

Endoscopic submucosal dissection for large early squamous cell carcinoma—traction assisted methods

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Abstract: Endoscopic resection is a minimally-invasive treatment for superficial esophageal tumors compared with surgery or chemoradiation therapy. Endoscopic submucosal dissection (ESD) is a wellestablished method with accurate histological evaluation and favorable procedural outcomes. However, ESD requires a high level of skill, and is therefore technically challenging and time-consuming. Traction-assisted ESD has been introduced to facilitate ESD and provides adequate submucosal visualization and satisfactory tissue traction. We reviewed the scientific literature in English to evaluate the efficacy of traction-assisted ESD for esophageal lesions, including the clip-with-thread (CT) method and the submucosal tunneling (ST) method. The CT method is a simple and affordable technique that uses commercially available hemoclips. Two randomized controlled trials and two retrospective studies showed that the CT method resulted in shorter procedure times and reduced local injection compared with conventional ESD, and no cases of perforation. The ST method does not require specific devices and facilitates the procedure by securing a stable submucosal visual field and maintaining a submucosal liquid cushion. Two retrospective studies reported shorter procedure times with similar en bloc resection rates and complete resection rates using the ST method compared with conventional ESD. Although a combination of the ST method with the CT method seems to be effective for large lesions, its efficacy and safety should be confirmed by a largescale study. In the future, robotic traction has a great potential to be a breakthrough for esophageal ESD, providing appropriate and multi-directional traction to the lesions via an operator-controlled robotic arm. There is no doubt that traction assistance is key to facilitating esophageal ESD. Further studies are needed to elucidate the best method from the perspective of efficacy, safety, and cost.

Keywords: Esophageal lesion; endoscopic submucosal dissection; traction assist; clip-with-thread method; submucosal tunneling method

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Introduction

Surgical resection for esophageal cancer requires esophageal subtotal resection with lymph node dissection, as well as organ reconstruction using the stomach, large intestine or small intestine, which is extremely invasive to the body. Meanwhile, endoscopic resection is a minimally invasive treatment that only removes the mucosa of the esophagus and the incidence of procedural adverse events is lower than that for surgical resection (1,2). Endoscopic mucosal

resection (EMR) was first performed for esophageal cancer in the late 1980s, and EMR with a cap-fitted panendoscope (EMR-C), a modified EMR method enabling treatment of larger lesions, was reported by Inoue *et al.* (3,4) in the early 1990s. However, because these methods used a snare, there were cases where the lesion was resected into pieces depending its location and size, resulting in incomplete endoscopic resection or additional surgical resection (5). In the late 1990s, endoscopic submucosal dissection (ESD) for gastric cancer appeared and has gradually gained popularity

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because of its accurate histological evaluation and favorable procedural outcomes (6-10). From Japan, it has been reported that the en bloc resection rate of ESD ranges from 95% to 100% and the complete resection rate from 88% to 94.6% (11-13). In addition, Yamashina et al. (14) reported long-term outcomes for 394 cases of superficial esophageal cancer treated by endoscopic resection, and the 5-year survival rate was 90.5% for epithelium/lamina propria mucosa, 71.1% for muscularis mucosae and 70.8% for submucosal cancer. Tsujii et al. (15) also reported that the 3- and 5-year recurrence-free survival rates after ESD were 91.5% and 84.8% in the curative resection group and 76.0% and 72.7% in the non-curative resection group, respectively. Furthermore, esophageal ESD is often performed as a total biopsy because of its diagnostic advantages and minimally invasive nature, and it is thought that diagnostic ESD will be further implemented in the future, based on the results of JCOG0508 (16). However, since the esophagus is located in the mediastinum and surgical intervention is invasive, adverse events related to esophageal ESD tend to be more severe than those in gastric ESD. Furthermore, esophageal ESD is thought to be more difficult and requires longer procedure times than gastric ESD because the esophagus has a narrow lumen and a thin muscular layer. To increase the use of esophageal ESD, it is essential to reduce the difficulty of the procedure. The traction-assisted approach overcomes some of the technical difficulties associated with esophageal ESD. Here, we review studies on these technical aspects.

