Comparison Between Preincision Traction and On-Demand Traction in Assisting Colorectal Endoscopic Submucosal Dissection

Jun Li, MD[1,2], Yunlei Wei, MM[1], Di Zhang, MM[1], Xiaojia Hou, MD[1], Ming Shen, MD[3], Kan Chen, MD[1], Ruijin Wu, MD[1], Kangsheng Peng, MD[1] and Feng Liu, MD[1,2]

INTRODUCTION: **Adequate exposure of the dissection site is very important for colorectal endoscopic submucosal dissection (ESD). We aimed to investigate the safety and efficacy of the preincision traction (PIT) method using an internal clip-with-spring device in comparison with the conventional on-demand traction (ODT) method in assisting colorectal ESD.**

METHODS: **This was a prospective nested case-control study. A total of 26 patients for PIT-ESD and other 26 patients for ODT-ESD were involved. Data on clinical characteristics and therapeutic outcomes were collected and analyzed.**

RESULTS: **The *en bloc* resection rate (both 100%) and curative resection rate (92.3% vs 96.2%) showed no significant difference between the 2 groups. Compared with ODT-ESD, PIT-ESD significantly reduced the procedure time (29.8 ± 18.4 vs 57.4 ± 33.7 minutes, $P = 0.001$) and submucosal injection volume (49.6 ± 32.3 vs 70.8 ± 37.6 mL, $P = 0.034$), decreased the rate of intraoperative bleeding (26.9% vs 57.7%, $P = 0.025$) and muscular injury (7.7% vs 34.6%, $P = 0.038$), and shortened the postoperative hospital stay (1.8 ± 0.8 vs 2.5 ± 1.2, $P = 0.015$).**

DISCUSSION: **The PIT method could significantly improve the safety and efficacy of colorectal ESD.**

SUPPLEMENTARY MATERIAL accompanies this paper at http://links.lww.com/CTG/A884, http://links.lww.com/CTG/A885

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INTRODUCTION

Colorectal endoscopic submucosal dissection (ESD) is a challenging procedure, which usually involves difficulties in ideally exposing the dissection site to gain adequate visualization and establish a submucosal cavity (1). Several traction methods have been developed to overcome these problems (2). However, these methods are generally applied after mucosal incision, especially after difficulties for further dissection have arisen, which means "on-demand traction (ODT)." Recently, an early traction strategy initiated immediately after submucosal injection was reported by using a clip-with-line device or the S–O clip (3–5). This preincision traction (PIT) strategy has exhibited considerable advantages in assisting colorectal ESD. Currently, studies regarding this technique are very rare. The effectiveness of PIT and its superiority over ODT in assisting colorectal ESD remain not fully elucidated.

In this article, we present the first comparative study between the PIT and ODT method using an internal traction device in assisting colorectal ESD for patients with colorectal laterally spreading tumor (LST). We aimed to provide vital evidence on the safety and efficacy of PIT-assisted colorectal ESD to guide future clinical practice.

METHODS

Study design

This was a prospective nested case-control study. The main outcome for this study was the procedure time. According to a previous study, the median procedure time in the early clip-with-line (ECL) group and the non-ECL group was 66 (range 29–131) minutes and 90 (range 30–410) minutes, respectively (4). We assumed an average SD (σ) of about 20 minutes and defined a margin value (δ) of 10 minutes. The required sample size was calculated using a 2-mean superiority test with a

[1]Digestive Endoscopy Center, Shanghai Tenth People's Hospital, Tongji University School of Medicine, Shanghai, China; [2]Department of Gastroenterology, Shanghai Tenth People's Hospital Chongming Branch, Shanghai, China; [3]Department of Gastroenterology, Jiangyin Hospital of Traditional Chinese Medicine, Jiangyin Hospital Affiliated to Nanjing University of Chinese Medicine, Jiangyin, China. **Correspondence:** Feng Liu, MD. E-mail: drliuffeng@hotmail.com.
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statistical power of 80% and a 2-sided significance level of 0.05. With these parameters, the final required sample size was 26 patients for each group. This study was approved by the ethics committee and institutional review board of our hospital, and written informed consent was obtained from all participants.

