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Efficacy of the specialized scissor-type knife for gastric endoscopic submucosal dissection: a propensity score matched retrospective study

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ABSTRACT

Background and study aims Prevention of bleeding and perforation during gastric endoscopic submucosal dissection (ESD) is important. Scissor-type knives can accurately grasp and incise the targeted tissue using electrosurgical currents, thereby eliminating unexpected incisions. The SB Knife GX, a scissor-type knife specialized for gastric ESD, was released in June 2016 in Japan. The aim of the present study was to evaluate the efficacy and safety of gastric ESD using the SB Knife GX.

Patients and methods A total of 716 patients who underwent gastric ESD at Hiroshima University Hospital between July 2016 and December 2020 were retrospectively reviewed. From these, 671 patients underwent ESD using the IT Knife 2 (IT-2 group), while 45 underwent ESD using an SB Knife GX (SB-GX group). After propensity score matching, the procedure time, specimen size, en bloc and complete resection rates, and intraoperative bleeding, delayed bleeding, and perforation rates were evaluated.

Results No significant differences were observed in mean procedure time (SB-GX group: 115 ± 165 min; IT-2 group: 95 ± 61 min; P = 0.82) and en bloc and complete resection rates between the two groups. Intraoperative bleeding rates were significantly lower in the SB-GX group than in the IT-2 group (18 % vs. 40 %; P = 0.01), and there were no differences in delayed bleeding (4 % vs. 4 %) or perforation (0 % vs. 4 %) between the two groups.

Conclusions The SB Knife GX was proven to be useful for control of intraoperative bleeding during gastric ESD, although the procedure time tended to be longer.

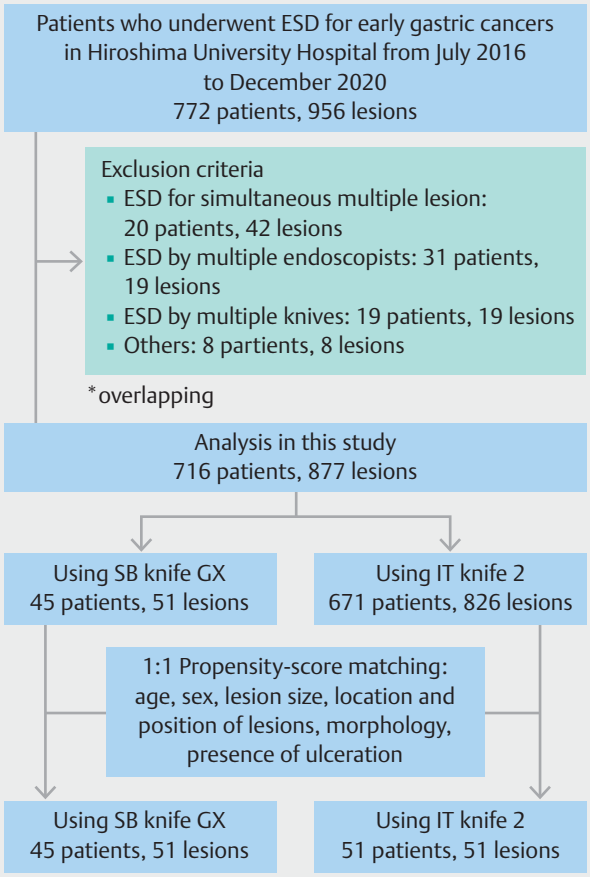
Introduction

Endoscopic submucosal dissection (ESD) was developed as an effective treatment for early gastric cancer and has been globally adopted [1–6]. Various endoknives have been developed to make the ESD procedure both easier and safer [7–12]; the most widely used endoknives for ESD are needle-type and insulated-tip knives [13–16]. The knives are used by simply placing the blade in contact with the submucosal tissue and applying an

electrosurgical current. However, these incisions are not fixed to the target tissue; thus, there is a possibility of inadvertent incisions due to the influence of heartbeat and breathing, which can lead to serious complications, such as perforation and bleeding. Scissor-type knives, therefore, have been developed for safe ESD [10, 11].

