学位論文

Efficacy of a new traction method using ring-shaped thread for endoscopic submucosal dissection in the pharynx

（リング糸を用いた新規トラクション法による咽頭内視鏡的粘膜下層剥離術の効率化）

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2022年度

Esophagus
https://doi.org/10.1007/s10388-022-00971-0

ORIGINAL ARTICLE

Efficacy of a new traction method using ring-shaped thread for endoscopic submucosal dissection in the pharynx

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Received: 28 June 2022 / Accepted: 9 November 2022

Abstract

Background Endoscopic submucosal dissection (ESD) is a minimally invasive treatment for pharyngeal cancers. However, pharyngeal ESD is sometimes technically challenging because of the narrow and complex space in which to work. Traction is important to complete the procedure efficiently. Here, we report the technical details and efficacy of a new traction method for pharyngeal ESD using ring-shaped thread and grasping forceps.

Methods We analyzed pharyngeal ESD performed between January 2016 and March 2021 at our Institute. We designated cases resected using ring-shaped threads "Group R" and those resected without ring-shaped threads as conventional "Group C", and compared the technical outcomes between them. Multivariate analysis and the inverse probability treatment weighting (IPTW) method using propensity scores were adjusted by confounding variables.

Results We analyzed 89 lesions from 68 patients, of which 46 were in Group R and 43 in Group C. Median procedure time and median dissection speed were significantly shorter in Group R than C (37 min vs. 55 min, and 16.0 mm^2/min vs. 7.0 mm^2/min, respectively, both $P < 0.05$). These results were confirmed by both multivariate analysis and after IPTW adjustment. All lesions were resected en bloc, and the complete resection rate was not significantly different between Group R and C (91.3% vs. 79.1%, $P = 0.14$). There were no treatment-related adverse events in either group.

Conclusions The traction method using ring-shaped thread increases the efficiency of pharyngeal ESD. This simple new traction method should be a useful option for pharyngeal ESD.

Keywords Pharyngeal cancer · Endoscopic submucosal dissection · Traction · Ring-shaped thread · Dissection speed

Introduction

Recent advances in image-enhanced endoscopy are resulting in more frequent detection of superficial pharyngeal cancer (SPC) at an early stage [1–4]. Endoscopic submucosal dissection (ESD) is now utilized for SPC in many medical facilities [5–9], since it became established in clinical practice for gastrointestinal cancer [10]. ESD is a minimally invasive treatment that preserves organ function and is reported to have good long-term outcomes [11–14]. However, pharyngeal ESD is sometimes difficult to accomplish, because the structure of the pharynx is complex [6, 8]. It has been reported that an extended procedure time was significantly associated with a higher incidence of pharyngeal edema [7] which may require tracheostomy.

Traction is important to complete the procedure efficiently, with one of the main traction methods in pharyngeal ESD being the manual use of grasping forceps [6]. However, the forceps often interfere with the endoscope, and even the grasping itself is sometimes difficult [15, 16]. To overcome these problems, we reported a method used in patient with pharyngeal ESD using ring-shaped thread as a holder for the forceps [17]. This simple traction method facilitates an easier grasp, well-visualized cutting layer, and good traction

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Published online: 01 December 2022

without interference between the forceps and the endoscope. Here, we report a comparison of the effectiveness of pharyngeal ESD performed with our traction method using ring-shaped thread relative to the conventional method.

Materials and methods

Patients

In our institute, pharyngeal ESD was indicated for the histologically proven squamous cell carcinoma lesion which was limited to the epithelium and subepithelial invasion. We analyzed pharyngeal ESD performed between January 2016 and March 2021 at our Institute. Resections using both ring-shaped threads and forceps were defined as the group using ring-shaped thread (Group R), and those resected using only forceps were defined as the conventional group (Group C). We excluded cases resected without forceps and those using the traction of "clip with line" method [18]. All procedures were carried out by 4 endoscopists who had each performed > 100 cases of gastrointestinal ESD. The study protocol was approved by the Institutional Review Board of Kumamoto University Hospital (No. 2046), and the study was performed in accordance with the Declaration of Helsinki.

