLTD; Boston Scientific Co. Ltd., Tokyo, Japan) with those of the experts' conventional-ESD group.

Results

Characteristics of the patients

We included 26 patients in this analysis (MLTD group, 13 patients; control group, 13 patients). There were no significant differences in age, tumor location, horizontal location, morphology, estimated tumor size, history of abdominal surgery, preoperative biopsy, and antithrombotic therapy between the two groups (Table 1).

Table 1
Characteristics of the patients

	MLTD group(n = 13)	Control group(n = 13)	P value
Age, mean (SD)	73.2(10.7)	66.9(7.4)	0.1
Tumor Location, n (%)			0.33
Right colon	8(61.5)	6(46.2)	
Left colon	4(30.8)	3(23.1)	
Rectum	1(7.7)	4(30.8)	
horizontal location, n (%)			0.68
~ 1/4	9(69.2)	8(61.5)	
1/4 ~ 1/2	4(30.8)	5(38.5)	
Morphology, n (%)			
LST-G	3(23.1)	6(46.2)	
LST-NG	10(76.9)	5(38.5)	
Others	0(0)	2(15.4)	
Estimated tumor size, mm (IQR)	20(20–30)	25(20–30)	0.57
Past surgical history, n (%)	4(30.8)	3(23.1)	0.66
Preoperative biopsy, n (%)			0.23
Yes	4(30.1)	7(53.9)	
Antithrombotic therapy, n (%)			1.0
Yes	1(7.7)	1(7.7)	

Treatment outcomes

The proportion of ESD self-completion in the MLTD group was 100%. There were no statistically significant differences in procedure time (50 min vs 30 min, $p = 0.38$), dissection speed ($19.9 \text{ mm}^2/\text{min}$ vs $28.7 \text{ mm}^2/\text{min}$, $p = 0.19$), and intraoperative perforation (0% vs 0%, $p = 1.0$) between both groups. In addition, there was no significant difference in adjunctive outcomes (Table 2).

Table 2
Treatment outcomes

	MLTD group(n = 13)	Control group(n = 13)	P value
MDZ dose, mg (IQR)	3(3–4)	2.5(2–4)	0.62
MucoUp dose, mL (IQR)	28(15–40)	20(16–40)	0.64
Maneuverability, n (%)			0.4
good/normal	10(76.9)	8(61.5)	
poor	3(23.1)	5(38.5)	
Procedure time, min (IQR)	50(33–63)	30(23–55)	0.38
Dissection speed, mm²/min (IQR)	19.9(14.4–26)	28.7(17–35.7)	0.19
Specimen damage, n (%)			1.0
Yes	0(0)	1(7.7)	
En-bloc resection, n (%)			1.0
Yes	100(100)	100(100)	
Resectability, n (%)			1.0
R0	100(100)	100(100)	
Resected tumor size, mm (IQR)	30(22–33)	24(20–36)	0.92
Resected specimen largest diameter, mm (IQR)	43(32–45)	34(30–45)	0.74
Resected specimen smallest diameter, mm (IQR)	30(22–33)	33(24–38)	0.61
Final pathology, n (%)			
Histology			0.12
Adenoma	9(69.2)	5(38.5)	
tub	4(30.8)	8(61.5)	
por, sig, muc	0(0)	0(0)	
Depth			0.29
Tis	3(23.1)	6(46.2)	
T1a	1(7.7)	2(15.4)	
T1b	0(0)	0(0)	

	MLTD group(n = 13)	Control group(n = 13)	P value
Intraoperative perforation, n (%)			1.0
Yes	0(0)	0(0)	
Intraoperative bleeding, n (%)			1.0
Yes	0(0)	0(0)	
Delayed perforation, n (%)			1.0
Yes	0(0)	0(0)	
Delayed bleeding, n (%)			1.0
Yes	0(0)	0(0)	
Surgery due to adverse events, n (%)			1.0
Yes	0(0)	0(0)	
Recurrence, n (%)			1.0
Yes	0(0)	0(0)	

