Efficacy and Safety of Single Clip Traction Assisted Endoscopic Submucosal Dissection for Colonic Neoplasms: A Propensity Score Matching Analysis

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AIM: Endoscopic submucosal dissection (ESD) for colonic neoplasms is a technically intricate procedure. Internal traction using a single clip has emerged as a promising supportive technique for colonic ESD. Therefore, this study aimed to comprehensively evaluate and compare the efficacy and safety of ESD with and without the aid of single-clip traction.

METHODS: This retrospective study encompassed 36 patients who underwent single clip traction-assisted colonic ESD and 66 who underwent the traditional method of colonic ESD at Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University. We employed the propensity score-matching method to mitigate disparities in resected specimen size and tumor location. Post-matching, we comprehensively assessed treatment outcomes and incidence of adverse events between the two treatment groups (single clip traction-assisted ESD (scESD) and conventional ESD (cESD)).

RESULTS: After propensity score matching, we observed 34 matched pairs. There were no significant differences between the two treatment groups regarding the en bloc resection rate, complete resection rate, and curative rate. However, the procedure duration was significantly shorter in the single clip traction-assisted ESD group compared to the conventional ESD group (20.00 [Interquatile Range (IQR)] (16.00–32.50) minutes vs 31.50 [IQR] (17.00–54.00) minutes, $p = 0.0474$). Furthermore, there was a significant increase in dissection speed in the single clip traction-assisted ESD group compared to the conventional ESD group (0.29 [IQR] (0.20–0.45) mm^2/min vs 0.19 [IQR] (0.11–0.35) mm^2/min, $p = 0.0015$). All lesions were resected in a single piece. Among the propensity-score-matched patients, only those treated with single clip traction-assisted ESD exhibited faster dissection speeds ($p = 0.015$). Furthermore, there were no substantial differences in adverse events such as intraoperative perforation, delayed perforation, or delayed bleeding.

CONCLUSIONS: Our findings suggest that single clip traction-assisted colonic ESD is preferable to traditional colonic ESD, owing to its shorter procedure duration and faster dissection speed.

Keywords: single clip traction; internal traction; endoscopic submucosal dissection; propensity score matching analysis

Introduction

Endoscopic mucosal resection (EMR) is a commonly used surgical technique for the treatment of superficial gastrointestinal tumors [1]. However, for larger lesions, piecemeal resection techniques can lead to postoperative residual tumors and recurrence. To address this challenge, endoscopic submucosal dissection (ESD) allows for the efficient removal of large lesions in one piece, providing complete histological evaluation of lateral and deep margins. This approach guides further treatment and effectively reduces the postoperative recurrence rate [2, 3, 4]. Endoscopic submucosal dissection (ESD), when applied to colonic lesions, may encounter technical challenges like limited traction and reduced visibility, elevating the risks of complications like perforation and bleeding [5]. However, ESD offers a significant advantage of complete resection regardless of lesion size, enhances pathological assessments, and contributes to lower recurrence rates [6, 7, 8, 9].

During the ESD procedure, various challenges often arise because of the colon's delicate walls, particularly in the proximal section, as well as bends, folds, and colonic contractions. The deep position of the colonic lesion and multiple bends make external traction unsuitable. Internal traction is commonly used in colonic ESD. Many traction methods, including S-O clip [10, 11], double-clip traction with rubber band [12], and magnetic anchor [13] have been developed to facilitate colonic ESD. These techniques aim to shorten procedure time and minimize the risk of complications.

