

Usefulness of “Nelaton Attachment” for endoscopic submucosal dissection of colorectal neoplasms




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ABSTRACT

Background and study aims Although colorectal endoscopic submucosal dissection (ESD) has enabled high en bloc resection rates regardless of tumor size, colorectal ESD is still a challenging procedure. We developed a novel device called the Nelaton Attachment, which allows endos-

copists to manipulate the ESD knives using two fingers of their left hand while holding the endoscope with their right hand. We retrospectively investigated the efficacy and safety of the Nelaton Attachment for colorectal ESD. We compared the efficacy and safety between Nelaton Attachment and non-Nelaton Attachment groups, and also conducted an ex vivo experiment to evaluate the effect of the Nelaton Attachment.

Patients and methods We retrospectively reviewed 36 consecutive patients with 37 colorectal tumors who had undergone ESD at Kishiwada Tokushukai Hospital and Nari-tatomisato Tokushukai Hospital between April 2016 and September 2018. The Nelaton Attachment was used for 22 of the 37 colorectal ESDs. In the ex vivo experiment, endoscopists inserted and withdrew an ESD knife 2 cm using two fingers of their left hand with and without the Nelaton Attachment.

Results Median procedure time was significantly shorter in the Nelaton Attachment group (38 min [range 6–195 min]) compared to the non-Nelaton Attachment group (75 min [range 17–198 min]; $P=0.030$). Median time to complete the ex vivo experiment five times was significantly faster with the Nelaton Attachment than without the Nelaton Attachment ($P=0.001$).

Conclusions Use of the Nelaton Attachment for colorectal ESD is feasible and safe, and may facilitate colorectal ESD procedures.

Introduction

Colorectal endoscopic submucosal dissection (ESD) has enabled high en bloc resection rates regardless of tumor size [1–3]. However, colorectal ESD is a more challenging procedure than conventional endoscopic mucosal resection (EMR) because of its technical difficulties, longer procedure time, and higher rates of perforation [4, 5]. Generally, endoscopists manipulate both ESD knives and endoscopes using their right hand during colorectal ESD. In an unstable situation, however, maneuvers with the right hand make it difficult for endos-

copists to maintain the endoscopic operative view once they release their right hand from the endoscopes to manipulate the ESD knives. To overcome this, we developed a novel device called the Nelaton Attachment, which allows endoscopists to manipulate the ESD knives using two fingers (index and middle fingers) on their left hand, dubbed the two-fingers method, while holding the endoscopes with their right hand [6, 7].

Some endoscopists use their left fingers to manipulate ESD knives during colorectal ESD, especially in unstable situations where they cannot release their right hand from the endoscopes. The concept behind our device is that even in a stable

situation, using left fingers to manipulate an ESD knife may facilitate colorectal ESD because the endoscopists can keep their right hand on the endoscopes. In fact, using the Nelaton Attachment, endoscopists can always use their left fingers to manipulate ESD knives without releasing their right hand from the endoscopes. We believe that the Nelaton Attachment will help endoscopists perform the two-fingers method more accurately, which will reduce procedure times and enhance safety.

Although we have used the Nelaton Attachment for colorectal ESDs in clinical practice, its safety and efficacy have not been evaluated. Therefore, we retrospectively investigated the feasibility and safety of the Nelaton Attachment for colorectal ESD.

Patients and methods

We retrospectively reviewed the records of 36 consecutive patients with 37 colorectal tumors who had undergone ESD at Kishiwada Tokushukai Hospital and Naritatomisato Tokushukai Hospital between April 2016 and September 2018. The Nelaton Attachment was used for 22 of the 37 colorectal ESDs. Patient and tumor characteristics including sex, age, and tumor location were investigated. Furthermore, treatment results including the tumor and resected specimen size, procedure time, en bloc resection rate, R0 resection rate, histological diagnosis, and complications such as perforation rate were analyzed.

We compared the characteristics of patients, tumors, and clinical outcomes of colorectal ESDs between patients that underwent colorectal ESD with use of the Nelaton Attachment (Nelaton Attachment group) and those that underwent colorectal ESD without use of the Nelaton Attachment (non-Nelaton Attachment group). We also investigated the effect of the Nelaton Attachment in an ex vivo experiment. This study was approved by the institutional review board, and all patients met the indication criteria recommended by the Japanese colorectal ESD/EMR guidelines [2], and written, informed consent for the ESD procedure was obtained from all patients.

