Accepted Manuscript online: 2023-01-11 Article published online: 2023-05-09

First clinical experience with esophageal ESD using a novel adjustable traction device

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submitted 18.12.2022
accepted after revision 29.12.2022
published online 11.1.2023

Bibliography
Endosc Int Open 2023; 11: E446–E450
DOI 10.1055/a-2011-1836
ISSN 2364-3722

Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

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ABSTRACT

Background and study aims In esophageal endoscopic submucosal dissection (ESD), the effectiveness of traction including clip-thread method has been reported, but it is difficult to adjust the direction of traction. Therefore, we developed a dedicated over-tube type traction device (ENDOTORNADO) that has a working channel and allows traction from any directions by rotating itself. We investigated the clinical feasibility and potential usefulness of this new device in esophageal ESD.

Patients and methods This was a single-center, retrospective study. Six cases of esophageal ESD with ENDOTORNADO from January to March 2022 (tESD group) were compared with 23 cases of conventional esophageal ESD performed by the same operator from January 2019 to December 2021 (cESD group) in terms of clinical treatment outcomes.

Results In all cases, en bloc resection was achieved without intraoperative perforation. The total procedure speed was significantly increased in tESD group (23 vs. 30 mm^2/min, $P=0.046$). In particular, the submucosal dissection time was significantly reduced to about one-quarter in tESD group (11 vs. 42 min, $P=0.004$).

Conclusions ENDOTORNADO creates the adjustable traction from any directions and may have the clinical feasibility. It would be an option for human esophageal ESD.

Introduction

Esophageal endoscopic submucosal dissection (ESD) is widely spread as a minimally invasive treatment for superficial esophageal cancer [1, 2], but it is often difficult to obtain adequate visualization due to its narrow lumen compared to the stomach and the colon. In particular, intraoperative perforation is reported to be relatively frequent in left-sided wall lesions [3], which may be due to the difficulty in getting enough traction by gravity to obtain an adequate visualization, in addition to the accumulation of water and blood due to gravity.

To solve this issue, some reports have suggested the effectiveness of traction, such as clip-thread method [4–7]. However, the direction of traction is limited, and the traction direc-

▶ **Fig. 1** Appearance of ENDOTORNADO. ENDOTORNADO is 400 mm long and the outside diameter is 21.0 mm. It has a 2.8-mm diameter working channel to deliver various devices and a soft inner tube to prevent mucosal damage when proceeded into the esophagus.

tion is closer to the tangential direction as the lesion diameter increases. Therefore, it is difficult to obtain effective traction when the lesion diameter or circumference increases. Given these difficulties, we developed an over-tube type dedicated traction device (ENDOTORNADO). It is 400 mm long and the outside diameter is 21.0 mm. It has a 2.8-mm diameter working channel to deliver various devices and allows the traction from any directions by rotating itself (▶ **Fig. 1**). We have reported it significantly shortened the procedure time of esophageal ESD in live porcine experience [8]. Consequently, we investigated the feasibility and potential usefulness of this new device in human esophageal ESD clinically.

Patients and methods

Study design and patient population

This was a single-center retrospective observational study. We analyzed six consecutive superficial esophageal cancer cases performed ESD by one operator using ENDOTORNADO between January and March 2022 (tESD group). Twenty-three consecutive cases performed conventional esophageal ESD as usual by the same operator from February 2018 to December 2021 (cESD group) were chosen as controls. This operator had over 400 cases of esophageal ESD experience at the beginning of this study. Cases performed under general anesthesia with intubation were excluded, and anesthesia was provided by Flunitrazepam or Dexmedetomidine Hydrocholoride. Esophagogastric junction cancer were excluded, and when multiple lesions were resected at the same time, the largest lesion was included in this study.

This study was performed in accordance with 2008 version of the Declaration of Helsinki. We obtained informed patient consent to analyze the data, and the study protocol was approved by the institutional review board of our institution (20190139).

Surgical equipment

ESD was performed using a high-vision therapeutic endoscope with a water jet function (GIF-H290T; Olympus Medical Systems, Tokyo, Japan). Submucosal injections of a 10 % glycerin solution (Glyceol; Chugai Pharmaceutical Co, Ltd, Tokyo, Japan) were performed with a 25G needle (NeedleMaster, Olympus Medical Systems, Tokyo, Japan). For difficult cases, 0.4 % sodium hyaluronate (MucoUp, Boston Scientific, Marlborough, Massachusetts, United States) was used as required.