Patients' enrollment

A total of 26 consecutive patients with colorectal LST were prospectively enrolled for PIT-ESD (PIT group) from July to November 2021 in Shanghai Tenth People's Hospital. Another 26 consecutive patients with colorectal LST who had underwent ODT-ESD (ODT group) from January to June 2021 in our hospital were involved as controls. Among them, 10 patients had intradissection traction (IDT), whereas other 16 patients underwent ESD without any traction. For all patients, the inclusion criteria were ages 35–80 years, lesion diameter ≥ 2 cm in the largest extent, and no regional lymph node or distant metastasis demonstrated by computed tomography or magnetic resonance imaging. Exclusion criteria were lesions with distinct characteristics of deep submucosal invasion that are not amenable to endoscopic resection (Narrow-Band Imaging International Colorectal Endoscopic classification III type or pit pattern Vn type), lesion diameter <2 cm in the largest extent, use of anticoagulant–antiplatelet agents that could not be suspended, and severe comorbidities or poor conditions that cannot tolerate the operation.

Equipment and devices

The internal traction device used in this study has been reported in our previous study (6). It is a novel clip-with-spring device consisting of a metal clip and a 5-mm long spring with 1 end fixed between the 2 claws and the other end shaped as a ring. It could be easily inserted through the working channel when claws of the clip are closed (Figure 1a). When the claws are unfolded, the spring could sway to either side of the claw plane to facilitate clip anchoring (Figure 1b). All ESDs were performed using a water-jet colonoscope (EC-760ZP-V/M; Fujifilm, Tokyo, Japan) with a transparent cap attached. Initial submucosal injection was performed by an injection needle (Interject; Boston Scientific, IN). Mucosal incision and submucosal dissection were performed by a Flush Knife (Fujifilm). Hemostasis was performed using the Flush Knife or hemostatic forceps (FD-410LR; Olympus, Tokyo, Japan). The mucosal defects were closed with metal clips (AGS MEDTECH, Hangzhou, China).

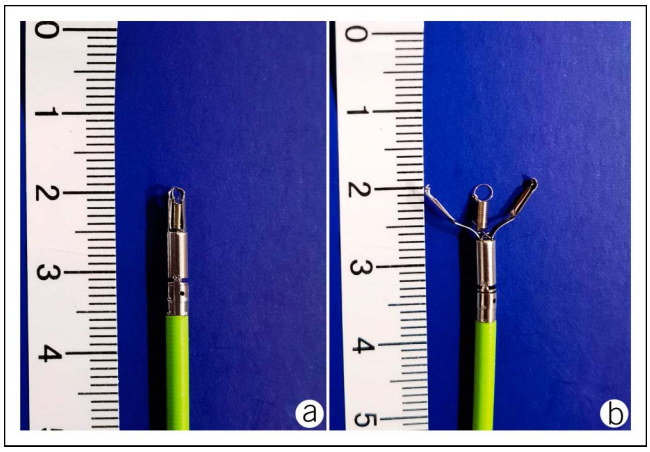

Figure 1. Novel clip-with-spring device consists of a metal clip (a) and a 5-mm spring fixed between the 2 claws of the clip (b).

ESD procedure

All ESD procedures were performed by a high-skilled endoscopist (F.L.) with experiences of more than 1,000 colorectal ESDs. For ODT-ESD, the procedures were performed as follows (1): after visualization of the border of the tumor, submucosal injection was conducted using sterile normal saline premixed with 0.1% sodium hyaluronate, 1% indigo carmine, and 1:10,000 epinephrine (2); a partial circumferential incision of the mucosa at about 3–5 mm outside the lesion margin was made from the anal side and initial submucosal dissection was performed immediately; when difficulties emerged in exposing the submucosal dissection site, attempts by none-assisted ESD were allowed for no longer than 5 minutes, and then IDT would be conducted (3); after half of the dissection was finished, an oral circumferential mucosal incision was performed; and (4) complete removal of the lesion and closure of the defects by metal clips. The typical procedures of IDT-ESD are shown in Figure 2. For PIT-ESD, after submucosal injection, the clip-with-spring device was anchored to the anal side of the lesion. Another clip grasped the ring to pull and fix it to the opposite colorectal mucosa. The traction direction could be adjusted by changing the anchoring site on the opposite colorectal mucosa. Then, the mucosal incision and submucosal dissection were performed regularly. After resection, the specimen together with the clip-with-spring device was retrieved using grasping forceps. The procedures of PIT-ESD are illustrated in Figure 3 and are shown in a typical case in Figure 4 and Video 1 (see Supplementary Video 1, http://links.lww.com/CTG/A884).