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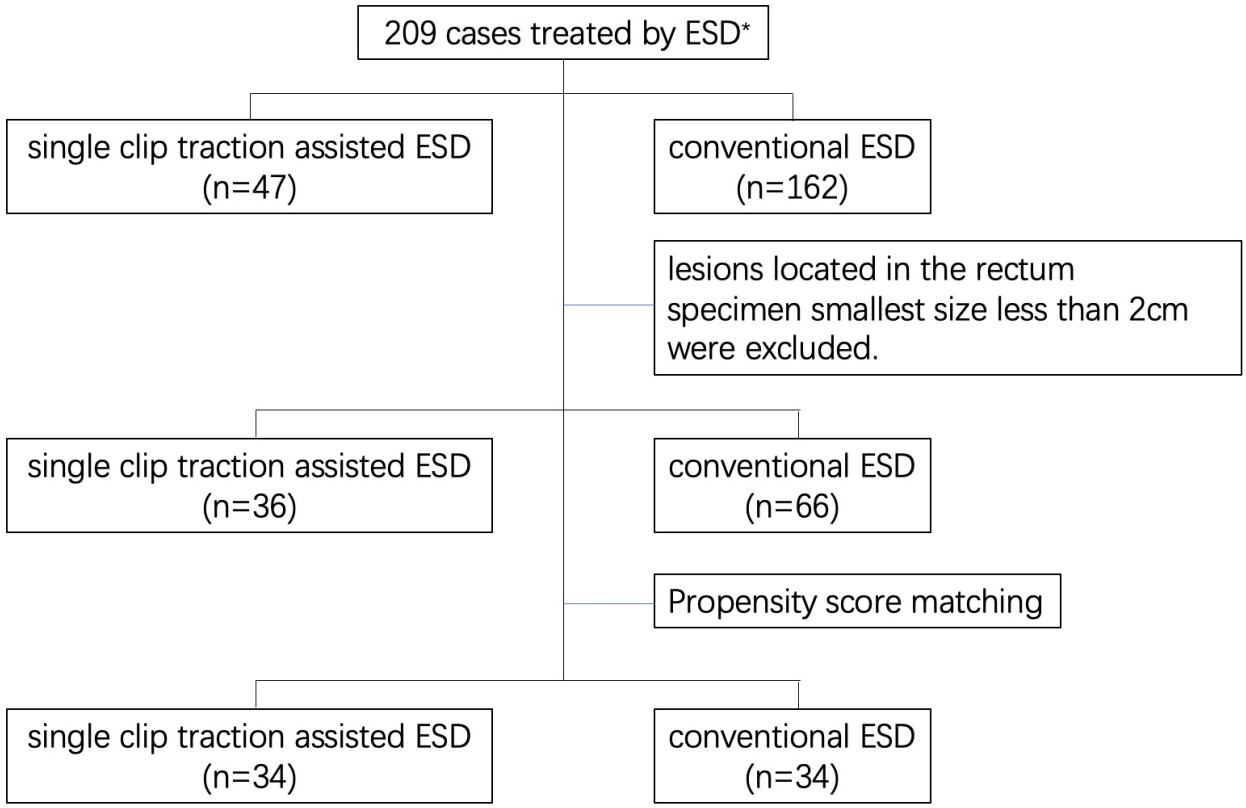

Fig. 1. A flowing chart of the patient's selection process. ESD, endoscopic submucosal dissection.