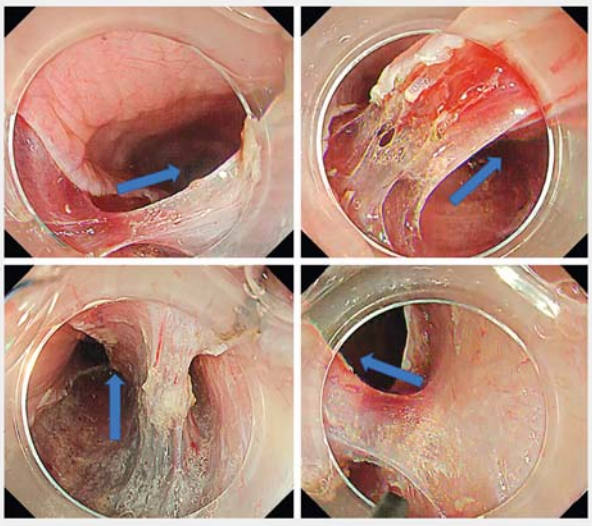
As an energy device, the operator used a needle type knife with injection function (DualKnife J, Olympus Medical Systems, Tokyo, Japan) in all cases. In tESD group, DualKnife J was only used for marking, mucosal incision and creation of small mucosal flap, and a high-frequency scissors forceps (ClutchCutter, Fujifilm, Tokyo, Japan) was used for submucosal dissection. DualKnife J was powered by a high-frequency electrosurgical unit (VIO 3, ERBE Elektromedizin, Tübingen, Germany), which supported lesion marking (soft coagulation function, effect 6.0), hemostasis with the knife tip (spray coagulation function, effect 1.2), mucosal incision (dry cut function, effect 2.2), and submucosal dissection (swift coagulation, effect 3.5). ClutchCutter was also powered by VIO3, which supported submucosal dissection (Endocut I function [effect 1.0, duration 1, interval 1] and forced coagulation [effect 3.0]).

Description of technique

After identifying the area of the lesion, markings were made around the lesion. A full circumferential mucosal incision was made and a small mucosal flap was created on the oral side of the lesion. Then, ENDOTORNADO was inserted and placed in the esophagus with the scope as a guide. The tip hood was reattached and the scope was re-inserted to the oral side of the lesion. The snare forceps were delivered through the side hole of ENDOTORNADO and the snare was expanded. The clip forceps was delivered through the forceps hole of the scope, and the clip was set through the expanded snare. Then the clip was deployed on the small mucosal flap created on the oral side of the lesion, and the clip was grasped by tightening the snare. In this step, the assistant's task was successfully relieved by using a clothespin to maintain the snare grasping state. Thereafter, the traction from any directions was possible by the assistant making a torque to ENDOTORNADO (▶ **Fig. 2**). The submucosal dissection was performed using a high-frequency scissors forceps (ClutchCutter, Fujifilm, Tokyo, Japan) while adjusting the traction direction appropriately (▶ **Video 1**).

Outcome measures

We collected data, such as age, sex, lesion location, occupied circumference, size, macroscopic type, preoperative invasion depth, en bloc resection rate, R0 resection rate, adverse events (intraprocedural perforation and delayed bleeding), specimen size and total procedure time from patient medical records. Total procedure time was divided into the time required for mucosal incision and submucosal dissection respectively, and in tESD group, the time required for device setup was also included. The length of mucosal incision line and the resection area were



▶ **Fig. 2** Traction created by ENDOTORNADO. Arrows indicate the traction direction. The traction can be obtained from any directions depending on the various situations.

VIDEO

▶ **Video 1** Esophageal endoscopic submucosal dissection (ESD) using ENDOTORNADO. Esophageal ESD using ENDOTORNADO for superficial esophageal cancer after radiation therapy for thymoma. Although the lesion was located on the scar after radiotherapy and severe fibrosis of the submucosal layer was observed, en bloc resection was achieved safely and smoothly without any adverse events.

calculated by assuming the specimen to be an ellipse in shape using the largest and smallest diameters of the specimen. The mucosal incision speed was calculated by dividing the length of mucosal incision line with the mucosal incision time. The submucosal dissection speed and the total procedure speed were also calculated by dividing the resection area with the submucosal dissection time and the total procedure time respectively.