Pharyngeal ESD with the conventional method

Pharyngeal ESD is carried out under general anesthesia after intubation. A laryngoscope (10342100; Nagashima Medical Instruments Co, Ltd, Tokyo, Japan) was inserted by the otolaryngologist to create an adequate working space. The tumor margin is confirmed using a high-definition endoscope (H260Z, H290Z; Olympus Medical Systems, Tokyo, Japan) with magnifying NBI followed by Lugol staining in most cases. The marking dots are placed around the lesion with a Dual knife (KD-650Q; Olympus). For subepithelial injection, 1:1 mixture of normal saline with 0.4% sodium hyaluronic acid (MucoUp®; Boston Scientific, Marlborough, Mass, USA) with indigo carmine is used. A dual knife is used for incision and dissection. The electrosurgical unit VIO300D (Erbe, Tübingen, Germany) was used for these procedures. A single-channel endoscope (GIF-Q260J; Olympus) was used for the process from the injection to the completed dissection, with a transparent hood mounted on the tip of the endoscope.

Figure 1 shows the process of pharyngeal ESD using the conventional method. The initial incision followed by a circumferential incision is performed, and an oral-side flap is formed by trimming the subepithelium. When an appropriate oral-side flap is formed, so that the forceps do not interfere with the endoscope, the flap is grasped by the forceps and dissection can be performed under traction.

Pharyngeal ESD with traction using ring-shaped thread

We introduced the traction method using ring-shaped threads for pharyngeal ESD in October 2019. Since then, we have carried out pharyngeal ESD with this method in most cases. A ring-shaped thread was created and used as follows: a thread is wound once around a 5 or 10 ml syringe, tied, and trimmed. This is then attached to a clip and housed within the delivery sheath immediately before use. We mainly create the ring-shaped thread with a 5 ml syringe. When we perform ESD for the lesion at the anal side of the hypopharynx, we sometimes create the ring-shaped thread with a 10 ml syringe for easier grasping. At first, we used nylon surgical thread, but from the middle of the period of this report, silicone elastic thread has been used to prevent tissues from being damaged by excessive tension.

Figure 2 shows the process of pharyngeal ESD with traction using ring-shaped thread. The process up to a circumferential incision is the same as with the conventional method. The ring-shaped thread with a clip was usually placed at the oral side of the lesion after the trimming minimal enough to allow the clipping. Otolaryngologists grasped the thread using curved forceps, and adjusted the towing direction appropriately to optimize visibility and tension on the subepithelial layer. Dissection can be performed efficiently under traction from immediately after the circumferential incision to the end of the procedure. In most cases, the procedure was completed with a single ring-shaped thread. If traction was getting insufficient during the dissection procedure, we placed additional clips or grasped the lesion itself after an adequate mucosal flap is formed for better traction. Otolaryngologists continued to hold the grasping forceps until resection was completed. Finally, we retrieve the thread with the specimen.

Histological evaluation

Resected specimens are extended on a board and held with pins, fixed in 10% formaline, and sectioned with 2-mm slices. Tumor size, invasion depth, lymphatic and vascular involvement, and tumor involvement in the lateral and vertical margins is histologically assessed. The complete resection was defined on the basis of tumor-free margins.