Clip-with-thread method

During surgery, surgeons use their right and left hands for open abdominal surgery, and their skills have expanded to include laparoscopic surgery through multiple or single ports, and robotic surgery. In all of these surgical methods, there is a significant benefit to employing counter-traction with the other hand, clearly exposing the area of the surgical field and cutting plane for swift operation. In contrast, endoscopists are required to manage a perplexing situation single-handedly during ESD because there is no so-called "surgeon's left hand" (17). Adequate visualization during ESD is essential for technical success and to reduce the incidence of adverse events. Applying vertical traction to the partially resected lesion significantly helps to maintain stable visualization. Oyama et al. (18) demonstrated a counter-traction method, the clip-with-thread (CT) method, for esophageal endoscopic treatment in which they attached a thread tied to a hemoclip to the lesion and achieved adequate visualization by pulling on the thread. Various other traction methods have been attempted to alleviate the difficulties of esophageal ESD. However, these interesting methods have not been widely adopted, because they are complicated, costly, or invasive (19-25). The modified CT method reported by Suzuki *et al.* (26) and Yoshida *et al.* (27,28) was simply to tie a length of commercially available dental floss (REACHORR, Johnson & Johnson K.K., Tokyo, Japan) to the stainless-steel arm of the clip with a surgeon's knot (*Figure 1*). The CT method is recognized as the simplest traction technique and has become the most popular method in Japan (29,30).

Two randomized controlled trials (RCT) and two retrospective comparative studies have been reported (summarized in Table 1). Koike et al. (32) conducted a randomised controlled trial (RCT) in 2015 comparing conventional ESD and the CT method in which the mean dissection time of the conventional ESD was 31.8 min, whereas that of the CT method was 19.8 min (P=0.044). Although the CT method seemed a promising treatment method with great potential to shorten the procedure time, the RCT had a small sample size and was limited to two operators at a single facility, requiring more solid evidence. In 2020, Yoshida et al. (34) reported a nationwide largescale multicenter RCT in Japan (CONNECT-E study). CONNECT-E was a well-structured RCT and included lesions (117 in conventional ESD vs. 116 in the CT method) with a size of 20 mm or more, because small lesions (such as those 15 mm or smaller) are well managed by EMR-C (35,36). In the CONNECT-E study, the median ESD procedure duration was significantly shorter using the CT method compared with conventional ESD (44.5 vs. 60.5 min, P<0.001). Moreover, in six (5.2%) patients undergoing conventional ESD, the procedure was converted to the CT method to overcome technical difficulties arising during the procedure (perforation, n=3; prolonged procedure duration, n=3) and handover to another operator during ESD tended to occur more frequently in conventional ESD (6.0% vs. 0.9%, P=0.066). Although traction-related damage to the specimen was observed in 1.7% of the CT method, there was no significant difference between the two methods regarding the rate of horizontal margin involvement (10.3% vs. 6.9%, P=0.484). Additionally, the study analyzed the risk factors for experiencing technical difficulties, defined as follows: procedure duration >120 minutes; perforation; piecemeal resection; inadvertent incision; or handover to another operator. The results confirmed that the CT

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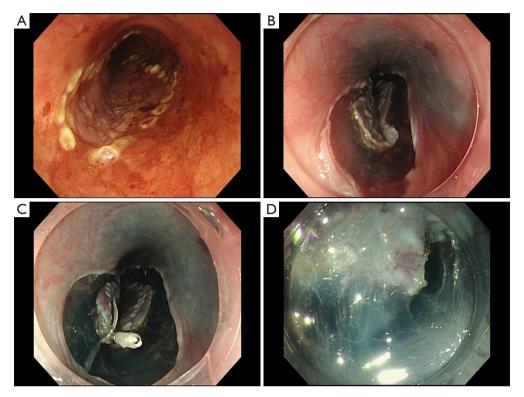


Figure 1 Technical steps of the clip-with-thread method. (A,B) Circumferential mucosal incision was performed as in conventional ESD. (C) The clip-with-thread was applied to the proximal edge of the specimen after trimming. (D) Appropriate tension and better visualization were obtained by pulling on the thread through the patient's mouth. ESD, endoscopic submucosal dissection.

method reduced the risk of technical difficulties during ESD for large esophageal cancers (odds ratio: 0.265, 95% confidence interval: 0.094–0.649, P=0.005). Although there were no significant differences in the frequency of adverse events in the two RCTs, perforation was not observed with the CT method, indicating that the CT method is safer compared with conventional ESD. Ota *et al.* (31) and Xie *et al.* (33) also reported that the CT method had a lower rate of muscularis propria injury in their retrospective studies.