Statistical analysis

We compared the clinical outcomes between cESD group and tESD group. Chi-squared test or Fisher's exact test were used for comparison of categorical variable, and Wilcoxon's rank sum test was used for comparison of continuous variable. All statistical analyses were performed using JMP version 16.2.0 (SAS Institute, Inc., Cary, North Carolina, United States). $P < 0.05$ was considered statistically significant.

Results

Procedures were completely achieved in all six patients in tESD group. The ENDOTORNADO-related adverse event was only one minor mucosal peeling of the cervical esophagus associated with its insertion into the esophagus.

Comparing the two groups, there were no significant differences in patient and lesion characteristics (▶ **Table 1**). En bloc resection was achieved in all cases in both groups. R0 resection was achieved in all cases in tESD group. No intraoperative perforation or postoperative bleeding was observed in both groups.

The total procedure time was significantly shorter in tESD group than in cESD group even though it included the setup time in tESD group. In particular, submucosal dissection time was significantly reduced to about one-quarter in tESD group. The mucosal incision speed, the submucosal dissection speed, and the total procedure speed were also significantly increased in tESD group (▶ **Table 2**).

Discussion

This is a first study to investigate the clinical feasibility and safety of ENDOTORNADO in human esophageal ESD. It always provided the good traction, so each time was shortened and each speed was increased. The significantly shorter mucosal incision time might be due to the influence of treatment strategy in tESD group, in which a full circumferential mucosal incision was made at the beginning, when sufficient tension was more likely to be obtained. Considering that submucosal dissection time accounted for a large proportion of the total procedure time, we assume that the reduction in submucosal dissection time had a greater contribution to the reduction in total procedure time. In addition, the operator of all cases in this study had been already an expert, but nevertheless, the use of this new device improved treatment outcomes compared to conventional ESD. This fact implies more potential usefulness of this device. These results suggest the clinical feasibility and safety of this device.

Conventional ESD requires close approach to the lesion in order to obtain adequate visualization, so it is difficult to grasp the whole image of the lesion. In contrast, ENDOTORNADO allows the operator to obtain adequate visualization from a distance. In other words, this device does not require moving the scope to create adequate visualization, so it is suitable for scissors type energy devices because they also do not require moving the scope to dissect the tissue. In fact, the operator did not need additional submucosal injection during submucosal dissection. These facts also contributed to the shortened total procedure time. In addition, the adjustable traction direction is very effective in esophageal ESD. In the clip-thread method,

▶ **Table 1** Clinical characteristics of the analyzed cases (n = 29).

Factors		cESD (n = 23)	tESD (n = 6)	*P* value
Age	Mean ± SD	69.1 ± 6.0	69.2 ± 11.2	0.91
Sex	Male	19 (82.6 %)	5 (83.3 %)	1.00
Location	Lt	13 (56.5 %)	3 (50.0 %)	1.00
	Others	10 (43.5 %)	3 (50.0 %)	
Horizontal location	Left wall	4 (17.4 %)	1 (16.7 %)	1.00
	Others	19 (82.6 %)	5 (83.3 %)	
Occupied circumference	< 50 %	17 (73.9 %)	6 (100.0 %)	0.30
	≥ 51 %	6 (26.1 %)	0 (0.0 %)	
Lesion size	Median [IQR], (mm)	25 [15–35]	23 [12–30]	0.57
Macroscopic type	0-IIc	16 (69.6 %)	3 (50.0 %)	0.63
	Others	7 (30.4 %)	3 (50.0 %)	
Preoperative invasion depth	EP/LPM	15 (65.2 %)	5 (83.3 %)	0.63
	Others	8 (34.8 %)	1 (16.7 %)	

Lt, lower thoracic esophagus; EP, epithelium; LPM, lamina propria mucosa.

▶ **Table 2** Clinical outcomes of esophageal ESD (n = 29).