Definition

ESD procedure time (minutes) is defined as the time from the first injection to the completed dissection. Dissection speed (mm^2/min) is defined as the specimen area divided by

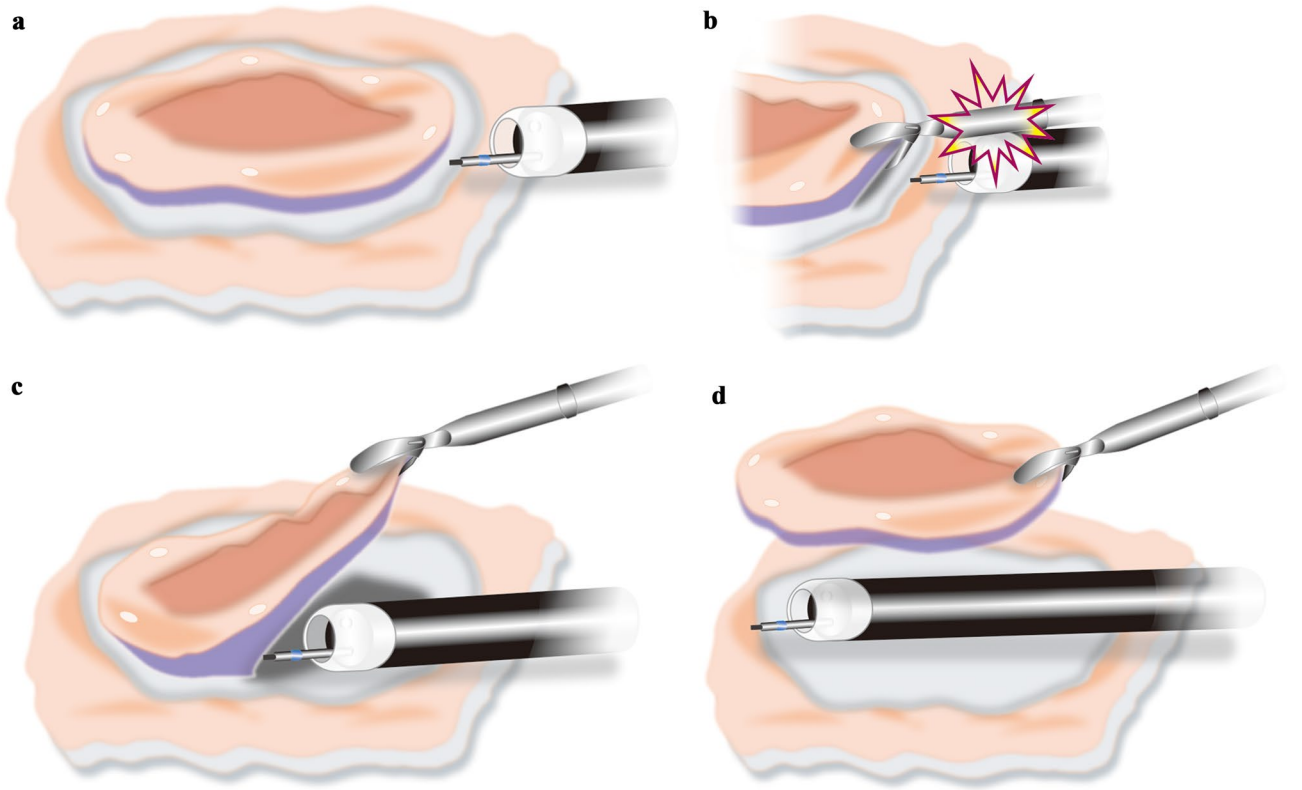

Fig. 1 Pharyngeal ESD with the conventional method. **a** The circumferential incision. **b** The endoscope cannot approach the lesion because of interference with the forceps before a sufficient oral-side flap is formed. **c** When a sufficient oral-side flap is formed, the flap is grasped by the forceps and the dissection is finally performed under counter-traction. **d** En bloc resection is performed