Nelaton Attachment

The Nelaton Attachment was prepared by cutting a 10-Fr transurethral catheter (inner diameter: 2.1 ± 0.1 mm, SAFEED Nelaton Catheter; Terumo, Tokyo, Japan) to a length of 8 to 10 cm. The catheter was slit along its length and attached to the sheath of a FlushKnife BT-S (Fujifilm Co., Tokyo, Japan) (► Fig. 1 and ► Fig. 2).

ESD procedures using the Nelaton Attachment

Patients were sedated with intravenous flunitrazepam, pethidine hydrochloride and dexmedetomidine during the procedures. Normal saline was first injected into the submucosa to facilitate subsequent injections of sodium hyaluronate solution (MucoUp; SEIKAGAKU Co., Tokyo, Japan) into an appropriate submucosal plane. Sodium hyaluronate was then injected to create adequate protrusion of the targeted mucosa. A mucosal incision around the tumor and submucosal dissection of the tumor were both performed using a 1.5-mm FlushKnife BT-S until the tumor was completely excised. Carbon dioxide insufflation was used instead of air insufflation to reduce patient discom-



► Fig. 1 Nelaton Attachment on the sheath of a FlushKnife BT-S.



► Fig. 2 Control of the FlushKnife BT-S with the Nelaton Attachment.

fort. When the tumor was located at the rectum or distal colon, a GIF-HQ290 (Olympus Optical Co., Tokyo, Japan) was mainly used. On the other hand, when the tumor was located at the proximal colon, a PCF-260AZI (Olympus Optical Co.), CF-HQ290 (Olympus Optical Co.), or PCF-H290I (Olympus Optical Co.) was used. A transparent hood was attached to the endoscopic tip in all procedures to make the lesion more visible. A VIO300D (Erbe Elektromedizin, Tübingen, Germany) was used as the electrosurgical generator. After reaching the tumor, a 1.5-mm FlushKnife BT-S was inserted inside the forceps channel of the endoscope, setting the tip of the knife at the usual position to incise and dissect the tumor, and then the Nelaton Attachment was attached to the sheath of the 1.5-mm FlushKnife BT-S. Medical tape was placed on the sheath of the FlushKnife BT-S just above the distal part of the Nelaton Attachment to prevent positional dislocation. All colorectal ESDs were carried out by a single endoscopist (T.Y.) with experience performing more than 100 ESDs. The procedure time was defined as the time from the first submucosal injection to the completion of

dissection. Insertion or withdrawal of the 1.5-mm FlushKnife BT-S was controlled using the two-fingers method (► **Video 1**, ► **Video 2**) [7].

Ex vivo experiment

The ex vivo experiment involved inserting and withdrawing an ESD knife 2 cm using the two-fingers method with and without the Nelaton Attachment. Before starting the experiment, a 1.5-mm FlushKnife BT-S was inserted inside the same endoscope (PCF-260AZI; Olympus Optical Co.) until the tip of the knife could be seen in the endoscopic view. The knife was then withdrawn slightly until the tip of the knife could not be seen in the endoscopic view. An endoscopist inserted the knife 2 cm and subsequently withdrew the knife using the two-fingers method. A cycle comprised one insertion and one withdrawal. Two different endoscopists (with 4 and 6 years of ESD experience) performed five cycles with and without the Nelaton Attachment. The experiment was repeated five times, and the average time to perform five cycles was calculated.

Statistical analysis

Sex, tumor location, morphology, histology, and perforation rate were compared using the Fisher's exact test. Age was compared using Student's *t*-test. Tumor size, resected specimen size, procedure time, and average time for the 2-cm insertion and withdrawal for five cycles were compared using the Mann-Whitney U test. The threshold for significance was $P < 0.05$. SPSS version 22.0 for windows (IBM Japan Ltd., Tokyo, Japan) was used for statistical analyses.