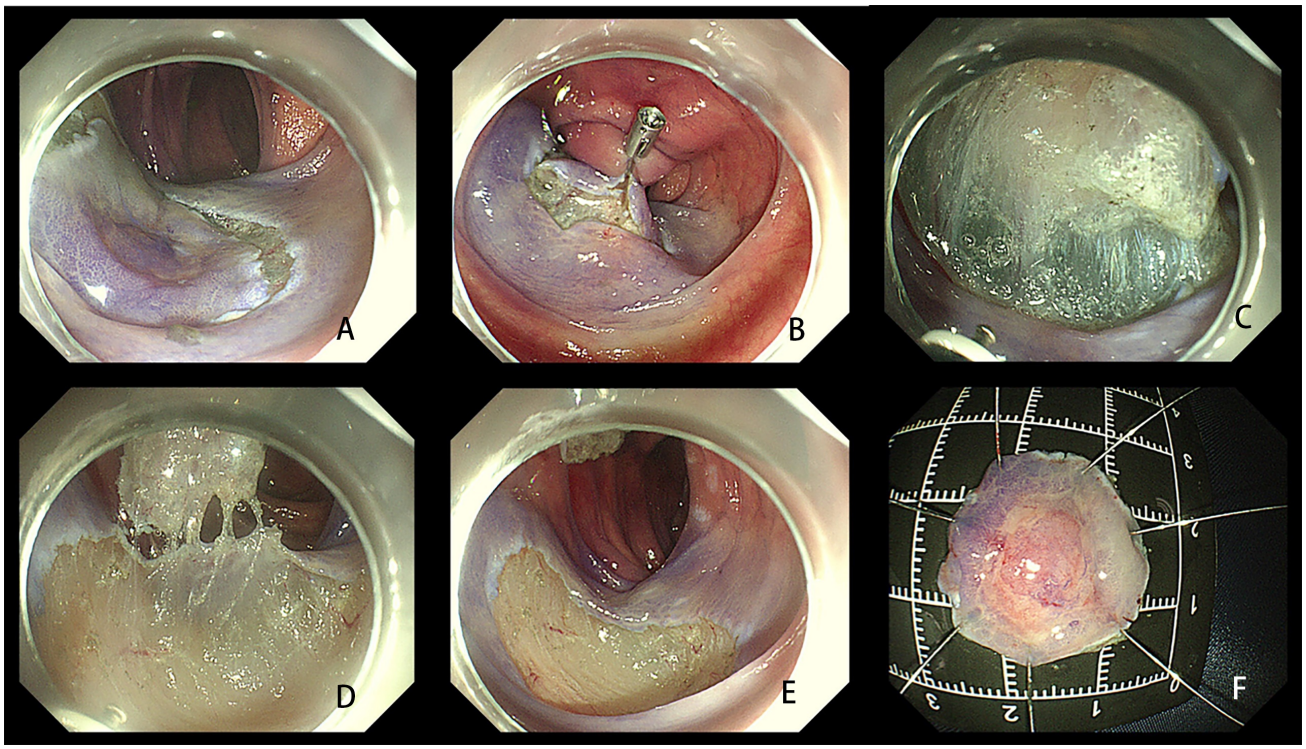

Fig. 2. Endoscopic submucosal dissection (ESD) procedure involving a single clip traction. (A) Circumferential mucosal incision was performed in transverse colon lesion. (B) A single clip was used to connect the lesion to the opposing colonic wall. (C,D) Clear visualization was obtained during the submucosal dissection. (E) Trauma of ESD. (F) Resected specimen.

Materials and Methods

Study Participants

This study included 47 patients who underwent endoscopic submucosal dissection (ESD) with the assistance of single clip traction and 162 patients who received conventional ESD at Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University (Nanjing, China) between January 2021 and April 2022. Before the surgical procedure, all patients underwent routine blood analysis, coagulation tests, abdominal CT scans, and colonoscopy. We meticulously collected and retrospectively analyzed data from medical records, procedural videos, and endoscopic reports. We excluded cases involving rectal lesions and those with specimen sizes smaller than 2 cm. In patients with multiple lesions, we focused solely on the first one treated. After rigorous review, we compiled a retrospective dataset consisting of 36 cases of single-clip traction-assisted ESD and 66 cases of conventional ESD. The selection procedure of the study participants is shown in Fig. 1.

All participants were thorough informed consent of the study and the potential risks and benefits of the surgery. The informed consent was obtained prior to undergoing ESD. The Medical Ethics Committee of Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University approved this retrospective cohort study (2022-477-145). The study design adhered to the declaration of Helsinki.