Definitions

The procedure time was measured as the time between submucosal injection of the first dot and complete removal of the lesion. Intraoperative bleeding was defined as oozing or pulsating bleeding, necessitating the use of hemostatic forceps during the procedure. Muscular injury was defined as any coagulating or cutting injury to the muscularis propria without visible perforation. Delayed bleeding was defined as hematemesis, melena, or decrease in the hemoglobin level >2 g/dL after ESD. Curative resection was defined as *en bloc* resection achieving tumor-free lateral and vertical margins without lymphatic or vascular involvement.

Statistical analysis

Statistical analyses were performed using SPSS software (version 23.0; SPSS). Continuous variables were presented as mean ± SD and were compared using the unpaired Student *t* test. Comparison of categorical variables was performed using χ^2 tests or Fisher exact test. A 2-sided $P \leq 0.05$ was considered statistically significant.

RESULTS

The clinical characteristics and therapeutical outcomes of the 26 patients undergoing PIT-ESD are listed in Table 1 and summarized in Table 2. The mean lesion diameter was 4.1 ± 1.0 cm, and the mean procedure time was 29.8 ± 18.4 minutes. PIT was placed to the oral direction in 12 (46.2%) patients and the anal

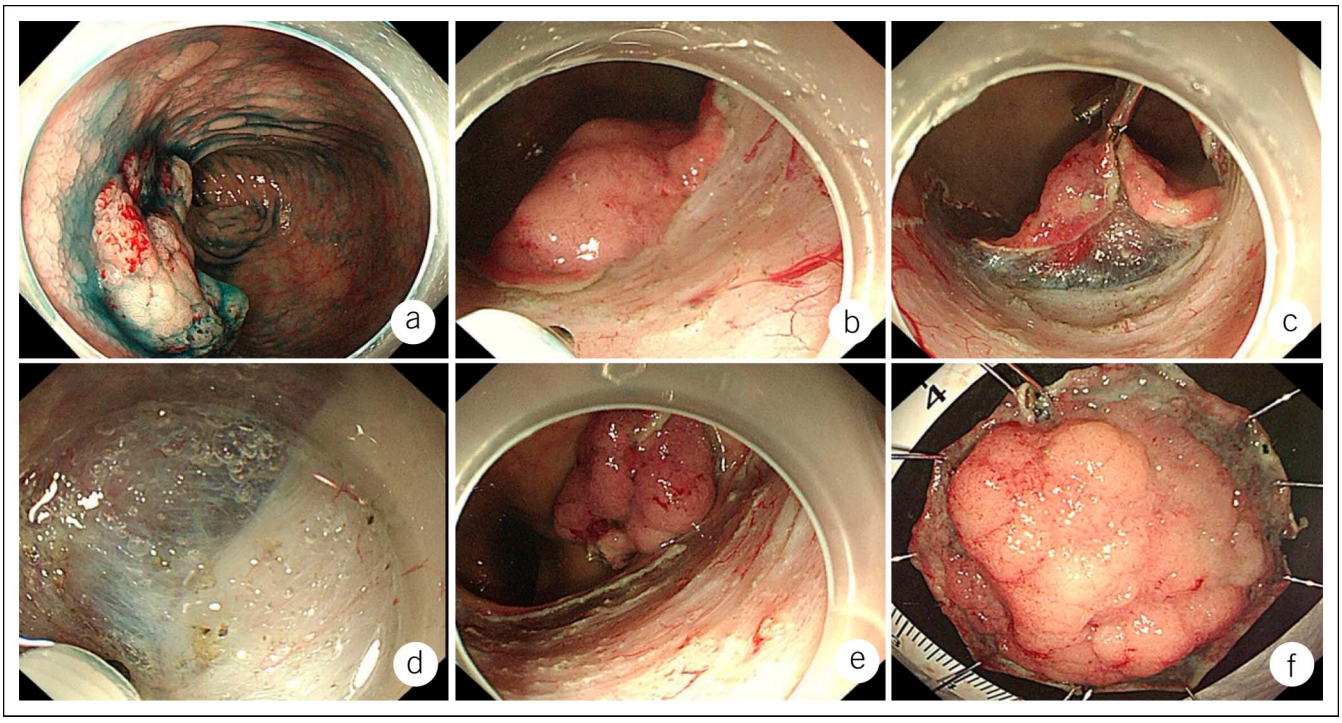

Figure 2. Procedures of on-demand traction-assisted colorectal endoscopic submucosal dissection. (**a**) Endoscopic view of the laterally spreading tumor. (**b**) After circumferential incision of the mucosa, difficulties emerged in exposing the dissection site. (**c**) Traction was applied using the clip-with-spring device. (**d**) Dissection became easy under countertraction. (**e** and **f**) Mucosal defect and the gross specimens.

direction in 14 (53.8%) patients. Submucosal cancer was confirmed in 5 (19.2%) patients, 3 of which were within SM1 (submucosal invasion depth $<$ 1,000 μm). Curative resection was achieved in 24 (92.3%) patients. All patients were discharged with no severe complication after a mean postoperative hospital stay of 1.8 $\pm$ 0.8 days.