Discussion

Although colorectal ESD has superior treatment outcomes, such as en bloc resection proportion, compared to endoscopic mucosal resection (EMR), it is difficult to standardize the training system due to poor maneuverability and risk of intraoperative perforation^[7]. To date, the introduction and training methods of colorectal ESD in trainees are still being discussed, and workshops and hands-on seminars are being actively held^[3, 4]. On an average, endoscopic experience at the time of human ESD initiation is 7.7 years (SD 4.1), and is generally initiated in the gastric antrum (90%)^[4]. In recent years, the use of traction devices in gastrointestinal ESD has been reported to shorten the treatment time, increase the speed of submucosal dissection, and reduce intraoperative complications^[5, 6]. Traction devices have also been applied to colorectal ESD, but the threshold for its introduction to trainees remains high. A literature search for “Multi-loop traction device” in PubMed since 2000 revealed six cases^[6, 8–12], of which two were relevant to this study^[6, 8]. To the best of our knowledge, no report pertaining to trainees with no colorectal ESD experience exist in literature, and our study was the first attempt. In this study, we compared the treatment outcomes of the MLTD group of trainees and the control group of experts and found no significant differences in primary and secondary outcomes. The use of MLTD enabled the safe introduction of colorectal ESD in trainees without experience in animals or upper gastrointestinal tract ESD. This study had some limitations in that it was performed in a single institution with a small number of patients. In the future, a randomized controlled trial should be conducted to ascertain these findings.

Methods

Study design and ethical statements

This was a retrospective cohort study conducted at the Saitama Medical University International Medical Center, Japan. This study was approved by the Institutional Review Board of Saitama Medical University International Medical Center (Institutional ID:20-202), and performed in accordance with the principles of the Declaration of Helsinki. We obtained informed consent from all patients prior to their inclusion in this study.

Patients

We included 26 consecutive patients who underwent colorectal ESD at our hospital between October and December 2021 in this study. All cases were conducted according to the Japanese Society for Cancer of the Colon and Rectum (JSCCR) guidelines 2019 for the treatment of colorectal cancer, as described below^[13]. The following were included:

- Early colon cancer with a maximum diameter ≥ 2 cm
- Early colon cancer accompanying fibrosis.

Trainees and experts

Two trainees and three experts participated in the study. The trainees had experience with fewer than 10 cases of upper gastrointestinal ESD and no case of colorectal ESD, while the experts had performed more than 200 cases of all gastrointestinal ESD. Both were doctors at our hospital.

Setting of colorectal ESD

We performed colorectal ESD in the endoscopy room under intravenous anesthesia using midazolam and pethidine. Scopolamine was used as an antispasmodic drug, and glucagon was substituted in patients with cardiac disease or benign prostatic hyperplasia. All ESD procedures were performed using therapeutic endoscopes (PCF-H290ZI or GIF-H290T; Olympus, Medical Systems Co., Tokyo, Japan) with a transparent cap (Olympus). Generally, PCF-H290ZI is used for colorectal ESD and GIF-H290T is often used for rectal lesions. We used a Dual knife J 1.5 mm (KD655Q; Olympus) to perform a mucosal incision or submucosal dissection. In the various settings of an electrosurgical generator (VIO 3, ERBE Elektromedizin, Tübingen, Germany), endoCUT I mode (effect 1 or 2, duration 2, interval 2), forced coagulation (effect 4.5 or 6.1), and spray coagulation (effect 1.2) were employed for mucosal incision, submucosal dissection, and hemostasis, respectively. To elevate the submucosa, local injection of 0.4% sodium hyaluronate (MucoUp[®], Boston Scientific, Tokyo, Japan) in combination with a small amount of indigo carmine were used for local injection.

Strategies of colorectal ESD using MLTD

Step 1: After the full circumferential mucosal incision around the lesion (Fig 1a), we attached the MLTD to the mucosal edge for elevation (Fig 1b). The MLTD was attached to either the lesion or normal mucosa contralateral to the lesion. As a precaution, sufficient MucoUp[®] was injected into the submucosa at the site of the MLTD attachment to avoid traction on the muscle layer.