Scissors-type knives can grasp, fix, and compress the target tissue as during a biopsy, thereby reducing complications such as unintended tissue resection, perforation, and unexpected bleeding. In addition, a single device can perform precutting, incision, dissection, and hemostasis, which is expected to both simplify and shorten ESD. The SB Knife GX (MD-47701; Sumitomo Bakelite Co. Ltd, Tokyo, Japan) (▶ **Fig. 1**), a scissor-type knife specialized for gastric ESD, was released in Japan in June 2016; thus far, there are few reports regarding its usefulness in gastric ESD [17, 18]. Here, we compare the outcomes of gastric ESD using the SB Knife GX and IT Knife 2 (KD-611L; Olympus Corporation, Tokyo, Japan) to examine the usefulness of the SB Knife GX.

▶ **Fig. 1** SB Knife GX. A scissor-type knife specialized for gastric endoscopic submucosal dissection.



▶ **Fig. 2** Flowchart of patient selection. The IT-2 group included 671 patients with 826 lesions, while the SB-GX group included 45 patients with 51 lesions.

Patients and methods

Patients

Seven hundred seventy-two consecutive patients (956 gastric cancers) treated by ESD between July 2016 and December 2020 at Hiroshima University Hospital were enrolled; of these, 56 patients (79 lesions) were excluded. The exclusion criteria were as follows: ESD for simultaneous multiple lesions, ESD performed by multiple endoscopists, ESD performed using multiple knives, and others. In total, 716 patients (877 lesions) were included in this study and categorized into two groups: those who underwent ESD with the IT Knife 2 (IT-2 group) and those who underwent ESD with the SB Knife GX (SB-GX group). The IT-2 group included 671 patients (826 lesions), while the SB-GX group included 45 patients (51 lesions). A flowchart of the patients enrolled in this study is shown in ▶ **Fig. 2**. All patients were histologically diagnosed with gastric cancer and met the absolute or expanded indications for gastric treatment according to the Japanese guidelines [19, 20]. Device selection was left to operator preference.

Gastric ESD procedure

For the ESD procedure, both expert and nonexpert endoscopists were included; nonexpert endoscopists were defined as those who had performed fewer than 40 ESD procedures for early gastric cancer, according to previous reports [21–24]. There were no significant differences regarding the level of expertise of the surgeons between the two groups before or after propensity score matching.

ESD was performed under intravenous sedation with midazolam and pentazocine in the endoscopy unit; a single-channel endoscope (GIF-H260Z or GIF-Q260J; Olympus Corporation) with a standard-tip hood (Olympus Corporation) was used as previously described [25–28]. The local solution to the submucosa was a mixture of 0.4 % sodium hyaluronate (MucoUp; Boston Scientific Japan K.K., Tokyo, Japan) and 10 % glycerin solution, with a small amount of indigo carmine. A simple ESD procedure includes marking of dots approximately 5 mm outside the margin of the cancer, initial and circumferential incision of the mucosa outside the dots, and submucosal dissection.

The SB Knife GX is a scissor-type knife with a blade length of 6.0 mm, and an opening width of 7.5 mm (Supplementary Table 1) [29]. The blade is curved to prevent coagulation of the muscle layer, while the base of the knife has a serrated edge to

prevent the grasped tissue from slipping; the handle is also equipped with a rotation control unit that contributes to improved rotation. During the mucosal incision and submucosal dissection, the tissue was grabbed and lifted, briefly coagulated in the soft coagulation mode, and cut in the endoCUT I mode. When VIO3 is used, the mucosa or submucosa was coagulated shortly with soft coagulation mode (Effect5, 60 W), and cut in the endoCUT I mode (Effect 1, Cut duration 3, Cut interval 1). When VIO300 D is used, soft coagulation mode (Effect 4.0), and the endoCUT I mode (Effect 1, Cut duration 3, Cut interval 1) were employed.

The IT Knife 2 is a needle-type knife with an insulated tip and a triangular metal plate on its edge [30]. After the initial incision was made, full circumferential incision and submucosal dissection were performed using the endoCUT I or swift coagulation mode, as appropriate.

Bleeding from thin vessels was coagulated using the SB Knife GX or IT Knife 2, while bleeding from thick vessels was stopped using hemostatic forceps (Coagrasper, FD-410LR; Olympus Corporation).