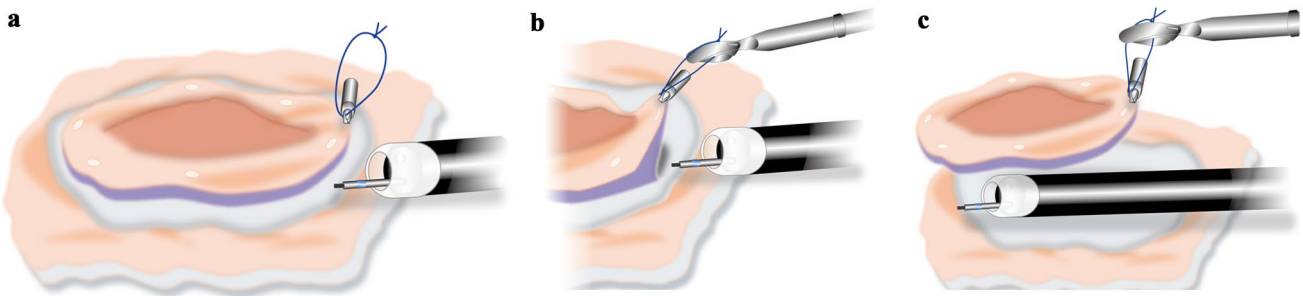

Fig. 2 Pharyngeal ESD with traction using ring-shaped thread. **a** The ring-shaped thread with a clip was usually placed at the oral side of the lesion after the trimming minimal enough to allow the clipping. **b** The ring-shaped thread is easily grasped and pulled by the forceps. Good counter-traction is obtained before the oral-side l flap is made, and endoscopic maneuver does not interfere with the forceps. **c** En bloc resection is performed

the ESD procedure time. The length (mm) of the longer axis and the shorter axis of the resected specimen is measured after pinning on a board, and specimen size defined as the length of the longest part of the resected specimen. Specimen area (mm^2) is calculated using the ellipse formula: specimen area = ([shorter axis length]/2) × ([longer axis length)]/2) × 3.14. Complete resection was defined as en bloc resection with tumor-free lateral and vertical margins. Endoscopists with at least 10 years' experience of endoscopic therapy and who had carried out > 300 cases of gastrointestinal ESD are defined as expert endoscopists. Those with less experience are defined as non-expert endoscopists.

Outcomes

ESD procedure time and dissection speed were compared between Group R and Group C. The en bloc resection rate and complete resection rate were also compared. The

frequency of treatment-related adverse events, delayed bleeding, emergency tracheotomy, extubation on the day after ESD, and reintubation were compared as safety evaluation items.

Statistical analysis

Continuous variables are presented as the mean and standard deviation or median and inter-quartile range, as appropriate for their distribution. Clinical outcomes were analyzed using the Mann–Whitney *U* test, Student's *t* test, Fisher exact test, or Chi-square test, as appropriate. Multivariate linear or logistic regression models were employed after adjustment for a propensity score composed by candidate confounding factors; age, sex, location, tumor size, macroscopic type, tumor depth, history of radiotherapy, number of operator's pharyngeal ESD experience at the time of the procedure, and operator skill. In addition, the "inverse probability of treatment weighting" (IPTW) method based on the propensity score was used to estimate the average treatment effect of the traction method compared to the conventional method in the target population of this study. To generate the propensity score, logistic regression was performed using the group R/C as outcome and the 9 variables described above as explanatory variables. In the logistic regression, C statistics were estimated as 0.82. Test for balance of this propensity score were performed using method by Imai and Ratkovic [19]. In these models, outcome variables, such as ESD procedure time or dissection speed, were log-transformed, because of their skewed distribution. Accordingly, coefficient β was estimated as the log-transformed ratio of Group R per Group C for respective outcomes. Probability values for statistical tests were two-tailed and $P < 0.05$ was considered significant. Statistical analysis was performed with R version 3.3.3 (R Foundation, Vienna, Austria) and STATA15.1 (StataCorp, Lakeway Drive, Texas).

Results

In total, we performed pharyngeal ESD for 83 patients with 109 lesions from January 2016 to March 2021 at our Institute. Of these, we excluded cases where no traction was used (9 lesions) and in which traction using clip-with-line method was used (4 lesions). We also excluded cases in which multiple lesions were resected in one specimen (7 lesions). Hence, we analyzed 89 lesions from 68 patients where manual traction was applied using grasping forceps with or without ring-shaped thread. We performed pharyngeal ESD for 46 lesions from 33 patients in Group R, and 43 lesions from 35 patients in Group C. There was no overlapped period of both groups. A flowchart for this is shown in Fig. 3.

