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

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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

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
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 undergone 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 nodal or distant metastasis demonstrated by computed tomography 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 χ² tests or Fisher exact test. A 2-sided P ≤ 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
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 ± 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 ± 18.4 vs

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.

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) Mucosal incision and submucosal dissection are performed under countertraction. (f) Complete removal of the lesion.
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 relatively 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...
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
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 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 retroflexion 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.

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 (%)                    | 10 (38.5)          | 9 (34.6)           | 0.773   |
| Adenoma                                          | 11 (42.3)          | 14 (53.8)          | 0.405   |
| HGIN or intramucosal 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 (%)                             | 7 (26.9)           | 15 (57.7)          | 0.025   |
| Intraoperative bleeding, n (%)                   | 2 (7.7)            | 9 (34.6)           | 0.038   |
| Muscular injury, n (%)                           | 0                  | 1 (3.8%)           | 1.000   |
| Delayed bleeding, n (%)                          | 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.
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.

 Financial support: This work was supported by grants from the Shanghai Municipal Health Commission Scientific Research Project General Program (No. 201940082).

 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 submucosal 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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