Patients of the ODT group and PIT group showed no significant difference in baseline characteristics (Table 2). The *en bloc* resection rate (both 100%) and curative resection rate (92.3% vs 96.2%, $P = 0.552$) also showed no significant difference between the 2 groups. However, the procedure time was significantly shorter in the PIT group than in the ODT group (29.8 $\pm$ 18.4 vs

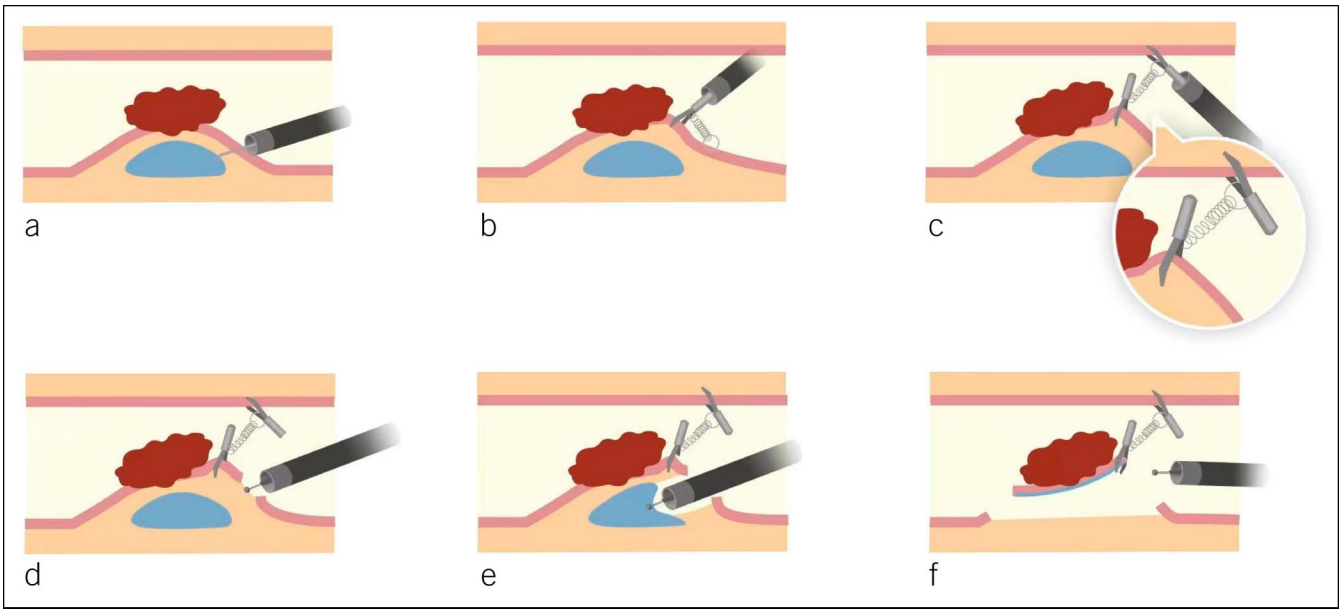

Figure 3. Illustration of the preincision traction-assisted endoscopic submucosal dissection. (**a**) Submucosal injection. (**b**) Before mucosa incision, the clip-with-spring device was anchored to the anal side of the lesion. (**c**) Ring is fixed to the opposite mucosa by another clip. (**d** and **e**) Mucosa incision and submucosal dissection are performed under countertraction. (**f**) Complete removal of the lesion.