Results

Participants and descriptive data

Twenty-one patients (8 men and 13 women) with 22 colorectal tumors were treated with the Nelaton Attachment (Nelaton Attachment group), whereas 15 patients (9 men and 6 women) with 15 colorectal tumors were treated without the Nelaton Attachment (non-Nelaton Attachment group). No significant differences in patient and tumor characteristics were found between the two groups. The characteristics of the patients, tumor location, and morphology are shown in ► **Table 1**.



► **Video 1** How to set up the Nelaton Attachment.

► **Table 1** Characteristics of patients and tumors.

	NA (+) N = 22	NA (-) N = 15	P value
Age, years, mean ± SD	69.7 ± 12.3	68.9 ± 10.9	0.82
Male/female, n (%)	8/14 (36/64)	9/6 (60/40)	0.19
Tumor location, n (%)			0.84
▪ Rectum	5 (23)	5 (33)	
▪ Sigmoid colon	3 (14)	0 (0)	
▪ Descending colon	1 (4)	1 (7)	
▪ Transverse colon	6 (27)	4 (27)	
▪ Ascending colon	4 (18)	3 (20)	
▪ Cecum	3 (14)	2 (13)	
Morphology, n (%)			>0.99
▪ LST-G	6 (27)	4 (27)	
▪ LST-NG	11 (50)	7 (47)	
▪ Others	5 (23)	4 (27)	

NA, Nelaton Attachment; SD, standard deviation; LST-G, laterally spreading tumor-granular type; LST-NG, laterally spreading tumor-nongranular type

Outcomes data

Median sizes of the resected specimens were 30 mm (range 23–46 mm) and 27 mm (range 17–94 mm) in the Nelaton Attachment and non-Nelaton Attachment groups, respectively. Median procedure time was significantly shorter in the Nelaton Attachment group (38 min [range 6–195 min]) compared to the non-Nelaton Attachment group (75 min [range 17–198 min]; $P = 0.030$). There were two cases of perforation in the non-Nelaton Attachment group. The Nelaton Attachment was successfully used in the Nelaton Attachment group. No technical or mechanical problems such as positional dislocation of the Nelaton



► **Video 2** How to use the Nelaton Attachment. We show a case of gastric ESD in which the endoscopist encountered an unstable situation during the procedure, requiring the use of his left fingers many times. The tumor was type IIa, 6 mm in size, and located at the pylorus.

Attachment occurred during any of the procedures. Clinical outcomes of the colorectal ESDs are shown in ► **Table 2**.

Results of the ex vivo experiment

Median time to complete five cycles of the 2-cm insertion and withdrawal was significantly faster with the Nelaton Attachment than without the Nelaton Attachment ($P=0.001$). Results of the ex vivo experiment are shown in ► **Table 3**.

Discussion

The aims of the current study were to retrospectively investigate feasibility and safety of the Nelaton Attachment for performing colorectal ESD, and to evaluate the effect of the Nelaton Attachment in an ex vivo experiment. Results of the ex vivo experiment clearly show that it is possible to manipulate the knife faster with the Nelaton Attachment than without the Nelaton Attachment using the two-fingers method.

Results of the clinical retrospective study demonstrate that the Nelaton Attachment was successfully used in the Nelaton Attachment group without technical or mechanical problems and that use of the device shortened procedure time. Perforation did not occur in the Nelaton Attachment group, whereas two cases of perforation occurred in the non-Nelaton Attachment group, suggesting that using the Nelaton Attachment does not increase occurrence of adverse events in colorectal ESD.

The two-fingers method involves using the index finger and middle finger of the left hand to manipulate the treatment device while holding the endoscope with the right hand. Although this method is effective, it does require some training to master. Moreover, the thin sheaths of the ESD knives can be difficult to manipulate using the two-fingers method, and moisture can make the sheaths slippery. Therefore, we designed a novel device, the Nelaton Attachment, which helps the endoscopists perform this technique easily.

The Nelaton Attachment increases the thickness of the FlushKnife BT-S sheath from 2.2 to 3.3 mm, which allows endoscopists to perform the two-fingers method quickly. The Nelaton Attachment is made of polyvinyl chloride, a waterproofing material, which prevents the fingers from slipping under wet conditions. Moreover, the stopper effect of the Nelaton Attachment enables endoscopists to insert the FlushKnife BT-S into the endoscope faster [7].

