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Research Article
Endoscopic submucosal dissection
using EndoTrac, a novel traction device

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Short Title: ESD using the EndoTrac device

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Keywords: ESD, endoscopic submucosal dissection, GI cancers, minimally invasive, device

Abstract

Background

Endoscopic submucosal dissection (ESD) is recognized as a minimally invasive and curative treatment for superficial gastrointestinal (GI) cancers. However, ESD is still challenging and time-consuming with a high risk of adverse events such as bleeding and perforation. Various traction methods have been explored for maintaining good visualization of the submucosal layer during ESD. We developed a novel traction device (the EndoTrac) which can easily tie the thread and has the ability to change the towing direction. The aim of this study is to evaluate safety and feasibility of ESD using the EndoTrac for GI neoplasms.

Patients and Methods

We retrospectively analyzed 44 patients (45 lesions) with esophageal, gastric, duodenal, and colorectal neoplasms who had undergone ESD using the EndoTrac device between June 2018 and May 2019. Primary outcome measures were preparation time, procedural success using the EndoTrac device, and ease of ability to change towing direction.

Results

Mean preparation time was 2 (2-5) minutes in esophagus, 3 (1-5) minutes in stomach, 6 (5-9) minutes in duodenum, and 4 (2-8) minutes in colorectum. The procedural success rate was 100% (8/8) in

esophagus, 100% (21/21) in stomach, 100% (4/4) in duodenum, and 100% (12/12) in colorectum. The rate of successful towing to both proximal and distal sides was 100% (8/8) in esophagus, 100% (21/21) in stomach, 0% (0/4) in duodenum, and 100% (12/12) in colorectum.

Conclusions: Use of the EndoTrac device appears to be a feasible approach to ESD for GI neoplasms.

Introduction

Endoscopic submucosal dissection (ESD) has been accepted as a minimally invasive and curative treatment for superficial gastrointestinal (GI) neoplasms. The tumor can be resected with one specimen regardless of size and shape of the lesion and allows curative *en bloc* resection, which would not be achievable with EMR [1]. ESD is also oncologically efficacious and associated with less morbidity than the surgical alternative [2]. Thus, ESD has been widely accepted worldwide as a promising treatment for superficial GI cancer excision [1]. However, despite the development of various devices and strategies, ESD is still a time-consuming procedure with high risk of adverse events such as bleeding and perforation [3]. To overcome these challenges, optimal exposure of the submucosal layer is technically important. Recently, various traction methods have been developed for maintaining visualization of the submucosal layer during ESD, and the efficacy of these methods has been clarified [4-6]. However, methods reported so far have not included the ability to change the towing direction during ESD; difficulty visually recognizing and accessing the submucosal layer in some situations may result in improper and ineffective traction, inability to adjust traction force, and challenges in managing the thin submucosal layer. In addition, several traction methods require complicated and time-consuming preparations. In order to facilitate ESD and make it more widely available, a simple traction method with the ability changing towing direction is desirable. We developed a novel traction device, the “EndoTrac.” This device has a simple structure that can easily tie the thread and has the ability to change towing direction [7, 8]. The aim of this study is to evaluate safety and feasibility for ESD using the EndoTrac for GI neoplasms.

Materials and Methods

Patients

This is a preliminary investigation conducted retrospectively at Kishiwada Tokushukai Hospital, a tertiary referral center in Japan, and via Live Endoscopy Events. The study involved 44 patients who underwent ESD with use of the EndoTrac device for dissection of their esophageal, gastric, duodenal, or colorectal neoplasms between June 2018 and May 2019. During this period, lesions that the operator judged to be challenging and conventional methods (e.g., Pocket-creation method (PCM) or

Conventional flap method) may be ineffective due to their size and location were selected. Target lesions were preoperatively estimated by conventional endoscopic and magnified chromoendoscopic examinations. Indications for ESD were defined according to Guidelines for Diagnosis and Treatment of Carcinoma of the Esophagus 2017; Gastric Cancer Treatment Guidelines 2018; and Japanese Society for Cancer of the Colon and Rectum (JSCCR guidelines), respectively [9-12]. Indication for ESD for duodenal neoplasm was determined based on Gastric Cancer Treatment Guidelines 2018. Outcome measures included preparation time, procedural success of the EndoTrac device, changing ability of towing direction, operation time, en bloc resection rate, R0 resection rate, and adverse events. Preparation time was defined as time from withdrawal of the endoscope to providing the traction to the lesion. Procedural success was defined by whether traction by the endoclip tying the EndoTrac was sustained without coming off the lesion until the end of the procedure. Changing ability of towing direction was by whether towing direction could be changed distally or proximally by pushing or pulling the sheath during ESD. The operation time was counted from the beginning of submucosal injection until completion of the resection. R0 resection was defined as en bloc resection with no tumor identified at lateral or vertical margins. To characterize adverse events, postoperative bleeding was defined as 1) requiring endoscopic hemostatic treatment; 2) total hemoglobin drop of more than 2 g/dL compared to the last preoperative level; or 3) massive melena after ESD with no other apparent source of bleeding [13,14]. Perforation was diagnosed by endoscopic finding during the endoscopic treatment or was diagnosed by the presence of free air on abdominal plain radiography or computed tomography (CT) [15]. All patients provided written informed consent before the procedure. This study was approved by the Kishiwada Tokushukai Hospital Institutional Review Board (No. 2019-1).

The EndoTrac device

The EndoTrac (16712; TOP Corporation, Tokyo, Japan) is composed of a thread with a clinch-knotted loop at its tip, which passes through a plastic sheath and has a T-shaped handle at its end (shown in Fig. 1. a, 1. b). To tie the thread to an endoclip, the loop is hooked over one jaw of the endoclip (shown in Fig. 2. a), and the T-shaped handle is pulled, which pushes the knot towards the tip of the sheath (shown in Fig. 2. b). The distance between the endoclip and plastic sheath tip can be adjusted by operating the handle (shown in Fig. 2. c).

ESD using the EndoTrac

Esophageal, gastric, and duodenal ESD procedures were conducted using gastroscope (GIF-H290Z or GIF-Q260J; Olympus Corporation, Tokyo, Japan) with distal attachment cap (16522; TOP Corporation, Tokyo, Japan). Colorectal ESD procedures were conducted using a colonoscope (PCF-Q260AI or GIF-

Q260J; Olympus Corporation, Tokyo, Japan) with a distal attachment cap (16524 or 16522; TOP Corporation, Tokyo, Japan). All ESD procedures were performed using the FlushKnife BT-S (DK2620J; Fujifilm Medical Co., Ltd., Tokyo, Japan). An electrosurgical generator (VIO 300D; ERBE Elektromedizin GmbH, Tübingen, Germany) was used for all the procedures. ESD using the EndoTrac device was performed as follows (retroflex approach): First, the endoscope was inserted without the EndoTrac. After submucosal injection, mucosa on the distal side of the lesion was incised and submucosal dissection was partially made. Then, remaining mucosa on the proximal side of the lesion was incised (shown in Fig. 3. a). After completion of the circumferential mucosal incision, an endoscope was withdrawn outside of patient, an applicator loaded with the endoclip was inserted into the channel, and the loop of the EndoTrac was tied to jaw of the endoclip. Then an endoscope was inserted into the patient with the EndoTrac running alongside the shaft of the endoscope. To reduce friction between the EndoTrac and the overtube, a small amount of lubricating jelly was applied to the sheath when the EndoTrac was inserted. The endoclip tied thread was deployed at the distal margins of the partially resected lesion (shown in Fig. 3. b). When gently pulling the sheath by hand, traction was provided to proximal side and the submucosal layer became easier to visualize (shown in Fig. 3. c). If traction to the proximal side is not effective, the towing direction can be moved to distal side by pushing the sheath (shown in Fig. 3. d). Once access to the submucosal layer is established (shown in Fig. 3. e), the submucosa was dissected easily, and completion of the resection achieved (shown in Fig. 3. f, 3. g). In a forward approach, after completion of the circumferential mucosal incision, the endoclip tied thread was deployed at the proximal side of the lesion. Then, pushing the sheath by hand, traction was provided to distal side. All procedures were performed by one experienced endoscopist.