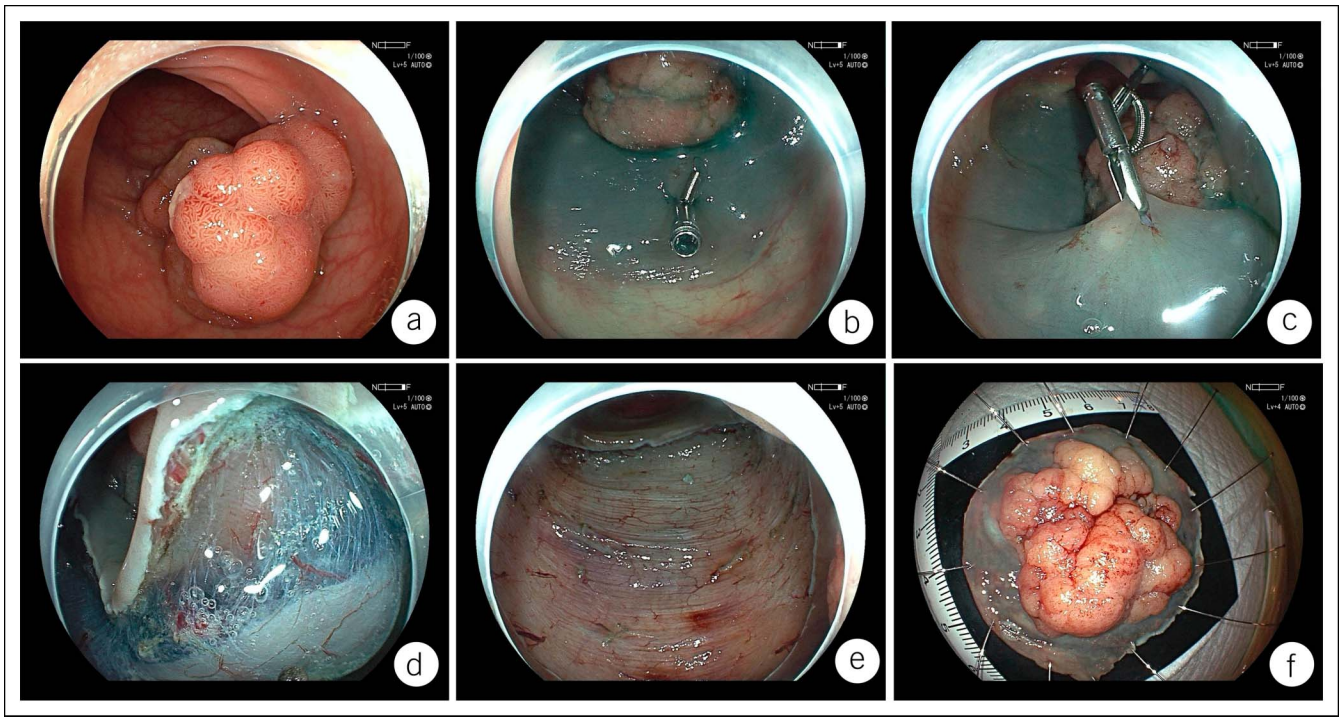

Figure 4. Procedures of preincision traction-assisted colorectal endoscopic submucosal dissection. (**a**) Endoscopic view of the laterally spreading tumor. (**b**) After submucosal injection, the clip-with-spring device was anchored to the anal side of the lesion. (**c**) Early traction was established before mucosa incision. (**d**) Resection became easy under countertraction. (**e** and **f**) Mucosal defect and the gross specimens.

57.4 ± 33.7 minutes, $P = 0.001$). PIT-ESD consumes a significantly lower volume of submucosal injection solutions than ODT-ESD (49.6 ± 32.3 vs 70.8 ± 37.6 mL, $P = 0.034$). Furthermore, PIT-ESD significantly reduced the rate of intraoperative bleeding (26.9% vs 57.7%, $P = 0.025$) and muscular injury (7.7% vs 34.6%, $P = 0.038$) compared with ODT-ESD. Consequently, the postoperative hospital stay was significantly shorter in the PIT group than the ODT group (1.8 ± 0.8 vs 2.5 ± 1.2, $P = 0.015$). Only 1 case in the ODT group presented with delayed bleeding and was managed successfully by endoscopic hemostasis. No patient presented with delayed perforation, massive bleeding, or any other serious complications. The total expenses for each patient had no significant difference between the 2 groups (18,774.6 ± 3,632.3 vs 19,756.4 ± 2,434.0 Chinese Yuan, $P = 0.258$).

We also compared the baseline characteristics and therapeutic outcomes between patients of the PIT group and IDT group (see Supplemental Table 1, http://links.lww.com/CTG/A885). The procedure time was also significantly shorter in the PIT group than the IDT group (29.8 ± 18.4 vs 43.0 ± 13.4 minutes, $P = 0.047$). PIT-ESD significantly reduced the rate of intraoperative bleeding (26.9% vs 70.0%, $P = 0.026$) when compared with IDT-ESD.