Submucosal tunneling method

When the size of the lesion is large, resected mucosa distally retracts the esophageal lumen during conventional ESD, which may cause an endoscopist to become disoriented. Moreover, rapid diffusion of the submucosal liquid cushion due to poor connective tissue of the submucosa of the esophagus worsens visualization of the submucosa, resulting in prolonged procedure times. To solve these technical difficulties, von Delius *et al.* (37) reported the submucosal tunneling (ST) method for the treatment of circumferential

esophageal lesions in a live porcine model in 2007. The ST method pushes up the resected mucosa with an endoscope and facilitates the procedure by providing stable submucosal visualization and appropriate traction to the submucosa. Additionally, the ST method enables a stable scope position to be achieved inside the submucosal tunnel. The ST method is summarized in *Figure 2*. After submucosal injection, mucosal incisions were made at both the proximal and distal sides of the lesion, and the submucosa under the lesion was dissected to create a communication between the proximal and distal incisions.

Two retrospective studies comparing conventional ESD and the ST method have been reported (*Table 2*) (40-42). In a propensity matching analysis by Huang *et al.* (38), there was a significant difference in the median procedural duration between conventional ESD and the ST method (48.0 *vs.* 38.0 min, respectively, P=0.006). Although there was no difference in the frequency of adverse events, a lower rate of muscular injury (52.6% *vs.* 28.9%; P=0.036) and a less frequent use of coagulation forceps (65.8% *vs.* 36.8%; P=0.012) was found with the ST method. The

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R0 resection, Perforation, P=1.00(P=1.00)(P=0.60)P=1.004.3/0 0/0 0/0 0/0 87.2/91.4 (P=0.30)99.1/100 resection, En bloc P=1.000(P>0.99) 100/100 % injection, ml Volume of P<0.001) P=0.001) 7.5/2.6* $40/30^{\dagger}$ 31.8/19.8* $60.5/44.5^{\dagger}$ Procedure (P=0.044)34.8/37.6* P<0.001) time, min P=0.003) (P=0.252)156/104* 24/30 42/41 Circumferential 5/15 ≥1/2 2/8 extent, n 75/75 13/12 26/20 <1/2 16/52 Lesion size, 27.0/24.0* 43.0/40.0 26.4/28.1 $30/30^{†}$ шш 117/116 20/20 50/50 20/67 Single center Single center Single center Multicenter Setting Retrospective Retrospective 3CT RCT Country Japan Japan China Japan 2015 2012 2017 Year Yoshida et al. (34) 2020 (32)(31) (33)Soike et al. Ota et al. Kie et al. Authors

The results are shown in the order of publication of the control/study arm. RCT, randomized controlled trial; "Mean; "Median; "Dissection time. ESD, endoscopic submucosal dissection authors speculated that less frequent use of forceps might indicate that fewer major bleeding events occurred in the ST method. Another report by Zhang *et al.* (39) showed that the mean dissection speed was faster in the ST method than in conventional ESD (conventional: 16.10 *vs.* ST: 21.54 mm²/min, P=0.002). In both retrospective studies, en bloc resection rates and complete resection rates were similar in the two methods.

The ST method seems effective for large-size lesions, especially those with circumferential extent of 3/4 or more. However, bleeding inside the submucosal tunnel hampers visualization of the cutting plane, leading to longer procedure times and more adverse intraoperative events. Operators should carefully monitor submucosal vessels and avoid bleeding inside the submucosal tunnel.

Clip-with-thread method vs. submucosal tunneling method

Although there are no trials that directly compare the CT method with the ST method, Jin *et al.* (43) assigned 15 beginners to the CT method, the ST method, or the conventional method, respectively, in an animal study. The procedural time was the shortest using the CT method (47.4 min with the CT method, 67.0 min with the ST method, 67.0 min using the conventional method). The CT method had the lowest rate of esophageal perforation (CT: 5.0%, ST: 20.0%, Conventional: 40.0%). Furthermore, learning curves analysis showed that the CT method was the easiest for the trainees to master. Although further studies are required, it would seem unlikely that the ST method is superior to the CT method. Furthermore, the use of the ST method seems difficult for lesions with a circumferential extent of 1/2 or less.