Single Clip Traction-Assisted ESD Procedure

An experienced person performed the ESD procedures. A mixture of normal saline, methylene blue, and adrenaline was carefully injected into the submucosa just outside the lesion. A circumferential mucosal incision was carefully made around the lesion site using a dual knife, maintaining a 5 mm margin. Once the mucosal incision was completed, the submucosal dissection was initiated from the proximal side of the lesion, creating a mucosal flap. After this, this flap was clamped with a single clip (Microtech, Nanjing, China), with an arm length of 5.5 mm and an opening size of 10 mm, and securely attached to the opposite intestinal wall of the lesion, offering the operator a clear view of the submucosal layer. After careful dissection, the specimen was gently removed from the contralateral mucosa using a snare. Single clip traction-assisted ESD procedure is shown in Fig. 2 and **Supplementary Video 1**.

Histological Evaluation

The histopathological assessments were conducted by skilled pathologists, utilizing the Vienna classification for histological observations. Tumor extension was evaluated based on the following criteria: (1) If no tumor was identified at the lateral or vertical margins, it was classified as R0. (2) If the tumor extended to the lateral or vertical margins, it was classified as R1. (3) If the margin could not be properly evaluated, the specimen was labeled as RX. These classifications provide a comprehensive assessment of tumor extension and aid in determining the most appropriate treatment plan.

The pathological evaluation covered a range of findings, including adenoma, low-grade intraepithelial neoplasia, high-grade intraepithelial neoplasia, dysplasia, intramucosal carcinoma, and submucosal carcinoma. These pathologies represent different stages and severities of cellular abnormality, providing crucial information for precise diagnosis and treatment planning.

Outcomes and Definitions

The primary focus of the study was to assess procedure time and dissection speed. Secondary outcomes included the rate of en bloc resection, the complete resection rate (R0 resection rate), and the occurrence of adverse events such as bleeding and perforation. Additionally, the resected specimen size, including its largest and smallest diameters, as well as the histological characteristics of the lesions, were examined as adjunctive outcomes.

The procedure time refers to the duration from the initial submucosal injection to the complete excision of colonic lesions. The resected specimen's area is computed using the following formula:

Area = (shorter diameter) $\times$ (longer diameter)/2 $\times$ 3.14.

The speed of dissection is determined by dividing the area of the specimen by the total procedure duration. Lesions are generally categorized into two regions: the right colon, which includes the cecum, ascending colon, and transverse colon, and the left colon, which includes the descending colon and sigmoid colon.

En bloc resection involves surgical removal of the entire lesion in a single continuous piece. A complete resection, on the other hand, is confirmed when the en bloc resection is pathologically found to be negative for cancer cells at both the horizontal and vertical margins. Furthermore, for resection to be considered curative, it must be complete and lack any of the following adverse characteristics: submucosal invasion deeper than 1000 micrometers, lymphatic invasion, vascular involvement, tumor budding exceeding grade 1, or poorly differentiated components.

Additionally, perforation was classified into intraoperative and delayed types. Intraoperative perforation was defined as tissue visualization outside the serosa during the ESD procedure. However, delayed perforation was identified when no intraoperative damage, abdominal pain, fever and other signs of peritonitis occurred within two weeks after surgery. Moreover, CT scans indicated free air in the abdominal cavity, abdominal fluid accumulation, and intestinal wall thickening. Delayed bleeding was defined as bleeding that required additional endoscopic intervention to stop it within two weeks after surgery.

Statistical Analysis

We applied a propensity-score matching analysis to reduce sampling bias and confounding variables, ensuring the ac-

Table 1. Comparison of baseline characteristics between single clip traction assisted ESD and conventional ESD groups before and after propensity score matching.