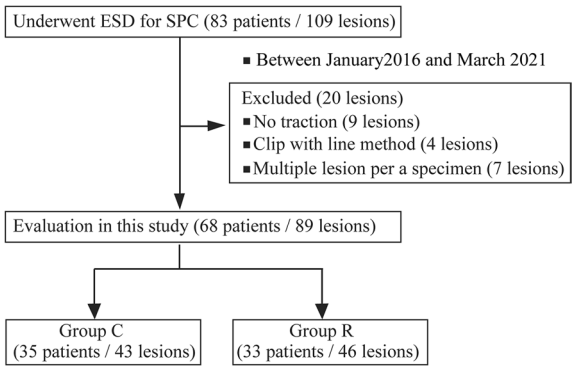

Fig. 3 Study flow diagram

The characteristics of all patients and lesions are shown in Table 1. There were two experts and two non-experts. The lesions were mainly located in the hypopharynx (77 lesions, 87%), and most of these were in the pyriform sinus. 61 lesions (69%) exhibited subepithelial invasion, and 14 lesions (16%) had a tumor thickness of more than 1000 µm. One patient, who had a previous history of radiotherapy for advanced pharyngeal cancer, had lymph-node recurrence. Age, sex, tumor size, tumor depth, the proportion of patients with a history of radiotherapy, and operator skill did not differ between the two groups. However, there were differences in the location and macroscopic type between the two groups. In Group R, additional clipping was required in 5 cases (10.9%).

Table 2 shows the technical outcomes of Group R compared to Group C. Median ESD procedure time was significantly shorter in Group R than in Group C (37 min.-vs.-60 min., $P < 0.05$). Median dissection speed was also significantly faster in Group R (16.0 mm^2/min-vs.-6.5 mm^2/min, $P < 0.05$). In the multivariate linear regression analysis comparing Group R with Group C, ESD procedure time was significantly shorter (ratio = 0.52, 95% CI 0.36–0.76, $P = 0.001$) and the dissection speed was significantly faster (ratio = 2.34, 95% CI 1.84–2.98, $P < 0.001$; Table 3). For the IPTW method, the estimated average ESD procedure time when using the traction method was significantly shorter compared to the conventional method (ratio = 0.54, 95% CI 0.42–0.68, $P < 0.001$), and the dissection speed was also significantly faster (ratio = 2.36, 95% CI 1.92–2.90, $P < 0.001$; Table 3).

All lesions were resected en bloc in both groups. The rate of complete resection was higher in Group R than in Group C, but this difference did not achieve statistical significance (91.3% vs. 79.1%, $P = 0.14$). Only one case had local recurrence in Group C. There were no treatment-related adverse events in either group.

Table 1 Clinicopathological characteristics of the patients and lesions in each group

