Thieme

A stag beetle knife can achieve stabler and safer endoscopic submucosal dissection in the esophagus

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ABSTRACT

Background and study aims Esophageal endoscopic submucosal dissection (ESD) has a higher complication rate than gastric ESD. Scissor-type devices, including the stag beetle (SB) knife, are reportedly safer and have shorter procedure times than tip devices. To clarify the characteristics of the SB knife, we compared the treatment outcomes of esophageal ESD with a tip-type knife to those with an SB knife combination.

Patients and methods Between January 2016 and March 2023, clinical data from 197 lesions in 178 patients who underwent esophageal ESD were analyzed retrospectively. Every lesion was assigned to either the tip-type group or the SB group based on the devices with which the submucosa was initially dissected. We compared procedure time and complications and analyzed the risk of muscular exposure using multivariate analysis.

Results Procedure time was not significantly different between the tip-type and SB groups (60.3±42.2 min vs. 58.8 ±29.1 min). The variation in procedure time was significant according to F test $P=0.002$). Incidence of muscular exposure was significantly lower in the SB group than in the tip-type group (24.5% vs. 11.1%, $P=0.016$). These differences were significant in resected specimens larger than 21 mm. Procedure time over 60 minutes (odds ratio [OR] 2.5, 95% confidence interval [CI]: 1.15–5.42, $P=0.02$) was a risk factor for muscular exposure, and submucosal dissection with an SB knife was a safety factor (OR 0.4, 95% CI: 0.18–0.89, $P=0.02$).

Conclusions Performing esophageal ESD with an SB knife is a safe procedure with less variation in procedure time and less muscule exposure.

Introduction

Endoscopic submucosal dissection (ESD) of the esophagus has become the standard treatment for early esophageal cancer in Japan [1,2]. ESD allows en bloc resection of large lesions and thereby effectively achieves a higher cure rate and lower recurrence rate than conventional endoscopic mucosal resection (EMR) [3,4,5]. However, esophageal ESD is considered more complex, and the complication rate is higher than that for gastric ESD [6,7]. Once the muscle layer is exposed during esophageal ESD, the risk of perforation or severe mediastinal emphysema increases because of anatomical characteristics, such as a thinner wall without serosa [8]. The incidence of perforation in the esophagus has been reported to be 1.4% to 5.2% [9,10], which is generally higher than that in the stomach [6,7]. In case of a severe perforation that is uncontrollable by conserva-

tive therapy, emergency surgery such as esophagectomy is required to resolve it. However, the mortality rate for esophagectomy in esophageal perforation was reported to be 24% [11].

In 2002, Oyama et al. reported a novel endoscopic treatment, which was later named ESD, using a Hook knife (Olympus Medical Systems Co., Tokyo, Japan) in Japan [12]. ESD-related devices have been developed one after another, such as the Flush knife (FUJIFILM Co., Tokyo, Japan), Dual knife (Olympus), and IT knife-nano (Olympus), all of which are categorized as tip cutting knives [6]. Moreover, two scissor-type devices, a clutch cutter (FUJIFILM) and a stag beetle knife (SB knife) (Sumitomo Bakelite, Tokyo, Japan), were commercialized. These electric devices can cut tissues after the operator has precisely grasped the target part, thereby preventing accidental cutting or tissue damage. Therefore, a high en bloc resection rate and increased safety have been reported for esophageal ESD [13, 14, 15] as well as gastric and colorectal ESD [16, 17, 18, 19].

It has been more than 20 years since the first device was commercialized. There are various devices available for esophageal ESD. However, the best device for esophageal ESD has not yet been determined. To date, there have been two reports in which tip-type and scissor-type devices were compared [13, 14]. In Japan, several devices have been utilized, depending on the preference of each endoscopist or each training institution. Nevertheless, the treatment outcome, such as procedure time, en bloc resection, and complication rate, seems to stabilize depending on experience with each device. In our institution, esophageal ESD had been performed with only tip-type knives, mainly Dual knife, by June 2018. The SB knife short type (hereafter called the SB-short knife) was introduced in July 2018. The length of the scissors is 6 mm in the SB-short knife, which is 1 mm shorter than the SB knife standard type. The SB-short knife was exclusively used for submucosal dissection in combination with a tip-type knife, with which circumference incision was performed. To clarify the characteristics of the SB knife, we compared the treatment outcomes of esophageal ESD with a tip-type knife to those with an SB-short knife combination.