Factors		cESD (n = 23)	tESD (n = 6)	*P* value
En bloc resection	yes, N (%)	23 (100.0 %)	6 (100.0 %)	–
R0 resection	yes, N (%)	20 (87.0 %)	6 (100.0 %)	1.00
Intraprocedural perforation	yes, N (%)	0 (0.0 %)	0 (0.0 %)	–
Delayed bleeding	yes, N (%)	0 (0.0 %)	0 (0.0 %)	–
Specimen size	Median [IQR], (mm)	45 [33–55]	41 [28–49]	0.29
Mucosal incision time	Median [IQR], (min)	18 [10–22]	8 [5–12]	0.010*
Setup time	Median [IQR], (min)	0 [0–0]	7 [7–8]	< 0.001*
Submucosal dissection time	Median [IQR], (min)	42 [18–57]	11 [4–16]	0.004*
Total procedure time	Median [IQR], (min)	58 [29–82]	26 [17–37]	0.015*
Mucosal incision speed	Median [IQR], (mm/min)	8 [6–11]	13 [12–20]	0.003*
Submucosal dissection speed	Median [IQR], (mm^2/min)	32 [26–44]	76 [69–142]	< 0.001*
Total procedure speed	Median [IQR], (mm^2/min)	23 [17–28]	30 [26–40]	0.046*

*Statistically significant.

which is one of the most common traction method, traction is directed toward the center of the lumen due to the traction provided by the threaded clip and the counter traction provided by the tip hood. The clip is often placed at the center and the most oral side of mucosal flap so traction is relatively easy in the central part, however, it is difficult to get effective traction on the lateral edges especially for large circumferential lesions. In addition, for lesions that are longer in the long axis direction, traction by threaded clip tends to be in the tangential direction, so it is difficult to obtain sufficient traction. On the other hand, ENDOTORNADO, which allows adjustment of the traction direction freely according to the dissection area, can overcome these weaknesses of the conventional traction method.

One of the major features of ESD using this device is that it is largely dependent on the skill and ability of the assistant because the assistant must appropriately adjust the traction di-

rection. In other words, even if the operators have less experience, they would get preferable outcome if sufficient support is given from the assistant. Therefore, ESD using this device might contribute standardize the procedure by bridging the gap among endoscopists with various skill level.

There are several issues with using this device. First, the created strong traction may result in adverse events, which sometimes pull the muscle layer in a tent-like shape, and may increase the risk of muscle layer injury and perforation especially at the early phase of submucosal dissection when the mucosal frap is tightly attached to the muscle layer. However, because the good traction improves visibility of the area to be dissected and the assistant can adjust the traction force by changing the strength of the torque, this is not a major issue by avoiding blind manipulation and observing the running of the muscle layer closely. Second, this new device is more expansive than traditional traction methods. Nevertheless, we would like to emphasize that there is still room for using this device for specific selected cases, such as difficult cases with fibrosis, circumferential or large lesions, or cases operated by trainees, even considering its high cost.

This study has several limitations. First, this was a single-center, retrospective study. Because the study period extended over about 3 years and was based on historical control, there were differences in methods and characteristics of patient and lesion, even though they are not significant differences. Second, we examined a small sample size, so selection bias cannot be denied. Third, the operator was limited to a single expert. In addition, the assistant had experience with more than 2500 ESDs at the beginning of this study, so he had the ability to appropriately adjust the traction direction. Fourth, in tESD group, the operator learning curve in use of this new device was undeniable because he experienced several cases in a short period of time. However, he was already an expert with sufficient experience with ESD, and the learning curve in his usual ESD skills can be considered irrelevant. Fifth, the operator used DualKnife J for submucosal dissection in cESD group, but he used ClutchCutter in tESD group, so the influence of the difference in device could not be ruled out. The improved treatment outcome was not due to ENDOTORNADO alone, but to the combination with ClutchCutter. Sixth, we could not demonstrate the superiority over the clip-thread method because the cESD group did not consist of cases in which the clip-thread method were used.

Conclusions

In conclusion, ENDOTORNADO creates adjustable traction from any direction and may have clinical feasibility. It could be an option for human esophageal ESD.

Competing interests

The authors declare that they have no conflict of interest.

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