Combination of the clip-with-thread and tunneling methods

The ST method improves the efficiency of the procedure for large lesions. However, the remaining submucosal layer is collapsed after the tunnel is created. Jacques *et al.* (44) conducted a prospective, single-arm study about the "tunnel + clip" strategy, a combination of ST with CT, and reported efficacy and safety even when performed by less experienced endoscopists. We also actively use a combination method for semi-circumferential or circumferential lesions in clinical practice as reported by Fraile-López *et al.* (45). The technical steps of the ST + CT method are as follows: (I)

Table 1 Comparison of clinical outcomes between conventional ESD and the clip-with-thread method

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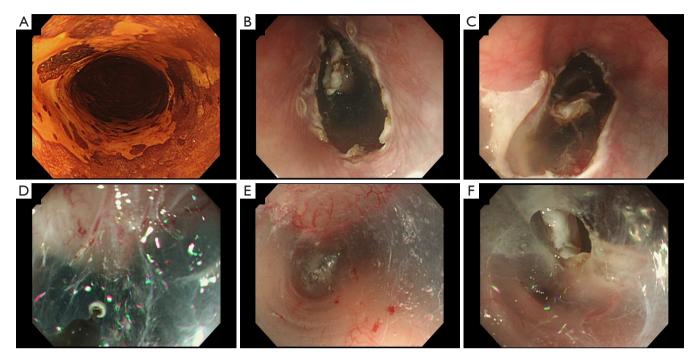


Figure 2 Technical steps of the submucosal tunneling method. (A) The full circumferential lesion was located on the thoracic esophagus. (B,C) Distal and proximal mucosal incisions were performed first. (D,E) A submucosal tunnel was created using an electrosurgical knife. (F) The pinhole was observed towards the true lumen, indicating the end of the tunnel.

create a submucosal tunnel under the lesion as mentioned above; (II) withdraw the endoscope from the tunnel; (III) perform trimming of the submucosal layer from the proximal side; (IV) place the CT on the proximal side of the mucosa where the submucosa remains longitudinally; and (V) proceed with submucosal dissection. For full circumferential lesions, we create an additional tunnel on the opposite side to the first tunnel. This promising technique could allow proper tension to be applied to the collapsed submucosal layer. Further studies are strongly desired.

Future perspectives for esophageal ESD

Recent advances in endoscopic equipment have enabled high complete resection rates of the esophagus. The traction assisted technique obviously facilitates esophageal ESD. However, it still has technical limitations in controlling the direction of the traction, adjusting the tension of the submucosal layer, and regrasping the tissue. To overcome these limitations, a robotic manipulation device is being developed. One or two robotic arms equipped with an endoscope enable holding of the tissue and provision of traction under the control of the operator (Figure 3). Hwang et al. (46) performed robotic armassisted ESD in the porcine model and reported faster dissection speeds compared with conventional ESD $(122.3\pm76.5 \text{ vs. } 47.5\pm26.9 \text{ mm}^2/\text{min, P}<0.001)$. Such a new endoscope equipped with "other hands" has substantial potential to alleviate technical difficulties in esophageal ESD. There is no doubt that traction assistance is key to facilitating esophageal ESD. Further studies are needed to elucidate the best method with respect to efficacy, safety, and cost.

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Authors Year	Country	Year Country Design	Setting	Setting Cases, n	Spec	Circumferential extent, n	rcumferential extent, n	Procedure	Dissection speed,	En bloc	En bloc R0 resection, Perforation,	Perforation,
					E E	<3/4 ≥3/4	≥3/4	ılme, min	mm²/min	resection, % %	8	%
Huang <i>et al.</i> (38) 2017	China	China Retrospective	Single 38/38 center	38/38	36.0/39.0	ı	ı	48.0/38.9* 17/23*	17/23*	100/100	94.7/100	0/6.7
								(P=0.006)	(P=0.006) (P<0.001) (P=1.000)	(P=1.000)	(P=0.152) (P=0.077)	(P=0.077)
Zhang et al. (39) 2018	China	Retrospective	Single	98/52	13.0/15.4†‡	72/29	26/23		92.4/93.2 [†] 16.1/21.5 [†] 88.8/96.1	88.8/96.1	86.7/84.6	1.0/1.9
								(P=0.944)	(P=0.002)	(P=0.126)	(P=0.944) (P=0.002) (P=0.126) (P=0.722) (P=0.646)	(P=0.646)

The results are shown in the order of publication of the control/study arm. *Median; †Mean; †Specimen area (cm?)

B
Bending Translation Rotation

C

Figure 3 Concept of robotic assistance. (A) The lesion is grasped by a robotic arm with appropriate tension. (B) Accessory instruments provide multi-directional traction and can be changed depending on the procedure. (C) The equipment is designed to be attached to a conventional endoscope.

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Footnote

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Table 2 Clinical outcome between conventional ESD and submucosal tunneling method

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Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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