Patients and methods

Study design

A total of 182 consecutive patients with esophageal neoplasms underwent ESD between January 2016 and March 2023 at the Fujita Health University Hospital. After excluding four patients because the procedure time was not written precisely in the medical records, we included 178 patients with 197 lesions in this retrospective study. Between January 2016 and June 2018, esophageal ESD had been performed exclusively with tip-type knives. After introducing the SB-short knife in July 2018, the submucosal dissection was performed tip-type or SB-short knife between July 2018 and March 2023. Each endoscopist selected the knife they used during this period, depending on their personal preference.

To compare treatment outcomes of esophageal ESD with a tip-type knife to those with an SB-short knife combination, every ESD was assigned to the tip-type or SB group based on the devices with which the submucosa was initially dissected. If an SB-short knife was used as a rescue device for a patient in an unexpected situation, we allocated the case to the tip-type group because the operator initially tried to perform ESD only with the tip-type knife. The main items evaluated in this comparative study were procedure time, en bloc resection rate, incidence of complications, and variation in procedure time. In addition, risk factors for muscle exposure were extracted by multivariate analysis. This study was performed according to Declaration of Helsinki guidelines. Written informed consent for ESD was obtained from all the patients, and the Ethics Committee of Fujita University approved this clinical observational study. Patients could withdraw from the study via the opt-out method provided on the hospital website.

Indications for esophageal ESD

The indications for ESD were determined by clinical depth of neoplasms based on the criteria from the Japanese Esophageal Association established in 2015 and 2019 [20, 21]. For squamous cell carcinoma, an indication was neoplasm within the epithelium or lamina propria. A relative indication was location within MM or SM1. For Barret's adenocarcinoma, an absolute indication was neoplasm within M. A relative indication was location within SM1. Neoplasms deeper than SM1 were sometimes treated after full consideration of both the necessity and curability of the procedure, given a patient's condition.

Terminology definitions

An endoscopist who performed no more than 50 esophageal ESD procedures was defined as a trainee, and one who performed more than 50 esophageal ESD procedures was defined as an expert. En bloc resection meant that the lesion was resected in one piece. Complete en bloc resection was defined as resection of a neoplasm with free horizontal and vertical margins. Curative resection was complete en bloc resection of a neoplasm confined to the mucosal layer without pathologically confirmed lymphatic or vascular infiltrations.

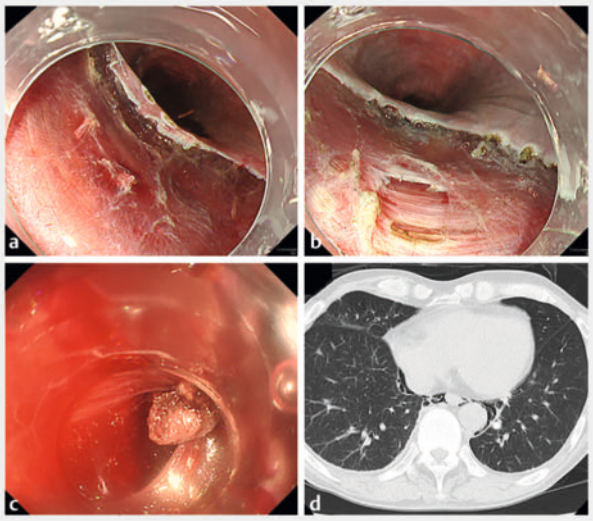
Endoscopic submucosal dissection procedure

We used a specific endoscope for therapy (GIF-Q260J or H290T; Olympus, Tokyo, Japan) and a high-frequency power supply unit (VIO300D or VIO3; ERBE, Tübingen, Germany) for electrocoagulation and carbon dioxide insufflation. Esophageal ESD was performed under conscious sedation using dexmedetomidine, midazolam, and pentazocine. After observation of the neoplasm with iodine spraying chromoendoscopy, circumferential makings were created 2 mm outside of the neoplasm. Then, 10% glycerin solution mixed with sodium hyaluronate (MucoUp; Boston Scientific, Tokyo, Japan) was injected into the submucosal layer. We incised the mucosal layer around markings circumferentially using a Dual knife (KD-650L, Olympus Medical Systems Co. Tokyo. Japan) or Flush knife BT1.5 (DK2620, FUJIFILM Co. Tokyo. Japan). In the tip-type group, submucosal dissection was performed with the same knife to complete the ESD treatment. In the SB group, submucosal dissection was planned to be performed with an SB-short knife (Sumitomo Bakelite Co., Ltd, Tokyo, Japan). In both groups, if

▶ **Table 1** Clinical characteristics.