DISCUSSION

Adequate tissue tension and good exposure of the dissection site are very important for safe and effective dissections during colorectal ESD (7). Although various traction methods using adjunctive devices have been developed in the past few years (2,8–11), there were still debates arguing that gravity is enough for effective dissection (12). One of the main issues related to these controversies may lie in the timing of traction, which generally was in relevantly later stages of dissection. In fact, difficulties for submucosal exposure usually emerge at very early stages when the flap has not yet been sufficiently prepared and gravity is insufficient to provide effective traction force. Unsuccessful attempts to create a submucosal cavity and dispose the dissection site may be time-exhausting and increase complication risks. Other strategies, such as the tunneling and the pocket creation method, were also developed to help establish the submucosal cavity and improve the efficacy and safety of colorectal ESD (13). However, they usually require a special-shaped transparent cap and the procedures to create the tunnel or the pocket were also very challenging at very early stages. Therefore, it is assumed that traction by devices from the early stages, typically preincision, may be more useful to provide adequate visualization and tissue tension and help quickly establish the submucosal cavity to facilitate the submucosal dissection.

To date, an early traction strategy has been reported in merely 2 kinds. Takashiro et al. (3) introduced an ECL method initiated immediately after submucosal injection during colorectal ESD. They performed a retrospective comparison study showing that ECL significantly reduced procedure time (4). Although the ECL method is simple and with low cost, the traction direction is limited in which the line is pulled. The mucosal flap usually falls toward the endoscope under proximal traction, making it difficult to approach the submucosa if the endoscope tip is not parallel to the colorectal wall. On the contrary, distal traction or vertical traction may be more effective in some occasions to enable visualization of the submucosa by turning over the mucosa and facilitate submucosal dissection by providing tension to

Table 1. Clinical characteristics and therapeutical outcomes of patients with colorectal laterally spreading tumor treated by endoscopic submucosal dissection with clip-with-spring preincision traction

No.	Age/ gender	Lesion location	Lesion diameter (cm)	Macroscopic morphology	Traction direction	Procedure time (min)	*En bloc* resection	R0 resection	Histology	Outcomes
1	71/male	Transverse	6.0	Granular	Anal side	60	Yes	Yes	Adenocarcinoma (intramucosal)	Surveillance
2	67/male	Sigmoid	3.0	Granular	Oral side	12	Yes	No	Adenocarcinoma (SM1)	Surgery
3	48/female	Ascending	3.0	Nongranular	Anal side	12	Yes	Yes	Serrated adenoma	Surveillance
4	62/male	Transverse	7.0	Granular	Anal side	22	Yes	Yes	Serrated adenoma	Surveillance
5	63/male	Transverse	4.0	Granular	Oral side	34	Yes	Yes	Adenocarcinoma (intramucosal)	Surveillance
6	70/female	Ascending	3.5	Nongranular	Oral side	58	Yes	Yes	Adenocarcinoma (SM2)	Surgery
7	70/male	Ascending	4.0	Nongranular	Anal side	75	Yes	Yes	Villous adenoma	Surveillance
8	69/male	Transverse	3.5	Nongranular	Oral side	46	Yes	Yes	Adenocarcinoma (SM1)	Surveillance
9	75/female	Ileocecum	3.5	Granular	Anal side	15	Yes	Yes	HGIN	Surveillance
10	71/male	Hepatic flexure	5.5	Nongranular	Anal side	60	Yes	Yes	HGIN	Surveillance
11	68/male	Sigmoid	3.5	Nongranular	Anal side	18	Yes	No	Adenocarcinoma (SM2)	Surgery
12	67/male	Sigmoid	4.5	Granular	Oral side	24	Yes	Yes	Serrated adenoma	Surveillance
13	34/female	Ileocecum	3.0	Nongranular	Anal side	21	Yes	Yes	Serrated adenoma	Surveillance
14	80/male	Ileocecum	4.0	Granular	Anal side	56	Yes	Yes	Villous adenoma	Surveillance
15	67/female	Sigmoid	4.0	Granular	Anal side	42	Yes	Yes	HGIN	Surveillance
16	72/female	Sigmoid	4.5	Granular	Oral side	25	Yes	Yes	HGIN	Surveillance
17	61/female	Sigmoid	3.5	Granular	Anal side	18	Yes	Yes	Adenocarcinoma (SM1)	Surveillance
18	47/male	Hepatic flexure	3.5	Granular	Oral side	17	Yes	Yes	Serrated adenoma	Surveillance
19	74/male	Ileocecum	3.5	Nongranular	Oral side	29	Yes	Yes	Tubular adenoma	Surveillance
20	70/female	Transverse	4.0	Nongranular	Oral side	31	Yes	Yes	Adenocarcinoma (intramucosal)	Surveillance
21	60/male	Ileocecum	4.5	Granular	Anal side	14	Yes	Yes	Serrated adenoma	Surveillance
22	76/male	Ileocecum	3.5	Granular	Oral side	12	Yes	Yes	HGIN	Surveillance
23	73/male	Sigmoid	4.0	Granular	Oral side	19	Yes	Yes	Adenocarcinoma (intramucosal)	Surveillance
24	81/male	Ascending	4.0	Nongranular	Anal side	19	Yes	Yes	Villous adenoma	Surveillance
25	62/female	Transverse	6.0	Granular	Oral side	10	Yes	Yes	HGIN	Surveillance
26	65/male	Ascending	3.5	Granular	Anal side	26	Yes	Yes	HGIN	Surveillance