Variables	Overall				Propensity score matching			
	scESD (n = 36)	cESD (n = 66)	z/χ^2	*p* value	scESD (n = 34)	cESD (n = 34)	z/χ^2	*p* value
Median age, years (IQR)	65.00 (58.50–70.50)	62.50 (53.00–67.00)	–1.475	0.14	63.50 (58.50–66.50)	62.5 (59.0–64.0)		0.585
Females, n (%)	14 (38.9)	27 (40.9)	0.04	0.842	14 (41.2)	12 (35.3)	0.249	0.618
Median resected specimen longer diameter, mm (IQR)	3.00 (2.50–3.75)	2.50 (2.20–3.30)	–1.647	0.099	3.00 (2.50–3.73)	2.50 (2.08–3.85)	–1.475	0.236
Median resected specimen shorter diameter, mm (IQR)	2.50 (2.00–3.10)	2.00 (2.00–3.00)	–1.961	0.0498	2.50 (2.00–3.05)	2.00 (2.00–3.13)	–1.573	0.072
Median resected specimen area, mm^2 (IQR)	6.23 (3.86–8.77)	4.18 (3.45–7.07)	–1.610	0.1075	6.31 (3.73–8.91)	4.24 (3.18–7.23)	1.170	0.112
Location			3.569	0.059			1.581	0.209
Left colon, n (%)	10 (27.8)	31 (47.0)			10 (29.4)	15 (44.1)		
Right colon, n (%)	26 (72.2)	35 (53.0)			24 (70.6)	19 (55.9)		
Histology			8.986	0.174				
adenoma, n (%)	12 (33.3)	21 (31.8)						
low-grade intraepithelial neoplasia, n (%)	1 (2.8)	3 (4.5)						
high-grade intraepithelial neoplasia, n (%)	8 (22.2)	22 (33.3)						
dysplasia, n (%)	7 (19.4)	2 (3.0)						
intramucosal carcinoma, n (%)	5 (13.9)	10 (15.2)						
submucosal carcinoma, n (%)	3 (8.3)	7 (10.6)						
Neuroendocrine tumor, n (%)	0 (0)	1 (1.5)						

scESD, single clip traction-assisted ESD; cESD, conventional ESD; IQR, Interquatile Range.

Table 2. Treatment outcomes and adverse events before and after propensity score matching.

Variables	Overall				Propensity score matching			
	scESD (n = 36)	cESD (n = 66)	z/χ^2	*p* value	scESD (n = 34)	cESD (n = 34)	z/χ^2	*p*-value
Median procedure time, min (IQR)	20.00 (16.00–32.50)	31.50 (17.00–54.00)	–1.982	0.0474	20.00 (16.00–31.25)	32.00 (17.00–52.00)	–1.997	0.053
Median dissection speed, mm^2/min (IQR)	0.29 (0.20–0.45)	0.19 (0.11–0.35)	–3.183	0.0015	0.29 (0.19–0.45)	0.20 (0.10–0.36)	–3.184	0.015
En bloc resection, n (%)	36 (100)	66 (100)	-	1	34 (100)	34 (100)	-	1
Complete resection, n (%)	36 (100)	61 (92.4)	-	0.158	34 (100)	31 (91.2)	-	0.239
Curative resection, n (%)	34 (94.4)	59 (89.4)	0.244	0.612	32 (94.1)	30 (88.2)	0.183	0.669
Intraoperative perforation, n (%)	1 (2.8)	2 (3.0)	0.293	0.588	1 (2.9)	0	-	1
Delayed perforation, n (%)	0	0	-	1	0	0	-	1
Delayed bleeding, n (%)	0	2 (3.0)	-	0.539	0	0	-	1

scESD, single clip traction-assisted ESD; cESD, conventional ESD.

curacy of our results. Using a logistic regression model, we calculated the propensity score for each case, considering factors such as age, gender, lesion location (whether in the right colon or left colon), and the length of the specimen in both directions. To further enhance the reliability of our findings, we employed a one-to-one nearest neighbor matching technique with a caliper of 0.05, ensuring that no sample was matched more than once (**Supplementary Fig. 1**).

To evaluate the efficacy of our matching approach, we compared both continuous and categorical variables in the unmatched and matched cohorts. The normality of continuous variables was assessed using the K-S test, and those not following the normal distribution were expressed as the median (P25, P75). For categorical variables, we used either the Fisher exact test or the chi-squared (χ^2) test to assess differences. For continuous variables, we applied the Mann–Whitney U test to identify significant disparities. A p-value less than 0.05 was considered statistically significant, indicating a high level of confidence in our findings. All statistical analyses were meticulously performed using Stata version 16 (SPSS Inc. IBM Company Headquarters, Chicago, IL, USA).