Results

Table 1 shows characteristics of patients and lesions. We enrolled 44 patients (with collectively 45 lesions) including 8 esophageal lesions (6: cancer, 2: atypical epithelium); 21 gastric lesions (18: cancer, 2: adenoma, 1: atypical epithelium); 4 duodenal cancers, and 12 colorectal lesions (9: cancer, 2: adenoma, 1: SSA/P). The lesion locations were: 3 of the cervical esophagus, 4 of thoracic esophagus, and 1 abdominal esophagus (in esophagus); 6 upper body, 6 middle body, 5 lower body, and 4 remnant stomach (in stomach); 3 second portion and 1 lower duodenal angle in duodenum, and 2 cecum, 3 ascending colon, 2 transverse colon, 1 sigmoid colon, and 4 rectum in colorectal sites. The median lesion size was 28 (20-60) mm in esophagus, 20 (5-90) mm in stomach, 37 (22-48) mm in duodenum, and 30 (15-100) mm in colorectum.

Table 2 shows detail of procedure-related outcomes. The median procedure time was 59 (38-280) minutes in esophagus, 84 (19-270) minutes in stomach, 64 (48-102) minutes in duodenum, and 83 (38-188) minutes in colorectum. En bloc resection rate was 100% in all organs. R0 resection was

achieved except for 1 case of gastric cancer. With regard to adverse events, pin-hole perforation occurred in one gastric case and post-ESD coagulation syndrome (PECS) occurred in one gastric case. Both cases were able to be treated conservatively.

Table 3 shows the results of the primary outcome. The preparation time was 2 (2-5) minutes in esophagus, 3 (1-5) minutes in stomach, 6 (5-9) minutes in duodenum, and 4 (2-8) minutes in colorectum. The procedural success rate was 100% (8/8) in esophagus, 100% (21/21) in stomach, 100% (4/4) in duodenum, and 100% (12/12) in colorectum. The rate of towing direction provided (both proximal and distal) was 100% (8/8) in esophagus, 100% (21/21) in stomach, 0% (0/4) in duodenum, and 100% (12/12) in colorectum. In 4 duodenal lesions, although traction to the proximal side was successfully provided, traction to the distal side was impossible.

Discussion

During ESD, various endoscopic approaches such as forward or retroflex approach are required depending on the location or the situation. In forward approach, at the beginning of submucosal dissection, traction to the endoscope side sometimes makes accessing the submucosal layer difficult, because the thread and the endoscope interfere with each other and the entrance of submucosal layer is not wide enough. In this situation, pushing the sheath to change the direction of traction to the opposite direction of the endoscope widens the entrance and facilitates access to the submucosal layer. In the retroflex approach, although the traction to the opposite side of the endoscope is effective at the beginning of submucosal dissection, creating a sufficient mucosal flap makes the submucosal layer thinner with excessive traction, which complicates submucosal dissection. In this situation, pressing the sheath and loosening the traction tension makes the submucosal layer thicker and facilitates submucosal dissection. Thus, an ability to change the towing direction is considered useful for facilitating the ESD procedure. In this study, the tractions to both proximal side and distal side were successfully provided in all cases except for duodenal lesions.

The EndoTrac has a simple structure consisting of a T-shaped handle, a plastic sheath, and a thread looped at the tip [7]. To attach the EndoTrac to an endoclip, the operator simply hangs the loop over the jaw of the endoclip and pulls the T-shaped handle. In the present study, preparation time was 4 minutes, which is relatively short and considered not to disturb operator's concentration.

Our results showed that the EndoTrac could be attached in a simple operation to provide sufficient traction until the end of an ESD procedure regardless of organ. Further, in most cases, the towing direction could be changed distally or proximally by adjusting the sheath achieving a high en bloc resection rate without adverse events.

Several reports have described the efficacy of traction method for not only esophageal or gastric ESD

but also colorectal ESD [6, 16]. Although various traction methods have been developed, a simple and easy-to-attach method is most likely to be widely used. The present study demonstrated that the EndoTrac could sustain stable application of the endoclip and thread to the lesion until the end of the procedure in all cases. In even duodenum or proximal colon, which is far from the insertion part of the endoscope, sufficient traction was successfully provided. In the method using only endoclip and thread, the thread interferes with the endoscope and tends to come off during procedure.

Furthermore, the traction force cannot be controlled. The EndoTrac has a structure in which the thread passes through the plastic sheath. The plastic sheath allows the endoscope to be easily maneuvered without interrupting the traction placed on the lesion. Furthermore, the clinch-knotted loop of the tip can be tied firmly to the endoclip. It is likely that both of these reasons contributed to it being less likely to come off during the procedure.

Even in the duodenal lesion, although traction to the proximal side was possible, that to distal side was impossible in all cases. This is because when the sheath of the EndoTrac is pushed, it bends in an S-shape within the large space of the stomach, and the pushing force is not transmitted to the duodenal lesion. However, traction force to the proximal side could be adjusted to some extent by controlling the sheath. The plastic sheath of the EndoTrac consists of a dual tube structure of polyetheretherketone and fluororesin with elasticity features that facilitate ease in transmission of pushing force. The characteristics of these materials might have contributed to the smooth change of towing direction. Another advantage of the EndoTrac is that, especially when considering a forward approach where the endoclip and the tip of the sheath are connected and it is difficult to access the submucosal layer due to interference from the sheath, disconnecting the endoclip from the sheath tip makes it easier accessing the submucosal layer by pushing the sheath [7]. Further, the towing direction could be changed (to the right or left) by altering positions of the endoscope and sheath (the crane technique) [8].

These techniques are also considered to improve the visibility of the submucosal layer and make complete resection easier. However, in order to apply the EndoTrac, withdrawal and reinsertion of the endoscope is required. Thus, for a colonic lesion in which insertion of endoscope is difficult or time-consuming, another traction method such as S-O clip or TAC that does not require the reinsertion of the endoscope [6,16]. Especially in proximal colons and difficult-to-insert patients, the use of S-O clips and TAC is preferable because reinsertion of the endoscope should be avoided if possible. In addition, an EndoTrac is relatively inexpensive but more expensive than a TAC without special devices.

Even though we have shown that this novel traction method is safe and feasible in a preliminary study, there are several limitations. First, it was a small and retrospective study. There might have been a bias in selecting lesions, and prospective comparative studies with other devices are needed to show its effectiveness. Second, the procedures were performed by one experienced endoscopist,

making it difficult to accurately assess what the en bloc resection rate or adverse event rate would be in less experienced hands.

In conclusion, we have demonstrated that ESD using the EndoTrac method seems to be feasible.

Further prospective studies are needed to fully evaluate the usefulness of this approach.

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Statement of Ethics

All patients or their guardians provided written informed consent.

This study was approved by the Kishiwada Tokushukai Hospital Institutional Review Board (No. 2019-1).

Disclosure Statement

Takashi Toyonaga has received EndoTrac patent royalties from TOP.

The other authors declare that they have no conflict of interest.

Funding Sources

Funding information is not available.