HGIN, high-grade intraepithelial neoplasia; SM1, submucosal invasion <1,000 μm; SM2, submucosal invasion ≥1,000 μm.

submucosa. Furthermore, the ECL method may bring friction between the line and the endoscope in the narrow lumen, which may interfere with the dissection and cause strong traction resulting in clip slip-off. Although the traction force could possibly be increased by pulling the line, it is difficult to be weakened. Previous studies have shown that a clip-with-line device provided limited usefulness and effectiveness in assisting ESD for lesions in the proximal colon (14). Moreover, the traction cannot be repositioned unless withdrawal and reinsertion of the endoscope. The other early traction method was reported by Kawaguchi et al. (5) using the S–O clip, which is a clip with a 5 mm spring plus a 4 mm nylon loop at 1 of the clip claws (15). This device is convenient to use and could provide internal traction in any direction. A previous study has reported the value of this device in

Table 2. Comparisons of baseline characteristics and therapeutic outcomes between patients of the preincision traction group and on-demand traction group

Variables	PIT group (n = 26)	ODT group (n = 26)	*P* value
Sex (M/F)	17/9	14/12	0.397
Age, mean ± SD, yr	66.3 ± 10.3	67.8 ± 10.9	0.604
BMI, mean ± SD kg/m2	22.5 ± 2.6	21.6 ± 2.6	0.228
Abdominal surgery history, yes/no	7/19	8/18	0.760
BBPS, mean ± SD	6.2 ± 0.9	6.1 ± 1.0	0.666
Lesion diameter, mean ± SD, cm	4.1 ± 1.0	4.4 ± 1.5	0.284
Lesion location (proximal/distal)	19/7	16/10	0.375
Macroscopic morphology (granular/nongranular)	16/10	18/8	0.560
En bloc resection, n (%)	26 (100)	26 (100)	1.000
R0 resection, n (%)	24 (92.3)	25 (96.2)	0.552
Procedure time, mean ± SD, min	29.8 ± 18.4	57.4 ± 33.7	**0.001**
Total submucosal injection volume, mean ± SD, mL	49.6 ± 32.3	70.8 ± 37.6	**0.034**
Histopathological type, n (%)			
Adenoma	10 (38.5)	9 (34.6)	0.773
HGIN or intramucosal adenocarcinoma	11 (42.3)	14 (53.8)	0.405
Submucosal adenocarcinoma	5 (19.2)	3 (11.5)	0.442
Postoperative hospital stay, mean ± SD, d	1.8 ± 0.8	2.5 ± 1.2	**0.015**
Complications, n (%)			
Intraoperative bleeding, n (%)	7 (26.9)	15 (57.7)	**0.025**
Muscular injury, n (%)	2 (7.7)	9 (34.6)	**0.038**
Delayed bleeding, n (%)	0	1 (3.8%)	1.000
Total expenses, Chinese Yuan	18,774.6 ± 3,632.3	19,756.4 ± 2,434.0	0.258

Significance for bold entries was *P* value ≤ 0.05.
BBPS, Boston Bowel Preparation Scale; BMI, body mass index; F, female; HGIN, high-grade intraepithelial neoplasia; M, male; ODT, on-demand traction; PIT, preincision traction.

ODT for colorectal ESD (16). However, no comparison study has been reported to prove the efficacy of this device in PIT for colorectal ESD. Whether the PIT strategy using an internal traction device could improve the safety and efficacy of colorectal ESD remains unelucidated.