Evaluation

Clinicopathological features, including sex, age, lesion size, lesion location, lesion position, morphology, histology, presence of ulceration, submucosal fibrosis, depth, and skill level of the surgeon, were matched between the two groups. The locations of the lesions were classified into upper, middle, and lower thirds of the stomach, while the positions were categorized based on their location in the anterior wall, posterior wall, lesser curvature, or greater curvature [31].

Procedure time, en bloc resection rate, complete resection rate, specimen size, intraoperative bleeding and adverse events (delayed bleeding, and perforation) were compared between the two groups. The total procedure time was defined as the duration from creation of the mucosal incision to completion of submucosal dissection. En bloc resection was defined as removal of the entire tumor as a whole. Complete resection was defined as en bloc resection with no tumor cells present in the lateral and vertical margins. Intraoperative bleeding was defined as poorly controlled bleeding that required multiple coagulations (≥10 times), as previously reported [27]. Delayed bleeding was defined as clinical bleeding after ESD requiring endoscopic or surgical intervention [32]. Perforation was diagnosed when mesenteric fat or the intra-abdominal space was observed during the procedure, or when free air was identified on simple chest and abdominal radiographs after ESD.

Propensity scores were calculated using a logistic regression model; the variables included were sex, age, lesion size, lesion location, lesion position, morphology, and presence of ulceration. After the propensity scores were estimated, one-to-one nearest neighbor matching was performed using a caliper set to 0.2.

This study was performed in accordance with the Declaration of Helsinki and its later amendments. Use of patient data for the purpose of this study was approved by the Institutional Review Board of Hiroshima University (No. E-1237-1). Because of the retrospective design, the need for patient consent was waived.

Statistical analysis

Quantitative data are shown as mean ± standard deviation or percentage and compared using Pearson's Chi-squared test, Fisher's exact test, or Wilcoxon's rank test; continuous variables were analyzed using Student's *t*-test. Statistical significance was set at $P<0.05$. We used propensity score matching analysis to adjust for significant differences in the baseline clinical characteristics of patients, as well as to reduce the influence of possible confounding factors. All statistical analyses were performed using JMP statistical software (version 15.0; SAS Institute Inc., North Carolina, United States).

Results

Clinicopathological characteristics of patients

The clinicopathological characteristics before propensity score matching are shown in ▶ **Table 1**, while the clinicopathological characteristics of the 51 pairs matched by propensity score matching are shown in ▶ **Table 2**. The rate of severe submucosal fibrosis and pT1b2 was significantly higher in the SB-GX group than in the IT-2 group (26 % vs. 4 % and 14 % vs. 2 %, respectively). There were no significant differences in other factors between the two groups.

Treatment outcomes

The treatment outcomes before and after propensity score matching are shown in Supplementary Table 2 and ▶ **Table 3**. After propensity score matching, there were no significant differences in procedure time, en bloc resection rate, complete resection rate, or specimen size between the two groups. The rate of intraoperative bleeding was significantly higher in the IT-2 group (40 %) than in the SB-GX group (18 %). The rate of delayed bleeding was not significantly different between the two groups. Regarding perforation, there were no significant differences between the two groups; however, it is worth noting that no perforation occurred in the SB-GX group.

Discussion

This is the first study to evaluate the efficacy and safety of the SB Knife GX for gastric ESD. Our data revealed that the SB Knife GX was superior to the IT Knife 2 for control of intraoperative bleeding during gastric ESD. ESD devices can be divided into three categories: blade-type knives (IT Knife, IT Knife 2, and Mucosectome), needle-type knives (DualKnife, Flush Knife, etc.), and scissor-type knifes (Clutch Cutter [CC], SB Knife GX, etc.). Various reports have compared the results of ESD for gastrointestinal tumors between these three types of knives [30, 33–36]; however, there are only a few reports regarding the usefulness of the SB Knife GX during gastric ESD. Sumida et al. [17] reported that the SB Knife GX was used to perform en bloc resection of the gastric hilum in early gastric cancer, as well as to stop bleeding during ESD. Kanazawa et al. [18] retrospectively compared outcomes with the SB Knife GX and DualKnife,

▶ **Table 1** Baseline characteristics of patients undergoing gastric ESD for early gastric cancers.