Author Contribution

Contributors Takashi Toyonaga, Shinwa Tanaka and Yuzo Kodama was responsible for the organization and coordination of the study. Hiroshi Takihara, Shinichi Baba, Eiji Tsubouchi, Yoshio Ikeda, Hitoshi Orita, Manabu Nakamoto, Yohei Horikawa, Hiroki Chiba, Hiromitsu Ban, Youhei Furumoto and Ryushin Morita were also responsible for the data collection and analysis. All authors approved the manuscript to be published, and agree to be 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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Figure Legends

Fig. 1. EndoTrac

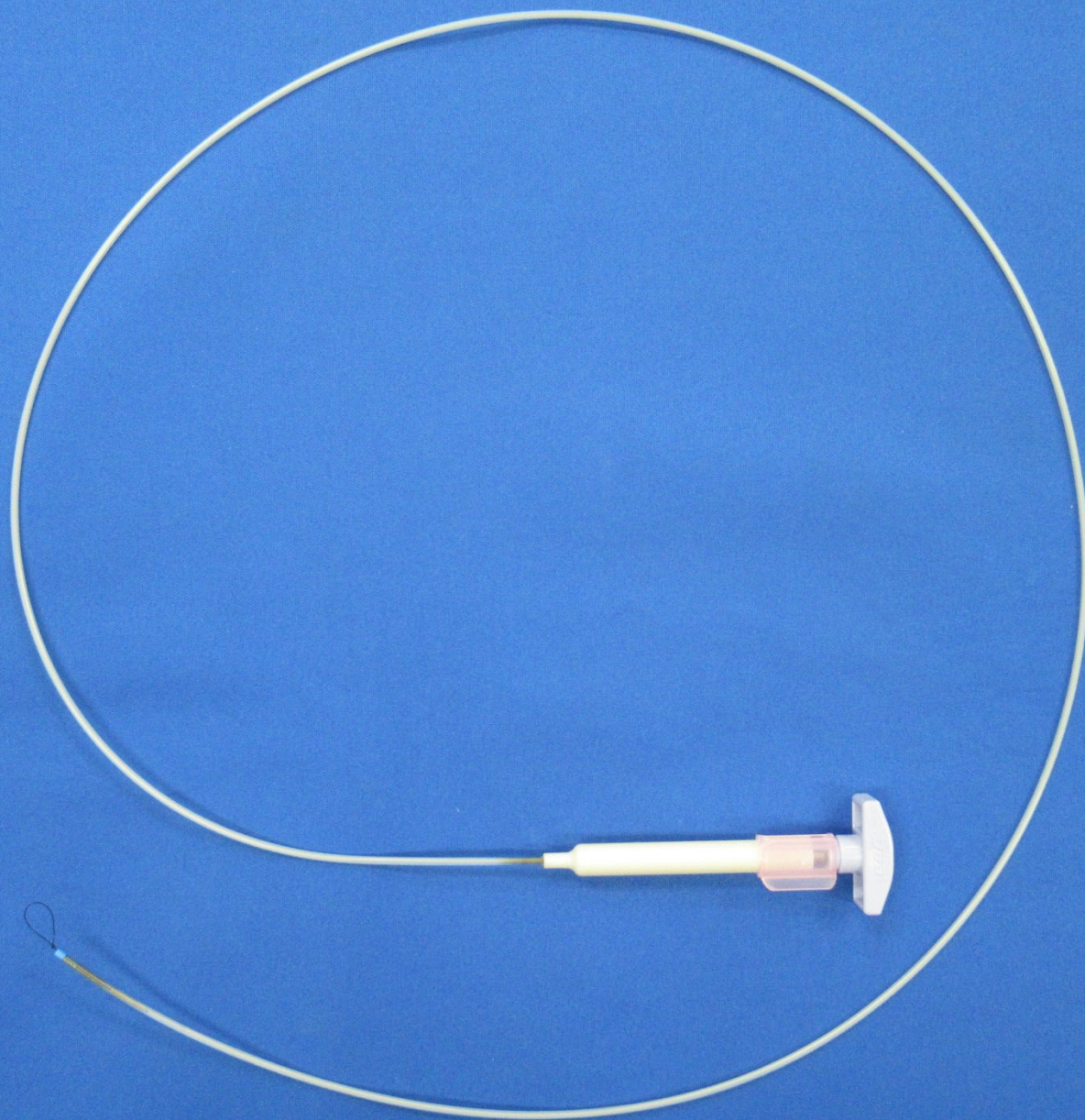
- a) Overview of the EndoTrac
- b) A clinch-knotted loop and T-shape handle

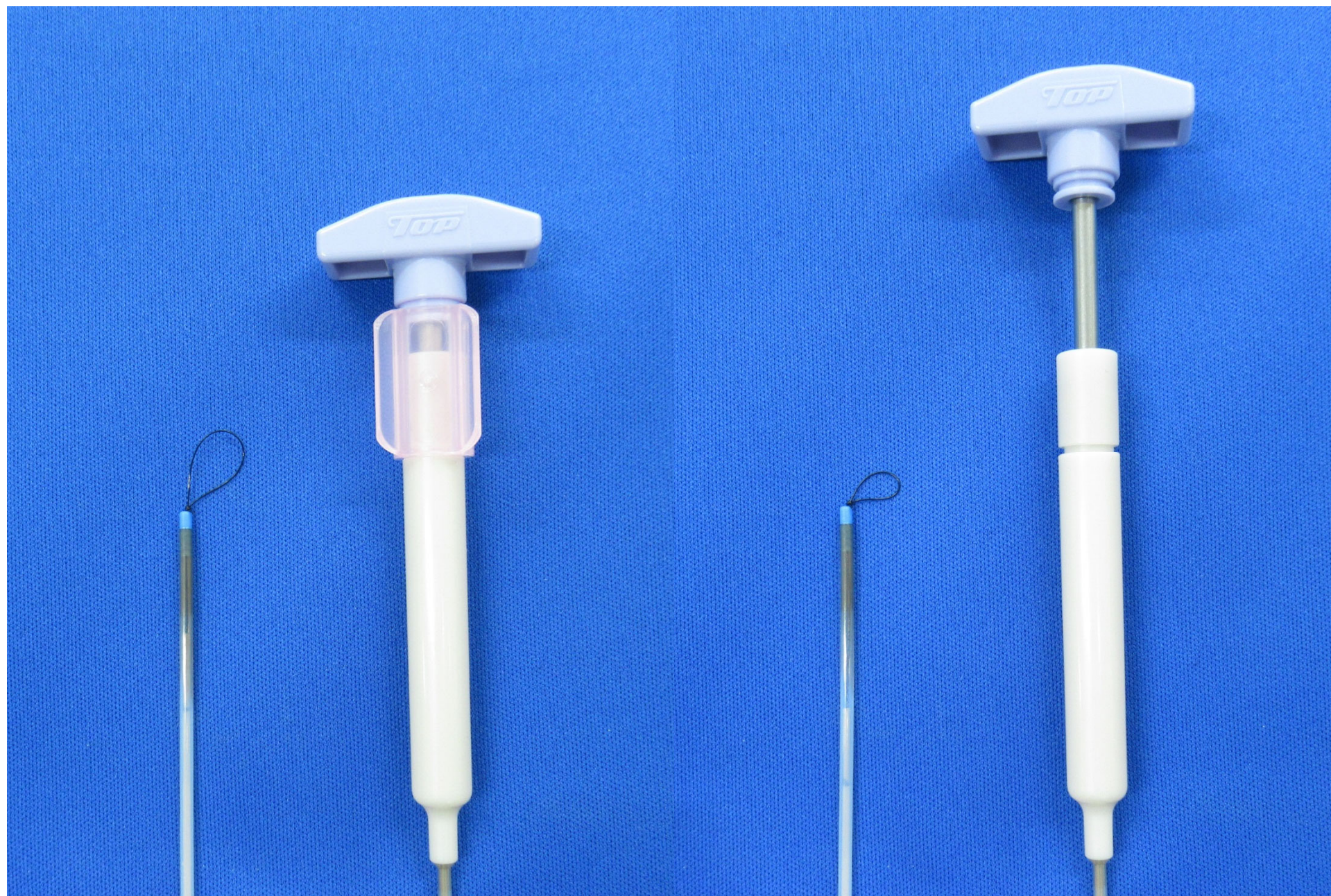
Fig. 2. Preparation of the EndoTrac

- a) The loop is hooked over one jaw of the endoclip.
- b) The T-shaped handle is pulled, which pushes the knot towards the tip of the sheath.
- c) The distance between the endoclip and plastic sheath tip can be adjusted by operating the handle.