In our hospital, we mainly use the FlushKnife BT-S for colorectal ESD. This knife has some merits in terms of its water jet function, which means that endoscopists can inject normal saline into the submucosal layer using the knife without the need to exchange it with other needles [8–10].

Frequent injection of saline into the submucosal layer keeps the layer expanded, which helps endoscopists dissect the submucosal layer safely. Although this water jet function is effective, injection of saline using the FlushKnife BT-S moves the endoscope in the opposite direction, which compromises the endoscopic view. With the Nelaton Attachment, however, endoscopists can grip the endoscope with their right hand steadily while injecting normal saline with their left two fingers,

► **Table 2** Clinical outcomes.

	NA (+) N=22	NA (-) N=15	P value
Tumor size, median (range), mm	21 (13–35)	20 (8–85)	0.27
Resected specimen size, median (range), mm	30 (23–46)	27 (17–94)	0.15
Procedure time, median (range), min	38 (6–195)	75 (17–198)	0.030
Histology, n (%)			0.37
▪ Adenoma	13 (59)	5 (33)	
▪ Mucosal	6 (27)	8 (53)	
▪ Submucosal invasion	1 (5)	1 (7)	
▪ Others	2 (9)	1 (7)	
En bloc resection, n (%)	22 (100)	15 (100)	
R0 resection, n (%)	22 (100)	15 (100)	
Perforation, n (%)	0 (0)	2 (13)	0.15

NA, Nelaton Attachment.

► **Table 3** Results of the ex vivo experiment.

	NA (+)	NA (-)	P value
Time (s), median (range) ¹	8.6 (7.1–17.2)	23.3 (11.0–32.6)	0.001

¹ Time to insert and withdraw an ESD knife 2 cm for a total of five times.

► **Table 4** Nelaton Attachment for different types of ESD knives.

Knife	Sheath diameter (mm)	NA (Fr)
Dual J	2.0	10
Splash M	2.7	12
IT 2/ nano	2.6	12
Hook J	2.6	12

ESD, endoscopic submucosal dissection; NA, Nelaton Attachment.

thereby preventing movement of the endoscope. In addition, they can push (or pull) the ESD knives using their left two fingers while pushing (or pulling) the endoscope with their right hand simultaneously. Because of these merits, the Nelaton Attachment enables endoscopists to control the ESD knives using their left fingers accurately and quickly (as if using their right hand) while holding the endoscopes with their right hand, thereby maintaining a good endoscopic operative view, which is one of the most important factors for quick and safe ESD.

There is another way that ESD knives can be manipulated. Kikuchi et al. reported the utility of the Smart Shooter, a device that enables endoscopists to manipulate ESD knives using their right thumb while holding the endoscope with their right hand

[11, 12]. Use of this device, however, requires endoscopists to learn how to control the treatment device with their thumb, which they rarely have a chance to practice. In contrast, endoscopists can practice the two-fingers method during several different procedures, including biopsy, EMR snare, and clipping. Furthermore, the Smart Shooter has some structural issues and use limitations [13]. Unlike the Smart Shooter, the Nelaton Attachment can be used with several different types of ESD knives and endoscopes. In fact, a 10-Fr Nelaton Attachment can be used with the Dual J Knife, and a 12-Fr Nelaton Attachment can be used with the Splash M Knife, IT2 and Hook J Knife [7] (► **Table 4**). Other advantages of the Nelaton Attachment are that it is inexpensive and available worldwide.

Limitations of the current study include all colorectal ESDs being performed by a single endoscopist, small sample size, and the research's retrospective nature. In addition, the non-Nelaton Attachment group was treated during the initial phase of this study while the Nelaton Attachment group was treated during the late phase. The possibility that a learning curve related to the two-fingers method, if any, that could affect the outcomes of the study cannot be denied. Prospective studies, a larger number of patients, and use of the Nelaton Attachment by different endoscopists are required to verify our results.

Conclusion

In conclusion, the Nelaton Attachment is feasible and safe for colorectal ESD, and may facilitate this procedure.

Competing interests

None

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