	Tip-type group (n = 88 pts) 98 lesions	SB group (n = 90 pts) 99 lesions	*P* value
Age, y, median, range	69.5 (41–88)	70 (18–92)	0.862
Sex			0.280
▪ Male	71	78	
▪ Female	17	12	
Maximum diameter of resected specimen (mm), median, range	26.5 (12–53)	30 (10–60)	0.001
Location			0.13
▪ Ce	4	2	
▪ Ut	14	13	
▪ Mt	54	61	
▪ Lt	12	13	
▪ Ae	14	5	
Gross type			0.461
▪ 0-I	7	5	
▪ 0-IIa	21	14	
▪ 0-IIb	65	75	
▪ 0-IIc	3	2	
▪ 0-IIa + IIc	1	3	
▪ SEL	1	0	
Pathological diagnosis	n = 96	n = 99	0.004
▪ SCC	77	94	
▪ tub1	11	4	
▪ tub2	2	1	
▪ Others	7	0	
Invasion depth	n = 90	n = 99	0.028
▪ EP	23	17	
▪ SMM	2	1	
▪ LPM	52	63	
▪ MM (DMM)	8	8	
▪ SM1	1	5	
▪ SM2	4	5	
Endoscopist			0.010
▪ trainee	22	39	
▪ expert	76	60	
Tip-type device			
▪ Dual knife	71	73	0.838
▪ Flush knife BT1.5	27	26	
▪ SB-short knife	7	99	<0.001
▪ Traction device	2	15	0.003

SB, stag beetle; Ce, cervical esophagus; Ut, upper thoracic esophagus; Mt, middle thoracic esophagus; Lt, lower thoracic esophagus; Ae, abdominal esophagus; SEL, subepithelial lesion; tub1, well differentiated adenocarcinoma; tub2, moderately differentiated adenocarcinoma; EP, epithelium; SMM, superficial muscularis mucosa; LPM, lamina propria mucosa; MM, muscularis mucosa; DMM, deep muscularis mucosa; SM1, submucosa (submucosal invasion depth <200 µm; SM2, submucosa (submucosal invasion depth ≥200 µm.



▶ **Fig. 1** Representative **a**-**c** endoscopy and **d** CT images. **a** No exposure of the muscle layer. **b** Muscular exposure. **c** Perforation. **d** Pneumomediastinum after muscle exposure.

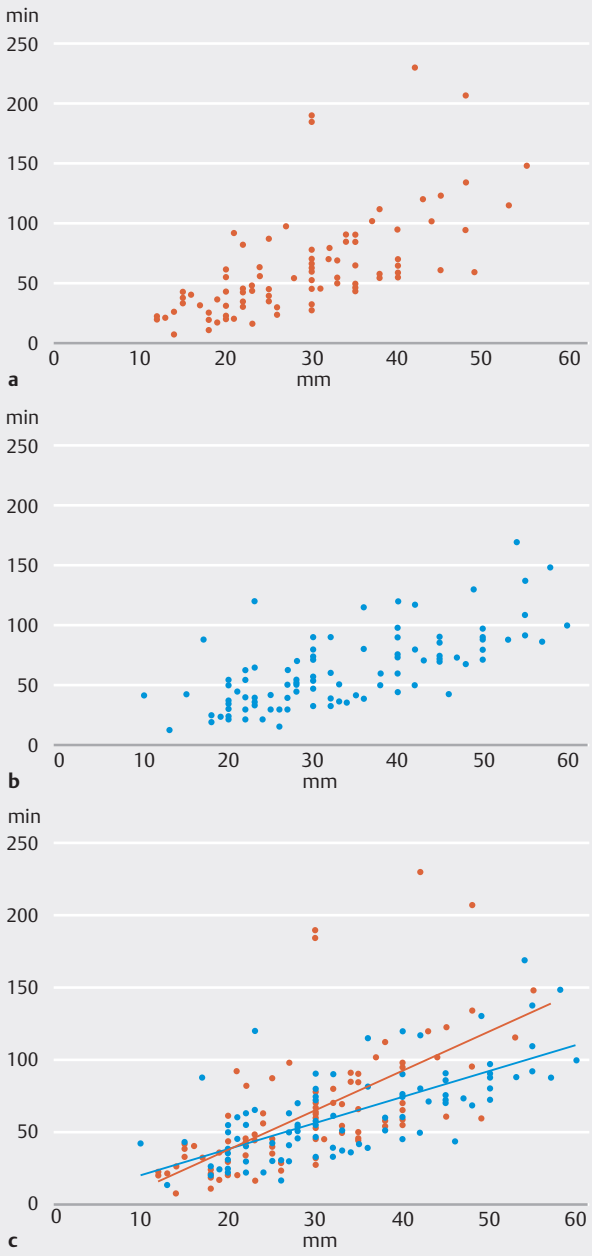
it was difficult to stop bleeding with the conventional knife, hemostasis forceps (Coagrasper; Olympus Medical Systems Co., Tokyo, Japan) were used for hemostasis. A traction device was sometimes used for difficult situations or large lesions. Since 2021, Endo Track C type (Top Corporation, Tokyo, Japan) has been exclusively utilized. If an SB-short knife was used in an unscheduled situation, we counted it in the tip-type group. If the muscle was exposed to a wide area during submucosal dissection, it was closed by clips as much as possible, and prophylactic antibiotics were injected intravenously for a few days (▶ **Fig. 1**). When perforation occurred, if clip closure was successfully performed, we treated it conservatively. If not, emergency surgical treatment was performed.