Group	Total	Group R	Group C	*P* value
No. of patients	68	33	35	
Age, mean ± SD, y	70 ± 8.4	70 ± 8.0	69 ± 8.8	0.66
Sex, male/female, no	64/4	32/1	32/3	0.65
Previous radiotherapy				0.30
Yes, no. (%)	8 (12)	2 (6)	6 (17)	
No. of lesions	89	46	43	
Tumor location, no. (%)				< 0.05
Hypopharynx	77 (87)	37 (81)	40 (94)	
Pyriform sinus	61 (69)	34 (74)	27 (63)	
Posterior wall	9 (10)	3 (7)	6 (14)	
Postcricoid	7 (8)	0 (0)	7 (16)	
Oropharynx	12 (13)	9 (19)	3 (6)	
Posterior wall	7 (8)	6 (13)	1 (2)	
Lateral wall	2 (2)	1 (2)	1 (2)	
Epiglottic vallecula	3 (3)	2 (4)	1 (2)	
Tumor size, median (min–max), mm	20 (2–68)	21 (4–68)	20 (2–44)	0.22
Macroscopic type, no. (%)				< 0.05
Protruded/non-protruded	23 (26)/66	16 (34)/30	7 (16)/36	
Depth of invasion, no. (%)				0.50
CIS/SEP	28 (31)/61	16 (35)/30	12 (28)/31	
Tumor thickness, no. (%)				0.78
< 1000 μm / ≥ 1000 μm	75 (84)/14	38 (83)/8	37 (86)/6	
Operator, no. (%)				0.08
Expert/non-expert	55 (62)/34	24 (52)/22	31 (72)/12	
Number of pharyngeal ESD	18 (10–29)	24 (15–31)	13 (6–28)	< 0.05

SD standard deviation, *IQR* inter-quartile range, *CIS* carcinoma in situ, *SEP* subepithelial invasion, *Number of pharyngeal ESD* number of operator's pharyngeal ESD experience at the time of the procedure

Table 2 Technical outcomes and complications

Group	Group R	Group C	*P* value
ESD procedure time, median (IQR), min	37 (17–51)	55 (31–75)	0.02
Dissection speed, median (IQR), mm^2/min	16.0 (11.6–20.9)	7.0 (5.2–10.8)	< 0.01
En bloc resection rate, %	100	100	> 0.99
Complete resection rate, %	91.3	79.1	0.14
Adverse events, %	0	0	> 0.99

We defined delayed bleeding, emergency tracheotomy, extubation on the day after ESD, and reintubation as adverse events

IQR inter-quartile range

In the subgroup analysis, we evaluated the impact of the endoscopist's experience and of the tumor location on the technical outcomes for Group R (Supplemental Table 1). Median procedure time and dissection speed were not significantly different between expert and non-expert in Group R. There were no significant differences in procedure time between hypopharynx and oropharynx. However, median dissection speed was significantly faster at the hypopharynx than oropharynx.

Discussion

In this study, we reported that the traction method using ring-shaped thread reduced ESD procedure time and improved dissection speed. These results were also confirmed by both multivariate analysis and after IPTW adjustment. The rate of complete resection was the same using our new method or the conventional method (91.3% vs. 79.1%, $P = 0.14$), each being similar to previous reports

Table 3 Technical outcomes for Group R compared with Group C by univariate, multivariate, and IPTW analytical methods

	Crude		Multivariate		IPTW	
	Ratio (95% CI)	*P* value	Ratio (95% CI)	*P* value	Ratio (95% CI)	*P* value
ESD procedure time	0.66 (0.48–0.91)	0.013	0.57 (0.37–0.88)	0.011	0.55 (0.42–0.72)	< 0.001
Dissection speed	2.04 (1.63–2.56)	0.013	2.14 (1.61–2.85)	0.001	2.06 (1.60–2.67)	< 0.001
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Complete resection rate	2.78 (0.78–9.88)	0.114	2.38 (0.78–7.28)	0.130	1.10 (0.99–1.23)	0.079

Crude, the linear or logistic regression model using the Group (Group C or R) as an explanatory variable; Multivariate, the multivariate linear or logistic regression model using propensity score composed by candidate confounding factors (age, sex, location, tumor size, macroscopic type, tumor depth, history of radiotherapy, number of pharyngeal ESD experience, and operator skill); IPTW, Inverse probability of treatment weighting methods using the propensity score; Ratio, the outcome (ESD procedure time, dissection speed) of Group R compared with Group C; Odds ratio, the outcome (complete resection rate) of Group R compared with Group C. The linear regression models were employed for ESD procedure time and dissection speed. The logistic regression models were employed for complete resection rate

(54.8–89.7%) [6–9, 16]. There were no treatment-related adverse events in any patient.