Results

Comparison of Baseline Characteristics between the Two Treatment Groups

Between January 2021 and April 2022, Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University treated 209 patients with colonic neoplasms using endoscopic submucosal dissection (ESD). Among these, 47 patients underwent single clip traction-assisted ESD (scESD), while 162 received conventional ESD (cESD). After applying predetermined exclusion criteria, such as lesions in the rectum or lesions smaller than 2 cm, the final study cohort included 102 patients, comprising 36 patients who underwent scESD and 66 who received cESD.

The patient selection process is outlined in Fig. 1, while the clinicopathological characteristics of the two experimental groups are summarized in Table 1. We observed a skewed distribution regarding the specimen's shorter diameter, procedure time, and dissection speed. Furthermore, there were substantial differences in the longer diameter and location of the resected specimens between the two treatment groups.

To minimize potential biases, we employed a propensity score matching technique. This approach matched patients based on three key parameters: the specimen's shorter diameter, the resected specimen's longer diameter, and the lesion's location. After this matching, we identified 34 pairs of patients, each consisting of one patient treated with cESD and the other with scESD. Importantly, after the matching process, there were no significant differences between the two groups regarding age, gender, resected specimen's longer diameter, specimen's shorter diameter, lesion location, and pathology. This finding suggests that the two ESD techniques were comparable regarding patient characteristics and resected tissue dimensions, offering a more accurate comparison of their clinical outcomes. A comparison of baseline characteristics between the two treatment groups is shown in Table 1.

Comparison of Treatment Outcomes and Incidence of Adverse Events between the Two Treatment Groups

Before propensity score matching, we observed that the median procedure time in the scESD group was substantially shorter than the cESD group (20.00 minutes versus 31.50 minutes, $p = 0.0474$). Moreover, the dissection speed was significantly faster in the scESD group compared to the cESD group (0.29 versus 0.19 mm^2/min, $p = 0.0015$).

However, after propensity score matching, the difference in procedure time between the two groups was insignificant ($p = 0.053$). Notably, the dissection speed remained faster in the scESD group than the cESD group (0.29 versus 0.20 mm^2/min, $p = 0.015$). Furthermore, both groups exhibited similar rates of en bloc resection, complete resection, and curative resection before and after propensity score matching ($p > 0.05$).

Regarding adverse events, there was one case of intraoperative perforation in the scESD group and two cases in the cESD group before propensity score matching. The scESD group reported no cases of delayed bleeding, while two cases were observed in the cESD group. However, no delayed perforation was observed in either group. After propensity score matching, the two treatment groups had no significant differences in intraoperative perforation, delayed bleeding, or delayed perforation. A comparison of treatment outcomes and incidence of adverse events between the two treatment groups is summarized in Table 2.

Discussion

We conducted a comprehensive analysis using propensity score matching [14] to assess the effectiveness of colonic ESD when assisted by single clip traction. Our unmatched cohort analysis revealed that this novel technique was significantly associated with shorter procedure time and faster dissection speeds. Notably, there were no significant differences in critical surgical outcomes such as en bloc resection rates, complete resection rates, or the incidence of intraoperative and delayed complications like perforation and bleeding. Additionally, our propensity score-matched analysis further confirmed that single clip traction-assisted ESD led to significantly faster dissection speeds than cESD methods.

Given the challenging anatomic location of colonic lesions, which are often deeply located and surrounded by numerous bends [6], external traction is generally impractical. Consequently, internal traction has emerged as a preferred method for colonic ESD. Over the years, various traction techniques have been developed, including using S-O clips [8, 12, 13],

double-clip traction with rubber bands [15], and magnetic anchors [16].