Statistical analysis

SPSS Statistics software (version 25.0; IBM Japan Ltd., Tokyo, Japan) was used for all analyses. Variables with P <0.05 on univariate analyses were subjected to multivariate logistic regression analyses. Other significant differences were analyzed using the chi-square test, Fisher's exact test, F test or Mann–Whitney U test. Statistical significance was set at P <0.05.

Results

In this retrospective study, 98 lesions in 88 patients were dissected in the submucosa of the esophagus with a tip-type device (tip-type group), and 99 lesions in 90 patients were dissected with an SB-short knife (SB group). Seven lesions in the tip-type group were also dissected with an SB-short knife as a rescue device. ▶ **Table 1** lists clinical characteristics of the patients and lesions. The maximum diameter of the resected specimens was larger in the SB group. The endoscopists (trainee or expert) were significantly different in the two groups. The use of traction devices was more common in the latter period (most often in the SB group). ESD outcomes are shown in ▶ **Table 2**. The procedure time was 51.5 minutes (7–230) in the tip-type group and 55.0 minutes (13–169) in the SB group. The two groups had no significant difference in procedure time or resection rate. On the other hand, there was a significant difference in



▶ **Fig. 2** **a** Scatter plot of the relationships between procedure time and resected lesion size in the tip-type group. The X- and Y-axes represent the resected lesion size and procedure time, respectively. **b** Scatter plot of the relationships between procedure time and resected lesion size in the SB group. **c** Scatter plots of **Fig. 2a** and **Fig. 2b**. The approximate line formula was y = 2.74x-17.20 in the tip-type group (orange dots) and y = 1.81x + 2.16 in the SB group (blue dots).

▶ **Table 2** ESD outcomes.

		Tip-type group (n = 88 pts) 98 lesions	SB group (n = 90 pts) 99 lesions	*P* value
Procedure time	Median (range)	51.5 (7–230)	55.0 (13–169)	0.610
	Mean SD	60.3±42.2	62.3±30.7	0.778
Resection	en bloc	96/98 (98.0%)	99/99 (100%)	0.472
	Complete en bloc	88/91 (96.7%)	94/99 (94.9%)	0.810
	Curative	82/91 (90.1%)	85/99 (85.9%)	0.499
Complications	Muscular exposure	24 (24.5%)	11 (11.1%)	0.016
	Perforation	2 (2%)	1(1%)	0.621
	Post-ESD bleeding	0	0	-

ESD, endoscopic submucosal dissection; SD, standard deviation.

▶ **Table 3** ESD result stratified by resected lesion size.