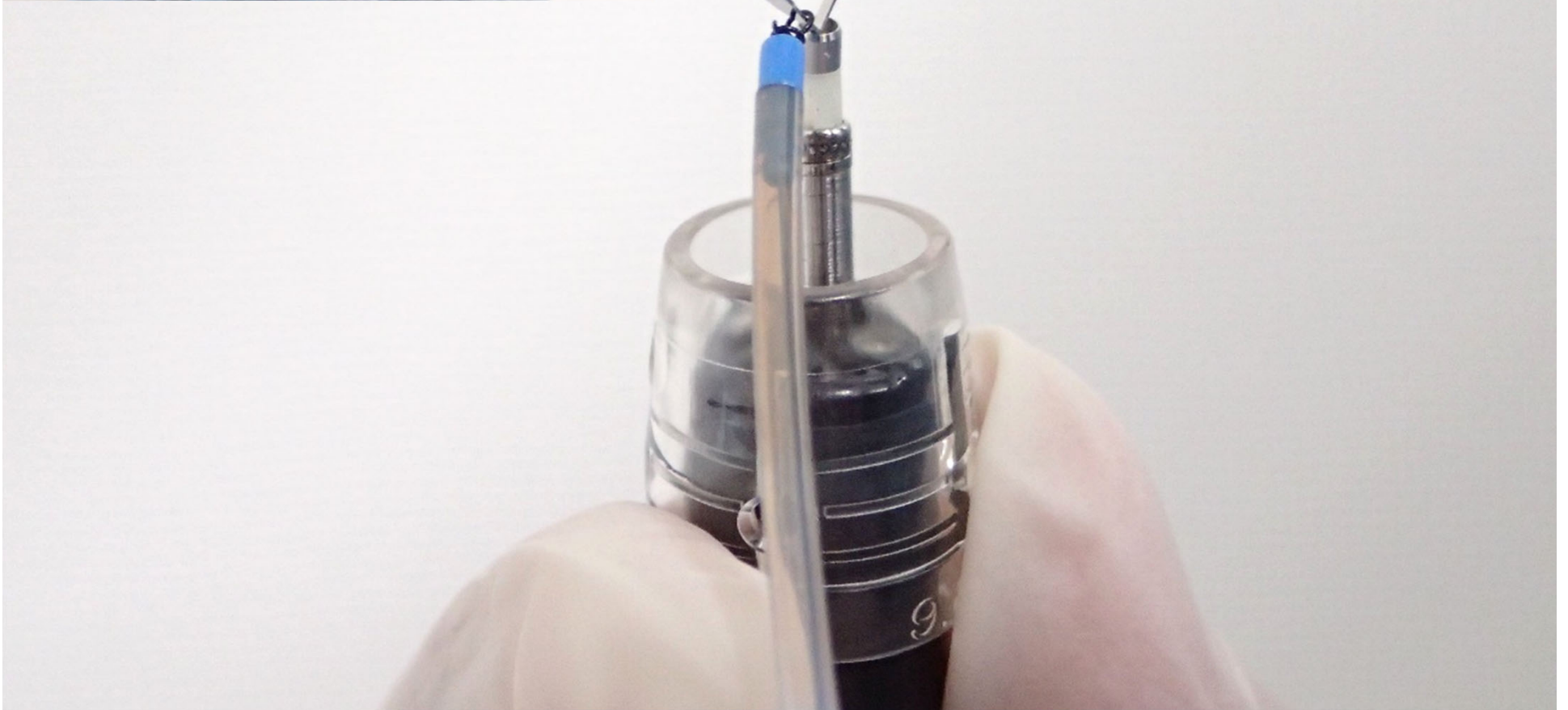
Fig. 3. Endoscopic submucosal dissection using the EndoTrac

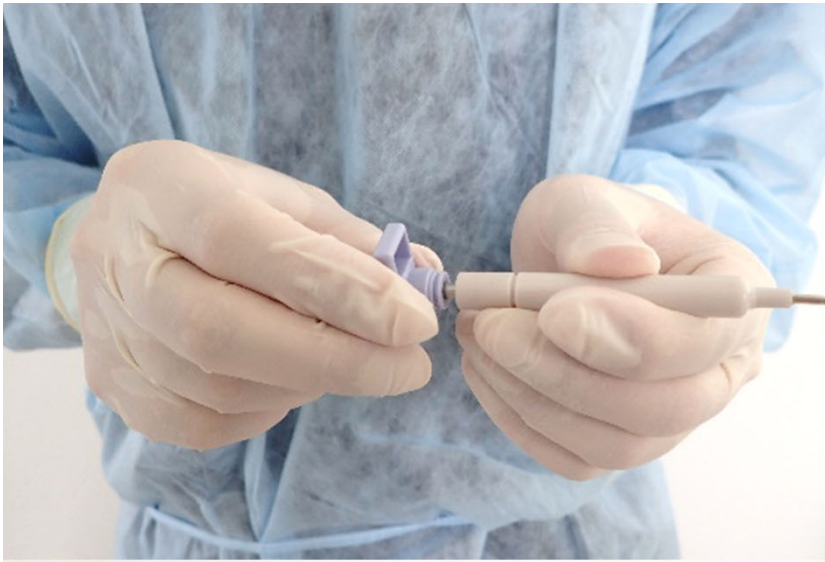
- a) The proximal side of the lesion was incised.
- b) The endoclip tied thread was grasped at the margin of the lesion.
- c) Pulling the sheath by hand, traction was provided to proximal side.
- d) By pushing the sheath, the towing direction could be changed to distal side.
- e) The submucosal layer was established.
- f) Complete resection was achieved.
- g) The resected lesion