The S-O clip-assisted ESD has demonstrated remarkable outcomes compared to traditional ESD, including significantly shorter procedure time, faster dissection speeds, and higher en bloc resection rates [17, 18]. However, the widespread implementation of this technique is hampered by the limited availability and high cost of the device [15]. Similarly, magnetic anchors have shown promise in colonic ESD. A prospective trial indicated that the median procedure time of patients treated with magnetic anchor-guided ESD was 76 minutes, with en bloc resections achieved in all cases [10]. Nevertheless, the complexity and expense associated with this technology have precluded its widespread use. Similarly, double-clip traction with rubber bands has been shown to be safe and reproducible, offering higher dissection speeds [9]. However, the traction force of this method tends to decrease rapidly as dissection proceeds, which may compromise its effectiveness. Overall, these traction methods require specialized equipment and are relatively complicated, which has limited their usefulness in colonic ESD [1].

The single-clip traction method is differentiated by its simplicity and versatility. The colon's natural flexibility allows the clip to establish a stable connection between the lesion mucosa and the contralateral mucosa, enabling continuous traction throughout the dissection. While this technique offers traction in only one direction and may require adjustments during endoscopy reversals, it is easily adaptable to diverse surgical scenarios.

The primary advantage of single-clip traction is its affordability and accessibility. Unlike more complex traction devices, it requires a standard clip which is widely available and inexpensive. The preparation for single-clip traction is straightforward and can be accomplished quickly, making it highly practical in clinical settings. Furthermore, this technique significantly improves visualization of the submucosa during colonic ESD, allowing surgeons to perform more precise dissection and minimizing the risk of intraoperative bleeding and perforation. Our study revealed that the single clip traction technique significantly shortened the procedure time and accelerated the dissection process.

From the ESD procedure, we have observed some critical points to consider. Firstly, it is crucial to keep the endoscope as far as possible and avoid forming loops, which helps ensure that the endoscope remains in the surgical area. Secondly, the traction direction is particularly important; it must align with the main direction of dissection to maintain its efficacy. The incorrect direction can reduce its overall benefits. Lastly, precise control of the amount of gas is crucial, as the traction method is adjusted by changing the amount of gas. Therefore, precise gas control is needed to avoid overinflation, which may lead to lesions tearing or the metal clip dislodging.

We also found that this method is especially effective for treating intestinal lateral developmental tumors (LST), which are challenging for establishing mucosal flaps. Furthermore, it offers a good traction effect for both large and small lesions. However, it is worth noting that this study has some limitations. Firstly, it was a retrospective study conducted at a single center, limiting the number of patients included. Secondly, while propensity score-matching analysis helped reduce biases resulting from observable differences between groups, it does not eliminate biases from unobservable differences. Hence, further evaluation through a randomized controlled study is needed to assess the effectiveness of the single clip for colonic ESD.

Conclusions

In summary, this study underscores the potential of the single clip traction technique in colonic ESD, offering shorter procedure time and faster dissection speeds than traditional methods. The simplicity and effectiveness of the single clip make it a promising approach for improving traction in colonic ESD procedures.

Abbreviations

ESD, endoscopic submucosal dissection; scESD, single clip traction-assisted ESD; cESD, conventional ESD; IQR, Interquatile Range.

Availability of Data and Materials

Data are available from the corresponding author, please contact chenggong_yu@nju.edu.cn.

Author Contributions

Formal analysis, XTD, MC; investigation, DDZ, XQZ; data analysis, XTD, CRW; conduct experiments, LW and CGY; writing-original draft preparation, XTD, DDZ; writing-review and editing, LW, CGY. All authors have been involved in revising it critically for important intellectual content. All authors gave final approval of the version to be published. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

All participants were thorough informed consent of the study and the potential risks and benefits of the surgery. The informed consent was obtained prior to undergoing ESD. The Medical Ethics Committee of Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University approved this retrospective cohort study (2022-477-145). The study design adhered to the declaration of Helsinki.

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Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.62713/aic.3441.

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