≤21 mm		Tip-type group 30 lesions	SB group 17 lesions	*P* value
Procedure time	Median (range)	25 (7–92)	35 (13–88)	0.088
	Mean SD	31.1±17.7	38.1±18.3	0.205
Complications	Muscular exposure	4 (13.3%)	0	0.281
	Perforation	0	0	–
	Post-ESD bleeding	0	0	–
>21 mm		**Tip-type group 66 lesions**	**SB group 82 lesions**	***P value***
Procedure time	Median (range)	61.5 (16–230)	63 (16–169)	0.355
	Mean SD	73.5±43.5	67.4±30.5	0.098
Complications	Muscular exposure	20 (30.3%)	11(13.4%)	0.025
	Perforation	2 (3.0%)	1 (1.3%)	0.590
	Post-ESD bleeding	0	0	–

ESD, endoscopic submucosal dissection; SB, stag beetle; SD, standard deviation.

variation in procedure time according to the F test ($P = 0.002$). Regarding complications, the incidence of muscle exposure was significantly lower in the SB group than in the tip-type group (24.5% vs. 11.1%, $P = 0.016$). Two cases of perforation occurred in the tip-type group. One patient underwent an emergent esophagectomy. Another was treated conservatively. Only one micro perforation occurred in the SB group. It was closed with clips and treated conservatively. No post-ESD bleeding occurred in either group.

To ESD data from every individual in the analysis of the relationship between the resected lesion size and procedure time, we plotted each maximum diameter as the X coordinate and the procedure time as the Y coordinate in the scatter plot. The tip-type group is shown in ▶ **Fig. 2a**, the SB group is shown in ▶ **Fig. 2b**, and ▶ **Fig. 2c** shows the two groups combined. The number of outliers decreased in the SB group. The approximate line formula was $y = 2.74x - 17.20$ in the tip-type group and $y = 1.81x + 2.16$ in the SB group. In addition, both straight lines intersect at the resected lesion diameter of 21 mm, suggesting that the procedure time may be shorter in the SB group than in the tip-type group if the resected lesion diameter is over 21 mm.

Based on the scatter plot analysis, we performed a subsequent analysis stratified by size (≤21 mm vs. >21 mm). As shown in ▶ **Table 3**, the mean procedure time between the tip-type and SB groups was not significantly different in the >21 mm or ≤21 mm groups (31.1 min vs. 38.1 min). In addition, there was no significant difference in the ≥21 mm group (73.5 min vs. 67.4 min). The complication of muscle exposure in the tip-type group was significantly more common in the >21 mm

▶ **Table 4** Univariate and multivariate analysis regarding muscle exposure.

		Univariate analysis			Multivariate analysis		
		OR	95% CI	*P* value	OR	95% CI	*P* value
Age (y)	≥75	1.23	0.54–2.75	0.62			
Sex	F	0.59	0.19–1.81	0.36			
Gross type	elevated	1.42	0.40–5.08	0.59			
Location	Mt	0.92	0.44–1.94	0.83			
Resected lesion size (mm)	>21	0.94	0.85–1.04	0.19			
Procedure time (min)	≥60	2.37	1.11–5.07	0.03	2.88	1.30–6.45	0.01
Invasion depth	SM	1.41	0.30–6.56	0.66			
Pathological diagnosis	Non-SCC	0.16	0.21–1.23	0.08	–	–	0.99
Endoscopist experience	Trainee	0.87	0.39–1.95	0.74			
Dissection device	SB-short knife	0.385	0.18–0.84	0.02	0.29	0.13–0.68	0.004
Traction device	+	1.94	0.46–8.86	0.39			

ESD, endoscopic submucosal dissection; OR, odds ratio; CI, confidence interval; Mt, middle

group than in the SB group. Variation in procedure time, which was evaluated using the F test, was not significant different in the ≤21 mm ($P=0.841$) but there was a significant difference in the 21 mm group ($P=0.002$) (Supplementary Fig. 1).

In the SB group, the traction device was used for 15 of 99 lesions. We evaluated whether the traction device affected procedure time or variation in it (Supplementary Table 1). The F test of the procedure time was 0.562, which means there was no significant difference in variation between the presence or absence of the traction device. That is, the traction device would not influence our result that the SB group had statistically less variation in procedure time. Univariate and multivariate analyses regarding muscle exposure showed that a procedure time >60 minutes was a significant risk factor (odds ratio [OR] 2.5, 95% confidence interval [CI]: 1.15–5.42, $P=0.02$), and submucosal dissection with SB was a safety factor (OR 0.4, 95% CI: 0.18–0.89, $P=0.02$) (▶ **Table 4**).