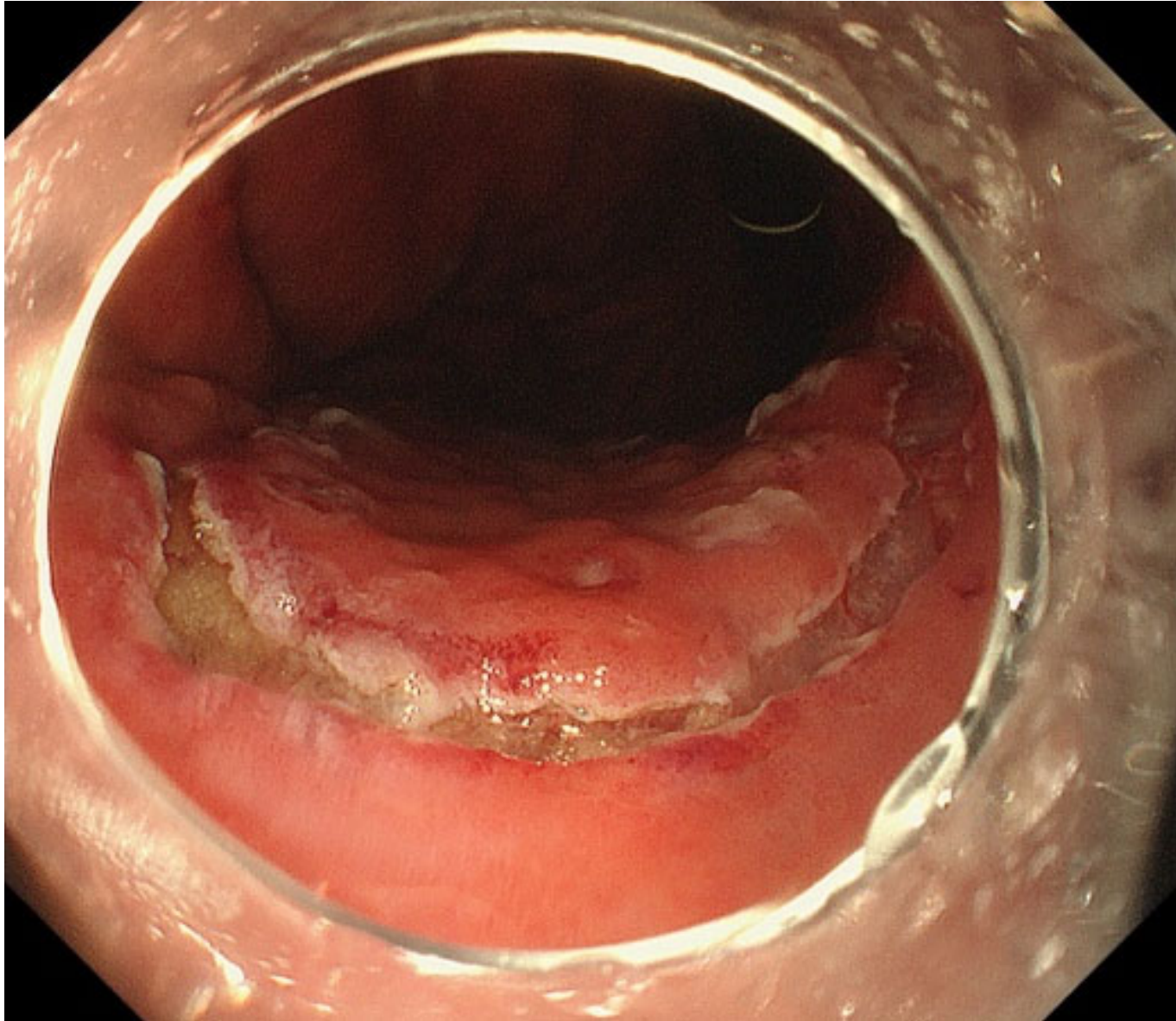


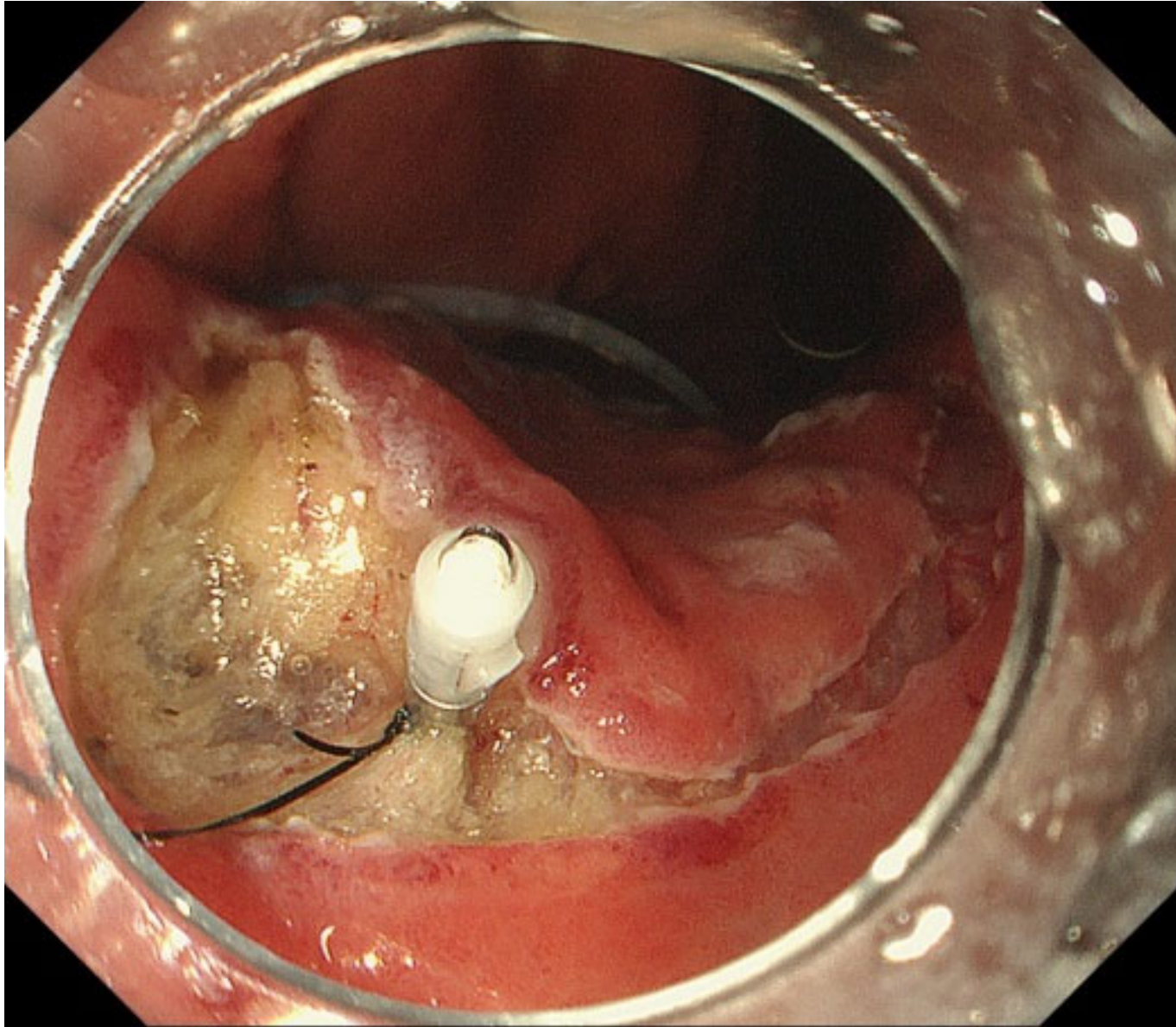


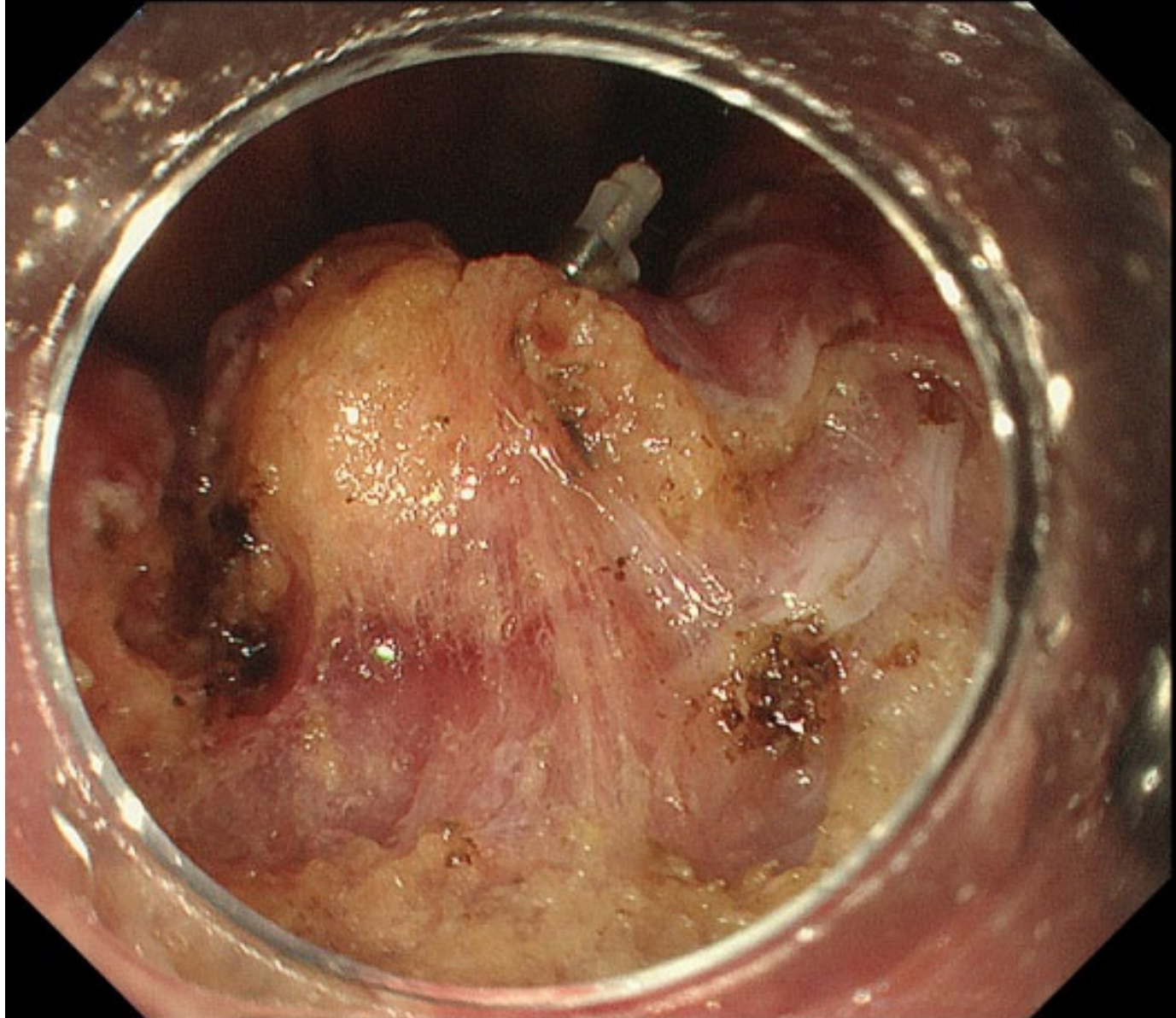


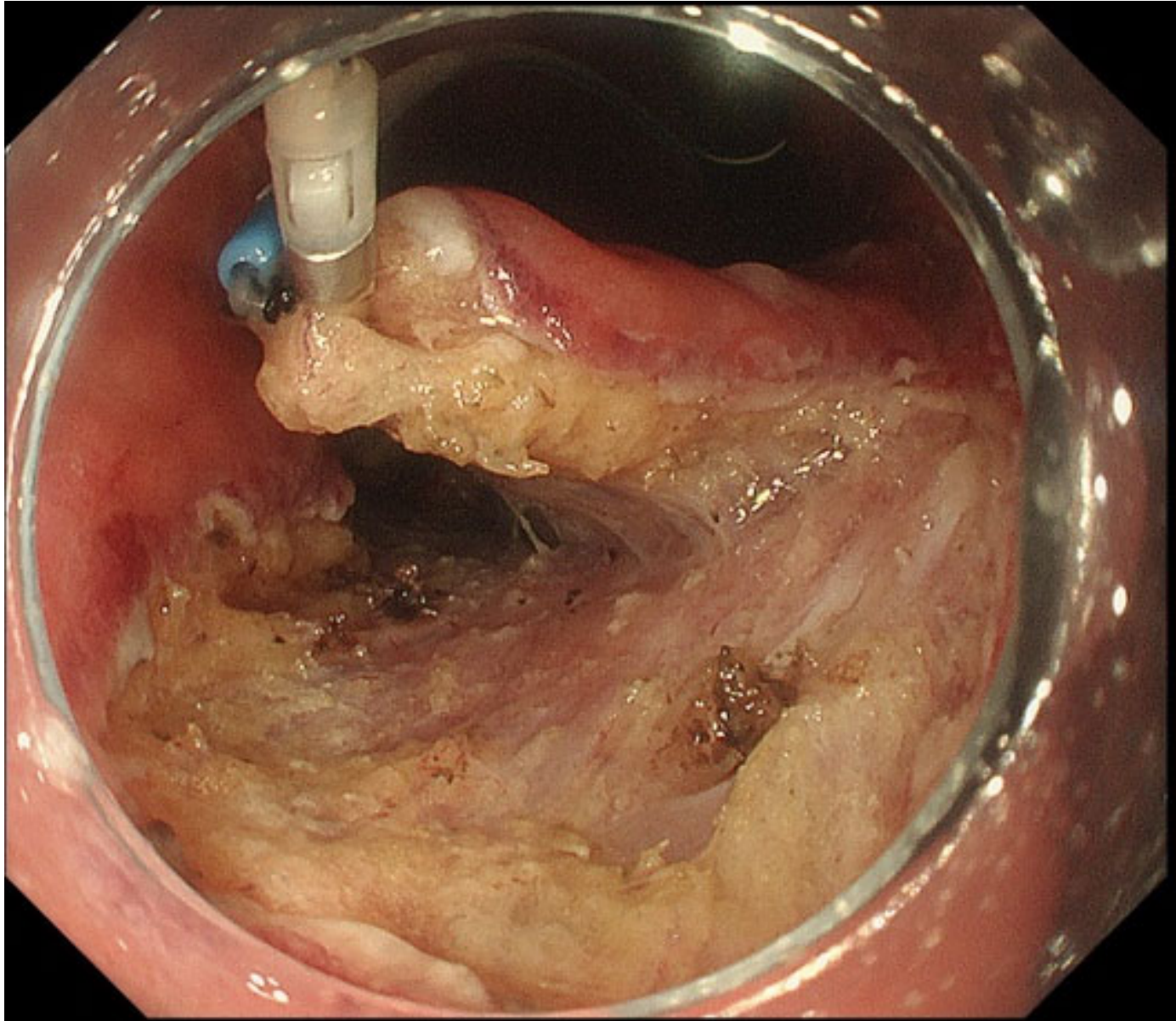


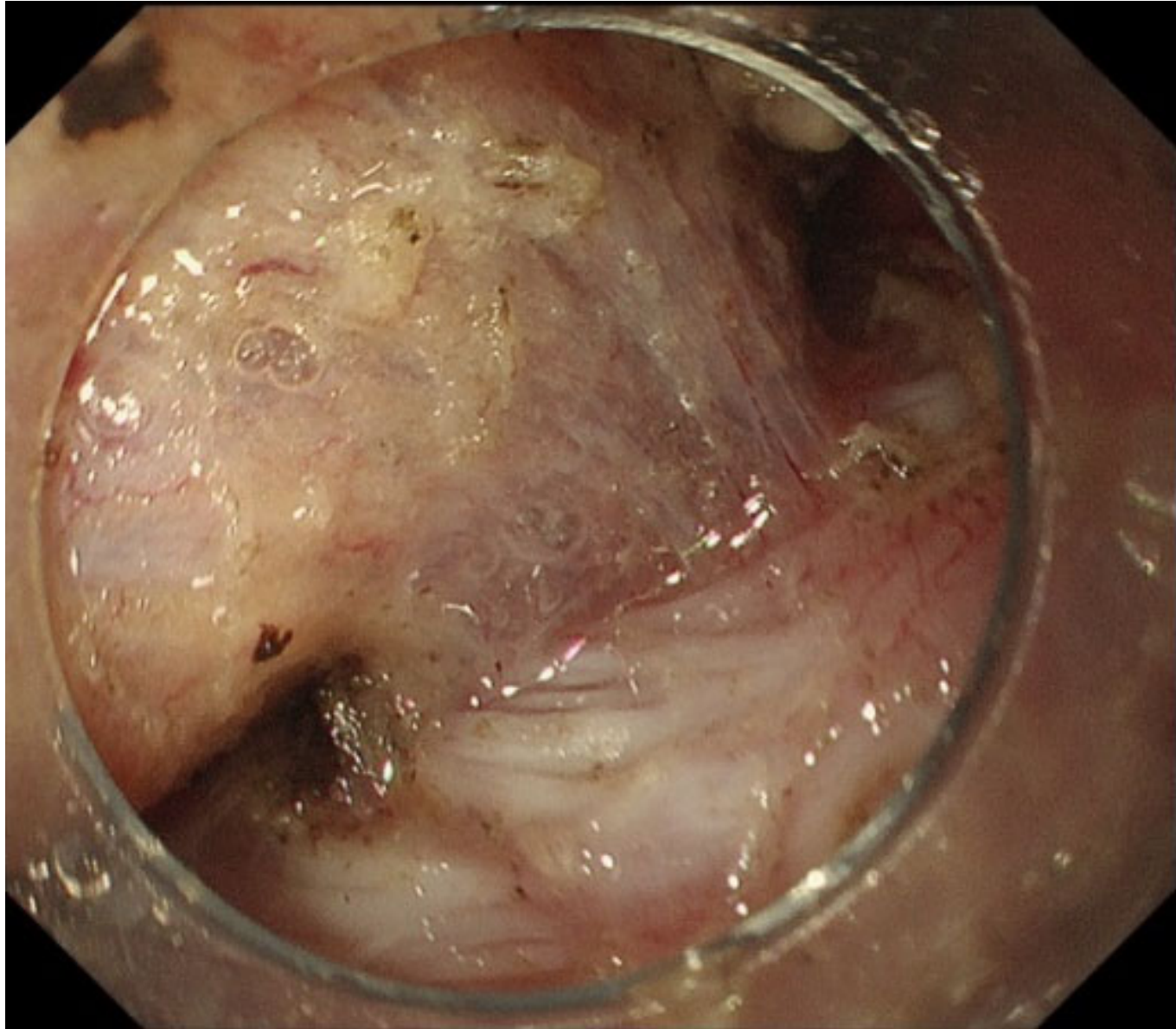


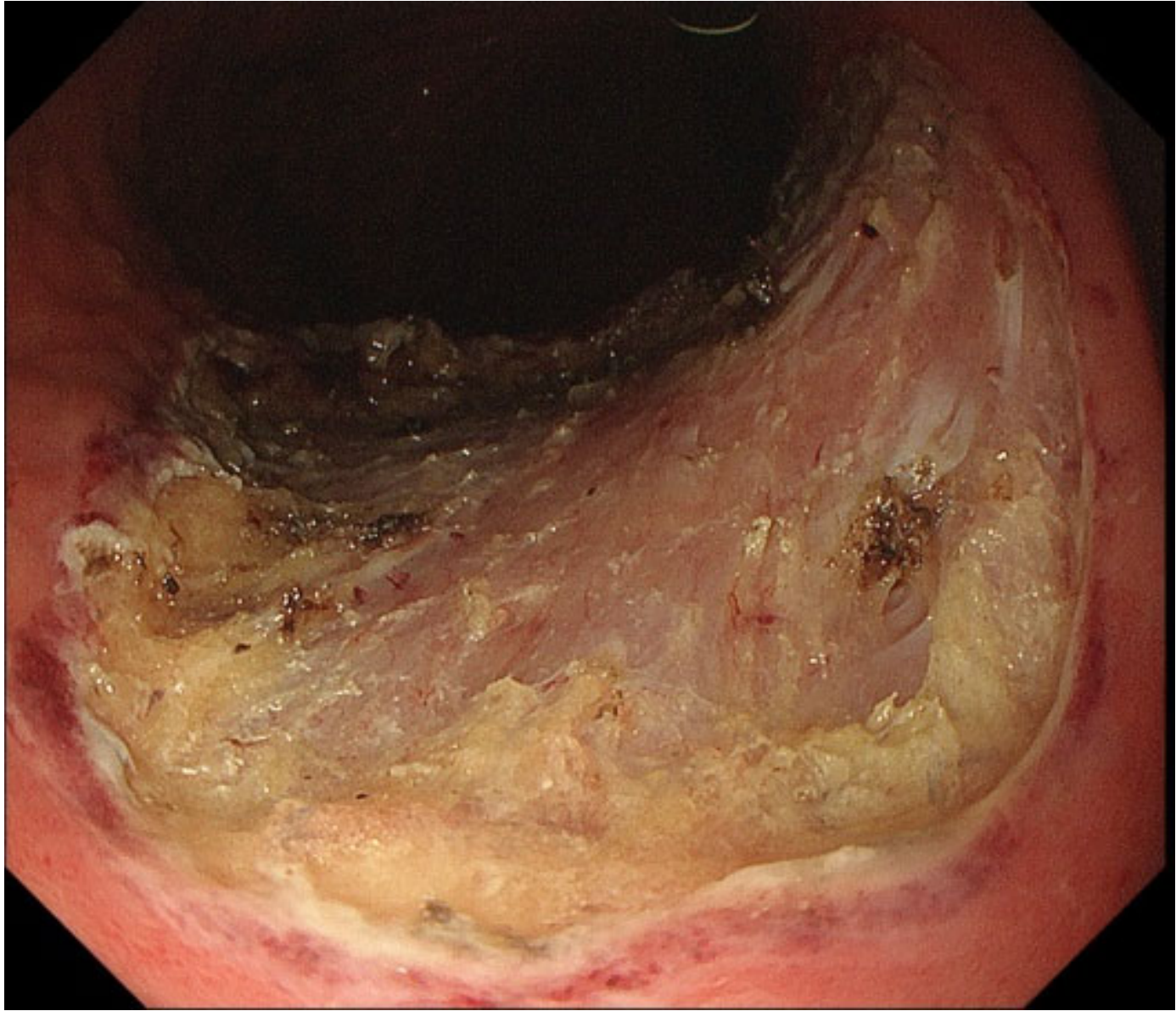












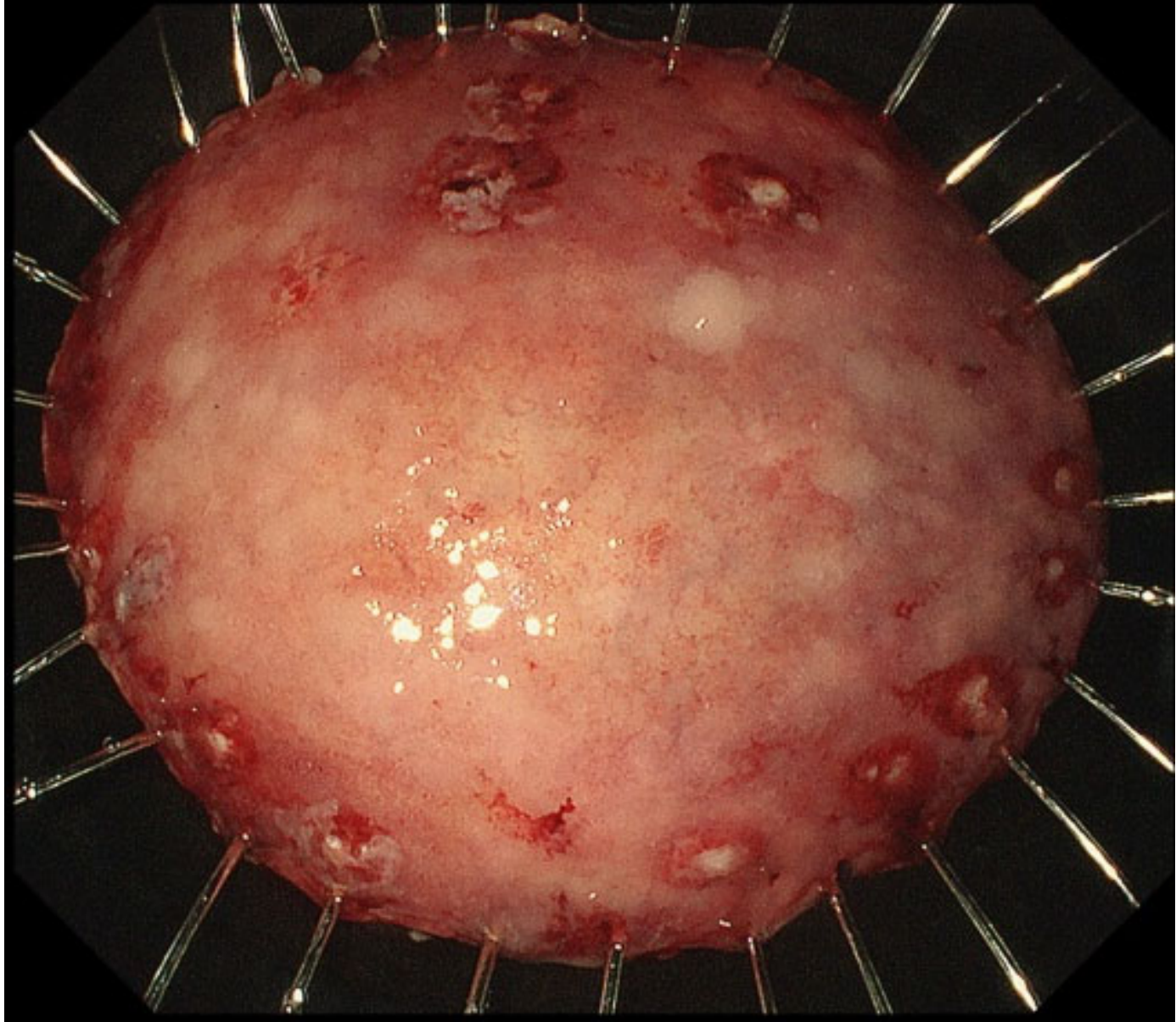


Table 1. Characteristics of patients and lesions

Organ	Location	Macroscopic Type	Median size (mm)	Depth of invasion	Lymphovascular invasion
Esophagus (n=8)	Ce 3	0- I + II a 1	28 (20-60)	T1a (scc) 5	none
	Thoracic 4	0- II a+ II b 1		T1a (tub1) 1	
	Ae 1	0- II b 3		atypical epithelium 2	
		0- II c 1			
		0- II c+ II b 2			
Stomach (n=21)	U 6	0- II a 10	20 (5-90)	T1a 16	none
	M 6	0- II c 7		T1b 2	
	L 5	0- II a+ II c 3		adenoma 2	
	Others 4	0- II c+ II a 1		atypical epithelium 1	