Characteristics	SB knife GX n = 51	IT knife 2 n = 826	*P* value
Sex, male/female	39 (76)/12 (24)	610 (74)/216 (26)	0.68
Age, mean ± SD, years	69 ± 12.1	72 ± 9.1	0.18
Lesion size, mean ± SD, mm	19.1 ± 11.8	14.1 ± 10.2	0.0004
Location of lesions			< 0.0004
▪ Upper	15 (29)	125 (15)	
▪ Middle	23 (45)	230 (28)	
▪ Lower	13 (26)	471 (57)	
Position of lesions			< 0.0001
▪ Lesser curvature	9 (18)	375 (46)	
▪ Greater curvature	30 (59)	201 (24)	
▪ Anterior wall	2 (4)	117 (14)	
▪ Posterior wall	10 (19)	133 (16)	
Morphology			0.99
▪ Elevated (0-I, 0-IIa)	16 (31)	291 (35)	
▪ Depressed (0-IIb, 0-IIc, 0-III)	34 (67)	519 (63)	
▪ Mixed (0-IIa + IIc, 0-IIc + IIa)	1 (2)	16 (2)	
Histology			0.012
▪ Differentiated adenocarcinoma	43 (84)	780 (94)	
▪ Undifferentiated adenocarcinoma	8 (16)	46 (6)	
Presence of ulceration	9 (18)	50 (6)	0.0061
Submucosal fibrosis			< 0.0001
▪ Mild	39 (76)	788 (95)	
▪ Severe	12 (24)	38 (5)	
Depth			0.0034
▪ pT1a	39 (76)	757 (92)	
▪ pT1b1	5 (10)	42 (5)	
▪ pT1b2	7 (14)	27 (3)	
Skill level			0.63
▪ No. of experts	3	3	
▪ No. of non-experts	6	13	
With traction method	36 (71)	474 (57)	0.042

ESD, endoscopic submucosal dissection; SD, standard deviation; pT1a, intramucosal cancer; pT1b1, submucosal invasive cancer, invasion depth ≤ 500 µm; pT1b2, submucosal invasive cancer, invasion depth > 500 µm.

reporting that procedure time tended to be shorter in the SB-GX group.

During ESD, control of complications is important, as is a high resection rate. Reduced intraoperative bleeding provides better visualization of the submucosal layer, allowing the operator to complete gastric ESD without stress, thereby improving ESD performance [37–39]. Akahoshi et al. [40] reported that in most cases of gastric ESD, hemostasis was achieved using the CC alone; the rate of massive intraoperative bleeding was 0 %. Dohi et al. [34] compared the CC with the IT Knife 2, reporting that in gastric ESD, use of the CC resulted in a lower rate of severe bleeding requiring hemostasis. In contrast, Nagai et al. [30] reported that the median number of intraoperative bleeding cases requiring the use of hot biopsy forceps during

▶ **Table 2** Clinicopathological characteristics of patients after propensity score matching.

Characteristics	SB knife GX n = 51	IT knife 2 n = 51	*P* value
Sex, male/female	39 (76)/12 (24)	42 (82)/9 (18)	0.46
Age, mean ± SD, years	69 ± 12.1	68 ± 11.1	0.48
Lesion size, mean ± SD, mm	19.1 ± 11.8	20.5 ± 15.7	0.95
Location of lesions			0.87
▪ Upper	15 (29)	13 (25)	
▪ Middle	23 (45)	23 (45)	
▪ Lower	13 (26)	15 (30)	
Position of lesions			0.93
▪ Lesser curvature	9 (18)	9 (18)	
▪ Greater curvature	30 (59)	31 (61)	
▪ Anterior wall	2 (4)	3 (6)	
▪ Posterior wall	10 (19)	8 (15)	
Morphology			1.00
▪ Elevated (0-I, 0-IIa)	16 (31)	14 (38)	
▪ Depressed (0-IIb, 0-IIc, 0-III)	34 (67)	36 (60)	
▪ Mixed (0-IIa + IIc, 0-IIc + IIa)	1 (2)	1 (2)	
Histology			0.37
▪ Differentiated adenocarcinoma	43 (84)	46 (90)	
▪ Undifferentiated adenocarcinoma	8 (16)	5 (10)	
Presence of ulceration	9 (18)	3 (6)	0.06
Submucosal fibrosis			0.001
▪ Mild	39 (76)	49 (96)	
▪ Severe	12 (24)	2 (4)	
Depth			0.03
▪ pT1a	39 (76)	48 (94)	
▪ pT1b1	5 (10)	2 (4)	
▪ pT1b2	7 (14)	1 (2)	
Skill level			0.64
▪ No of expert	3	3	
▪ No of non-expert	6	11	
With traction method	36 (59)	34 (67)	0.42