Step 2: The direction, distance, and gravity side should be checked thoroughly before attaching the MLTD because the traction effect depends on the MLTD attachment site.

Step 3: After MLTD attachment, a good visual field of the submucosa was obtained, and the submucosa was dissected safely and easily (Fig 1cd). Where the traction effect was inadequate, additional traction using the hole in the middle (Fig 2ab) or a new MLTD was prepared.

Step 4: After resection of the lesion, we removed the MLTD with a biopsy forceps and collected the lesion.

Definitions

Procedure time: Procedure time was defined as the time from the initial mucosal incision to the tumor resection.

Dissection speed: Dissection speed was calculated using the following equation. "The resected specimen largest diameter (mm) / 2 × the resected specimen smallest diameter (mm) / 2 × 3.14 / procedure time (min)"

Intraoperative perforation: Intraoperative perforation was defined as a perforation during ESD.

MDZ dose: MDZ dose was defined as the total amount of MDZ used during ESD.

MucoUp[®] dose: MucoUp[®] dose was defined as the total amount of MucoUp[®] used during ESD.

Maneuverability: For the maneuverability, three experts assessed and divided it into two categories: good/normal or poor.

Specimen damage: Specimen damage was defined as any damage to the specimen during ESD, including traction.

En-bloc resection: En-bloc resection was defined as a one-piece resection that included the whole tumor.

Resectability: The tumor resectability was evaluated by final pathology.

Intraoperative bleeding: Intraoperative bleeding was defined as bleeding that could not be treated by endoscopic hemostasis during ESD.

Delayed perforation: Delayed perforation was defined as a perforation diagnosed by computed tomography scan after the ESD.

Delayed bleeding: Delayed bleeding was defined as hemorrhage that required endoscopic hemostasis after the ESD.

Surgery due to adverse events: It was defined as a case that required surgery due to ESD-related complications.

Statistical analysis

We compared the treatment outcomes between two groups: the MLTD group of two trainees and the control group of three experts. The primary study outcome was the procedure time, and the secondary outcomes were dissection speed and intraoperative perforation. Adjunctive outcomes were MDZ dose, MucoUp[®] dose, maneuverability, specimen damage, en-bloc resection, resectability, resected tumor size, resected specimen largest diameter, resected specimen smallest diameter, final pathology, intraoperative bleeding, delayed perforation, delayed bleeding, surgery due to adverse events, and recurrence. In the two groups, binary variables were evaluated using Pearson's chi-square test and continuous variables were evaluated using the Mann–Whitney U test or Student's t-test. All analyses were carried out using STATA[®] version 17 (StataCorp, College Station, TX, USA), and statistical significance was set at $p < 0.05$.

Abbreviations

EMR, endoscopic mucosal resection

ESD, endoscopic submucosal dissection

MLTD, multi-loop traction device

CRC, colorectal cancer

JSCCR, Japanese Society for Cancer of the Colon and Rectum

MDZ, midazolam

R0, no tumor identified at the lateral or vertical margins

Declarations

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Author contributions

RJ wrote and edited the manuscript. RJ, TT, RT, KM, HK, TO, YN, YS, AF, YT, MM, YM, TK, and SR reviewed the literature and revised the manuscript for intellectual content.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author, TT or RJ, upon reasonable request.

Competing interests: The authors declare no competing interests.

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Figures

Figure 1

Strategies of colorectal ESD using Multi-loop traction device

- (a) Full circumferential mucosal incision around the lesion.
- (b) Attaching the MLTD on the mucosal edge to elevate it.
- (c) The visual field of the submucosa and muscle layer is good, allowing for safe submucosal dissection.
- (d) The lesion was successfully resected en bloc without intraoperative complications.

Figure 2

Additional traction

- (a) Where the traction effect was inadequate, additional traction using the hole in the middle (yellow arrow).
- (b) After additional traction.