Duodenum (n=4)	Second portion 3	0- II a 3	37 (22-48)	Tis 3	none
	LDA 1	0- II a+ II c 1		T1a 1	
Colorectum (n=12)	Cecum 2	LST-G 7	30 (15-100)	Tis 6	1/12 (8.3%)
	Ascending colon 3	LST-NG 3		T1b 3	
	Transverse colon 2	0- II a 2		Adenoma 2	
	Sigmoid colon 1			SSA/P 1	
	Rectum 4				

Ce: cervical esophagus

U: upper part

LDA: lower duodenal angle

Ae: abdominal esophagus

M: middle part

LST-G: laterally spreading tumor, granular type

L: lower part

LST-NG: laterally spreading tumor, nongranular type

others: after surgical operation

Table 2. Procedure-related outcome

Organ	Procedure time (min)	En bloc resection	R0 resection	Adverse events
Esophagus (n=8)	59 (38-280)	8/8 (100%)	8/8 (100%)	none
Stomach (n=21)	84 (19-270)	21/21 (100%)	20/21 (95%)	2/21 (9.5%)
Duodenum (n=4)	64 (48-102)	4/4 (100%)	4/4 (100%)	none
Colorectum (n=12)	83 (38-188)	12/12 (100%)	12/12 (100%)	none

Table 3. The detail of procedure related to the EndoTrac during endoscopic submucosal dissection

Organ	Location	Preparation time (min)	Procedural success rate	The changing ability of towing direction	
				Proximal side	Distal side
Esophagus (n=8)	Total 8	2 (2-5)	8/8 (100%)	8/8 (100%)	8/8 (100%)
	Ce 3	2	3/3 (100%)	3/3 (100%)	3/3 (100%)
	Thoracic 4	2 (2-5)	4/4 (100%)	4/4 (100%)	4/4 (100%)
	Ae 1	3	1/1 (100%)	1/1 (100%)	1/1 (100%)
Stomach (n=21)	Total 21	3 (1-5)	21/21 (100%)	21/21 (100%)	21/21 (100%)
	U 6	3 (3-4)	6/6 (100%)	6/6 (100%)	6/6 (100%)
	M 6	3.5 (1-4)	6/6 (100%)	6/6 (100%)	6/6 (100%)
	L 5	4 (1-5)	5/5 (100%)	5/5 (100%)	5/5 (100%)
	others 4	3	4/4 (100%)	4/4 (100%)	4/4 (100%)
Duodenum (n=4)	Total 4	6 (5-9)	4/4 (100%)	4/4 (100%)	0/4 (0%)
	Second portion 3	5.5 (5-6)	3/3 (100%)	3/3 (100%)	0/3 (0%)
	LDA 1	9	1/1 (100%)	1/1 (100%)	0/1 (0%)
Colorectum (n=12)	Total 12	4 (2-8)	12/12 (100%)	12/12 (100%)	12/12 (100%)
	Cecum 2	6.5 (6-7)	2/2 (100%)	2/2 (100%)	2/2 (100%)
	Ascending colon 3	4 (3-8)	3/3 (100%)	3/3 (100%)	3/3 (100%)
	Transverse colon 2	7.5 (7-8)	2/2 (100%)	2/2 (100%)	2/2 (100%)
	Sigmoid colon 1	5	1/1 (100%)	1/1 (100%)	1/1 (100%)
	Rectum 4	2 (2-3)	4/4 (100%)	4/4 (100%)	4/4 (100%)

Ce: cervical esophagus

U: upper part

LDA: lower duodenal angle

Ae: abdominal esophagus

M: middle part

LST-G: laterally spreading tumor, granular type

L: lower part

others: after surgical operation

LST-NG: laterally spreading tumor, nongranular type