ESD, endoscopic submucosal dissection; SD, standard deviation; pT1a, intramucosal cancer; pT1b1, submucosal invasive cancer, invasion depth ≤ 500 µm; pT1b2, submucosal invasive cancer, invasion depth > 500 µm.

gastric ESD was lower in the IT-2 group than in the CC group; however, this difference was not significant (1 vs. 2, $P = 0.053$). In addition, scissor-type knives are also reported to be useful for bleeding control during ESD of the esophagus and colon [36, 41].

Excessive intraoperative bleeding increases the procedure time, decreases the completion rate of gastric ESD, and affects perforation and postoperative bleeding rates [21, 27]. In addition, lesions in the gastric body exhibit a higher frequency of bleeding due to the abundance of fibrous tissue and blood vessels in the submucosa, as well as a larger diameter of blood vessels in the gastric body than of blood vessels in the antrum [42, 43]. Moreover, it is difficult to control bleeding in patients taking antithrombotic drugs or with concomitant disease [27, 44,

▶ **Table 3** Treatment outcomes of patients undergoing gastric ESD after propensity score matching.

Outcomes	SB knife GX n = 51	IT knife 2 n = 51	*P* value
Procedure time, mean ± SD, min	115 ± 165	95 ± 61	0.82
En bloc resection	51 (100)	51 (100)	NA
Complete resection	50 (98)	51 (100)	0.24
Specimen size, mean ± SD, mm	42.0 ± 14.8	42.8 ± 17.5	0.76
Intraoperative bleeding	9 (18)	20 (40)	0.01
Adverse event			
▪ Delayed bleeding	2 (4)	2 (4)	1.00
▪ Perforation	0 (0)	2 (4)	0.09

ESD, endoscopic submucosal dissection; SD, standard deviation.

45]. The most noteworthy aspect of this study was that the SB-GX group exhibited significantly less intraoperative bleeding than the IT-2 group, suggesting that the SB Knife GX may be useful for lesions and patients prone to bleeding. Good intraoperative bleeding control also reduces the use of hemostats, which may be significant in terms of cost-effectiveness of ESD. The SB-GX was useful in controlling intraoperative bleeding, but tended to increase treatment time. One reason may be that the scissors-type knife requires the processes of grasping, lifting, coagulation, and incision, whereas the blade-type IT-2 does not. The SB-GX group also had a higher percentage of pT1b cancers and submucosal fibrosis than the IT-2 group, which may have contributed to the longer treatment time. Regarding other complications, rates of delayed bleeding and perforation of the scissor-type knife during gastric ESD were both reported to be 0 % to 3.6 % [30, 34, 46, 47]. In our study, there was no difference in delayed bleeding (4 % in both groups); in addition, no perforation occurred in the SB-GX group. The SB Knife GX is used with the curved part of the scissors facing upward, and the entire body of the knife is insulated; thus, it may have been difficult for perforation to occur.

This study has some limitations. First, it was retrospective and performed at a single center. Second, a relatively small number of patients were evaluated, and although propensity score matching analysis was performed to reduce selection bias and other confounders, it was difficult to adjust for all potential confounders. Third, device selection was at operator judgment, and the criteria were unclear. Fourth, there may be some differences regarding the skills of the assistants when using the SB-GX.

Conclusions

In conclusion, the SB Knife GX was found to be superior for control of intraoperative bleeding, and it may be useful for gastric lesions and patients prone to bleeding, although the procedure time tended to be longer.

Competing interests

The authors declare that they have no conflict of interest.

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