The utility of ring-shaped thread has been previously reported for colorectal ESD [20], and here, we applied and modified it for pharyngeal ESD. In the conventional manual traction method employing only grasping forceps, the dissection process is performed without traction until an adequate flap is made. In addition, even after grasping the lesion with forceps, optimal dissection is sometimes difficult to achieve due to interference between forceps and endoscopes. With our traction method, we do not need to create an oral-side flap under no traction. Thus, we can perform most of the dissection efficiently under traction. Thus, we can perform most of the dissection efficiently under traction. We consider that the procedure time is shorter mainly for these reasons. Furthermore, this method is useful not only for endoscopic maneuvers but also for assistants. Otolaryngologists can easily grasp and manipulate forceps without interference. This advantage is particularly pronounced at the hypopharynx, which is far from the mouth. This might have led to the result that the median dissection speed was significantly faster at the hypopharynx than oropharynx in Group R.

Other reported traction methods for pharyngeal ESD include manual traction with grasping forceps [6], the clip-with-line method [21], and the double-scope method [16]. Our method reduced the difficulty of grasping the lesion and avoided interference between forceps and endoscopes, which are major disadvantages of manual traction with grasping forceps only [15, 16]. An advantage of the clip-with-line traction method is also less interference with the endoscope, but it is difficult to change the towing direction with this method. The double-scope method does not require an assistant but does require two endoscopes. To minimize the interference of the scope with the forceps, trans-nasal endoscopy is one possible choice [22]. However, trans-nasal endoscopes do not have a water supply function and choice of devices is limited. Our simple method requires no special equipment and little time for preparation.

Our study has several limitations. First, it is a retrospective analysis of procedures carried out at a single center. Second, we changed to a traction method using ring-shaped thread after the period of time in which we used the conventional method, without any overlap. Hence, no direct comparison can be made and the impact of a learning curve cannot be excluded. At this point, we included the number of pharyngeal ESD procedures per operator as a factor when creating the propensity score to reduce the influence of the learning curve. Third, we could not perform propensity score matching analysis due to the relatively small number of cases. At this point, we used the IPTW method based on the propensity score to adjust for confounding variables. Fourth, we cannot yet comment on any long-term outcomes of our new traction method, because it has only been about a year and a half, since we started using it. However, at this time, we have achieved higher complete resection rates using our method, with no serious adverse events, which will likely contribute to a good long-term outcome.

In conclusion, ESD with the traction using ring-shaped thread would be more effective for the complete removal of superficial pharyngeal cancer. We consider that this method may be attractive for many facilities, because it is simple and non-invasive. A multicenter trial is warranted to confirm the validity of this traction method.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10388-022-00971-0.

Acknowledgements This work was supported by Kumamoto University Hospital Research Revitalization Project. We especially thank all staff of the Department of Otolaryngology-Head and Neck Surgery at our institute. We also specially thank all staff of the Department of Endoscopic Diagnostics and Therapeutics at our Institute, in particular Hitomi Yoshida for assistance with the procedure. We thank Mariko Kuroda for editing the illustrations for this manuscript.

Author contributions KM, HM, RG, and YT were responsible for the design and drafting of the manuscript. KM, HM, TS, KW, SM, DM, and YO performed and assisted with the procedure. MT and HN were responsible for the revision of the manuscript. KM and JM were responsible for statistical analysis. All authors read and approved the final manuscript. This study was performed in accordance with the Declaration of Helsinki.

Funding This work was supported by Kumamoto University Hospital Research Revitalization Project.

Data availability statement The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical Statement This study was approved by the Institutional Review Board of Kumamoto University Hospital (Kumamoto, Japan), the registry number is 2046. Patients' information was kept strictly confidential in compliance with the Helsinki Declaration.

Conflict of interest There are no potential competing interests concerning this study.

Informed consent Informed consent was not obtained from the patients. Instead, all patients were informed of an opt-out method.

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