In this study, we performed the first prospective comparison study to investigate the safety and efficacy of the PIT strategy using an internal traction device in assisting colorectal ESD. We used a novel clip-with-spring device. This device requires no special preparation and can be used at any location. The traction direction can be controlled in any direction by adjusting the anchor site. The spring of this device is shorter in length, when compared with the S–O clip, enabling a continuous tension throughout the ESD process. The traction force can also be adjusted by inflating or collapsing the lumen to some extent. Although the ring seems very small, it brings no more technical difficulty to an ESD performer. In our experience, the ring could be easily anchored by another endoclip even by novices. Our results showed that PIT-ESD using this novel device could significantly reduce the submucosal injection volume and total procedure time, and prevent intraoperative bleeding and undesired muscular injury. The improved safety and efficacy of PIT-ESD during the procedure could enhance the confidence of early feeding and discharge of the patients, which was demonstrated by a significantly shorter postoperative hospital stay in the PIT group compared with that in the ODT group. Concerning the cost-effectiveness, although applying this technique involves additional use of 2 clips and the grasping forceps, the total expenses were not increased. This could be probably explained by the elevated consumption of sodium hyaluronate, prolonged hospital stays, and a higher likelihood of using hemostatic forceps or clips in the ODT-ESD group. It is noteworthy to address 1 possible concern that the PIT would affect the incision of the mucosa on the oral side of the lesion. Conventionally, the traction was applied after circumferential incision to prevent this affection. However, in our experience, no significant influence on oral-side mucosa incision was observed in all PIT-ESD procedures. Taken together, our study demonstrated great prospects of the PIT strategy in improving the efficacy and safety of colorectal ESD.

The procedures of colorectal ESD could be affected by a series of complex factors including lesion-dependent factors, such as size, anatomical location, and submucosal fibrosis, and patient-dependent factors as well. Some ESDs for lesions with specialized location or patients with extremely difficult colonoscopy intubation could give rise to unstable scope position, endoscopic control, and maneuverability. Therefore, there was inevitable variation in the procedure time and complication risks among the different patients. We did not include patients with rectal lesions in this study. The rectum is regarded as being the easiest location for colorectal ESD. The rectum lumen is straight and the wall is thicker than that of the colon. There are no obvious flexures and folds and peristaltic movements in the rectum. Furthermore, rectal ESD could be performed using a gastroendoscope, which is much more flexible than a colonoscope and allows retroflection for dissection. In addition, the thread-traction method, if needed, could be easily and effectively applied during rectal ESD due to convenient withdrawal and reinsertion of the endoscope. Given these aspects, the internal traction strategy using the novel clip-with-spring device may possess little significance for rectal ESD.

Our study had several limitations. First, it was performed on a relatively small number of patients. Second, all procedures were performed by a high-skilled endoscopist (F.L.) in a single center, which may affect the generalizability of the results. Third, it was unable to perform double-blinding. The possible subjectivity of the treatment decision may affect the overall generalizability of the results. However, given the diversified lesions and equivalent baseline characteristics between the groups, the results were inspiring to exhibit the advantages of the PIT method in assisting colorectal ESD. We will perform large-scale, randomized, controlled studies for further investigation.

In summary, the PIT method as a novel ESD strategy could significantly improve the safety and efficacy of colorectal ESD. PIT-ESD may serve as an appropriate method for colorectal ESD.

CONFLICTS OF INTEREST

Guarantor of the article: Feng Liu, MD.

Specific author contributions: Conception and design: F.L. Acquisition, analysis and interpretation of the data: J.L. Drafting of the manuscript: J.L. Critical revision of the article for important intellectual content: F.L. Technical or material support: Y.W., D.Z., X.H., M.S., K.C., R.W., and K.P. Study supervision: F.L. All authors approved the version to be published.

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Potential competing interests: None to report.

Study Highlights

WHAT IS KNOWN

- ✓ Adequate exposure of the dissection site is very important for colorectal endoscopic submucosal dissection (ESD).
- ✓ Several traction methods have been developed to facilitate colorectal ESD.
- ✓ No comparative study has been reported between the preincision traction (PIT) and on-demand traction using an internal traction device.

WHAT IS NEW HERE

- ✓ The first comparative study between PIT and on-demand traction method using an internal traction device in assisting colorectal ESD.
- ✓ PIT could provide adequate visualization and tissue tension and help quickly establish the subonemucosal cavity.
- ✓ PIT could significantly improve the safety and efficacy of colorectal ESD.
- ✓ PIT-ESD possesses great prospects to become a standardized strategy for colorectal ESD and is worth widespread generalization.

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