Discussion

The SB group, in which submucosal dissection was performed using an SB knife short type, had a lower incidence of muscle exposure during esophageal ESD than the tip-type group (11.1% and 24.5%, respectively, $P=0.016$). Although there was no difference in procedure time between the two groups, there was statistically less variation in procedure time in the SB group (62.3±30.7 min) than in the tip-type group (60.3±42.2 min) (F test, $P=0.002$). In particular, variation in procedure time was statistically small for resection of specimens >21 mm. Multivariate analysis revealed that procedure time (within 60 minutes) and dissection with an SB knife prevented muscle damage during esophageal ESD. In other words, an ESD with an SB knife should cause less muscle exposure and less variation in procedure time.

The merits of a scissors-type knife for ESD have often been discussed from a theoretical or empirical point of view [22]. For instance, it is harder to injure or perforate the esophageal wall because the electric device only cuts the part where the scissors pinch. It is unlikely that the muscle layer will be damaged if the submucosal layer is precisely grasped at a safe distance away from the muscle layer. In the present study, we confirmed stability in esophageal ESD using an SB knife with less variation in procedure time and less muscle exposure. Akahoshi et al. reported the advantage of a scissors-type knife for training and safety [13]. ESD experts can teach trainee endoscopists where or how to grasp the tissue before cutting to prevent inadequate cutting. This step is very useful for ESD training. In our study, the incidence of muscle exposure was lower in the SB group, even though more trainees performed ESD in this group. Maeda et al. reported that muscle exposure was an independent risk factor for severe mediastinal emphysema, followed by a high or long-lasting fever [8]. In our study, muscle exposure was considerably reduced in the SB group, as expected. Of note, muscle exposure was associated with inflammation, such as high levels of C-reactive protein and pain after ESD (Supplementary Table 2).

There have been two comparative studies of scissor-type devices thus far. In 2014, Fujinami et al. reported that esophageal ESD with an SB knife had a significantly shorter operative time and fewer complications than esophageal ESD with a Hook knife [14]. In 2020, using propensity score matching, Esaki et al. compared 36 procedures performed with a clutch cutter and 36 procedures performed with non-scissors-type knives [23]. However, there are two differences between our study and the previous studies. The first difference is the entire procedure method for esophageal ESD. In previous studies, ESD was performed exclusively via submucosal dissection with a scissor-type knife through a circumferential incision. However,

we performed ESD with an SB-short knife in combination with a tip-type knife. Specifically, the circumference incision was made using a tip-type knife because a scissor-type knife made the incision line dull by heat denaturation. The second difference is the shorter procedure time in previous studies. The procedure time was not shortened in the present study, but the variation in procedure time was significantly less in the SB group. In particular, the SB group had less variation in procedure time in resection of specimens > 21 mm. This indicates that ESD with scissor-type devices would be a better treatment for resection of large lesions without increasing complications. We think the reason why the SB group did not have a shortened procedure time is as follows. The average procedure time in the tip-type group was approximately 60 minutes, shorter than in other previous studies, even though the median resected specimen size was similar or larger. Because it has been 15 years since esophageal ESD was first established and proficiency with the procedure has been established, we speculate that there is little time to shorten the procedure time. Therefore, we would like to emphasize the benefit of the scissor-type device in achieving a more stable ESD with less muscle exposure rather than a "faster ESD." In terms of medical economics, using two devices, like a Dual knife and an SB-short knife, which cost a total of $500, may be a problem. However, we believe the safer ESD overcomes this issue.

There are several limitations to this study. First, it was a single-institution, retrospective study. Second, esophageal ESD with the tip-type group was performed in an earlier period than the procedures with the SB group. Third, each endoscopist selected the ESD device they used based on their own preference, which could be related to selection bias. Fourth, the clinical characteristics, such as the composition of endoscopists and the use of traction devices, differed between the former and latter periods. However, the aim of this study was to clarify the benefits of using an SB knife, not to determine which was the superior device. Therefore, a comparative study of which device is superior may not be needed.

For safety, we believe it is vital for each endoscopist or institution to choose a device based on the procedure for which it is being used, so the current study informs the characteristics of an SB knife for esophageal ESD.

Conclusions

In conclusion, performing esophageal ESD with an SB knife is safe, reduces variation in procedure time, and reduces muscle exposure.

thoracic esophagus; SCC, squamous cell carcinoma; SB, stag beetle.

Conflict of Interest

The authors declare that they have no conflict of interest.

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