

Acceptability of Hybrid Endoscopic Submucosal Dissection Using Multifunctional Snare for Small-sized Gastric Neoplasms: A Prospective Observational Study

Taiga Chiyo, Hideki Kobara, Noriko Nishiyama, Kaho Nakatani, Naoya Tada, Kazuhiro Koduka, Takanori Matsui, Nobuya Kobayashi, Shintaro Fujihara, Tatsuo Yachida, Tsutomu Masaki

Kagawa University, Faculty of Medicine, Department of Gastroenterology and Neurology, Kagawa, Japan

Address for correspondence:

Hideki Kobara

Kagawa University, Faculty of Medicine, Department of Gastroenterology and Neurology, Kagawa, Japan
kobara.hideki@kagawa-u.ac.jp

ABSTRACT

Background & Aims: The most suitable procedure for resecting small-sized gastric neoplasms remains unclear. Endoscopic mucosal resection leads to non-curative resection owing to slippage of the snare, and technically difficult endoscopic submucosal dissection (ESD) is instrumentally uneconomical. A novel, cost-effective, multifunctional snare called SOUTEN is available as a hybrid ESD (h-ESD) device developed for facilitating ESD. This study aimed to assess the acceptability of h-ESD using the SOUTEN for resecting small-sized gastric neoplasms.

Methods: This was a prospective observational study conducted at our single institution between March 2019 and March 2021. Fifty-seven consecutive patients who underwent h-ESD using SOUTEN for small-sized gastric neoplasms ≤ 15 mm involving adenoma and tubular-type mucosal carcinoma without ulceration were enrolled. The primary outcome was curative resection rate for h-ESD. Secondary outcomes were the rates of conversion to ESD, rate of total (h-ESD + ESD) curative resection, procedure time, rates of intra- and post-operative complications, and presence of additional knives excluding hemostatic forceps.

Results: The curative resection rate of h-ESD was 89.5% (51/57). The total (h-ESD + ESD) curative resection rate was 94.7% (54/57). The mean procedure time was 21.2 (± 16.5) minutes. One case of delayed bleeding occurred. Additional knives were applied in two cases.

Conclusions: The cost-efficient h-ESD using SOUTEN can be an acceptable procedure for resecting small-sized gastric neoplasms.

Key words: hybrid endoscopic submucosal dissection – SOUTEN – ESD – gastric cancer – endoscopy.

Abbreviations: EMR: endoscopic mucosal resection; ER: endoscopic resection; ESD: endoscopic submucosal dissection; h-ESD: hybrid ESD.

INTRODUCTION

With advancements in endoscopic technology, the early diagnosis of gastric tumors has become possible, and the detection of small lesions is increasing. Endoscopic resection (ER), which is a minimally invasive treatment, is continually advancing; ER methods can be divided into endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), and hybrid ESD (h-ESD), in which snaring resection is performed after whole-circumferential incision

followed by submucosal trimming. The EMR method was the first ER technique to be developed. Gastric EMR is inexpensive and simple; however, the snaring with sufficient tumor margin is unsatisfactory because of its slippage, resulting in a low en bloc resection rate (50–70% compared with 90–95% for ESD) and local recurrence [1, 2].

A meta-analysis demonstrated that ESD generally had better en bloc resection rates than EMR [3]. In addition, it was reported that the en bloc resection rate of EMR was significantly lower than that of ESD when the tumor size exceeded 1 cm [4–6]. Local recurrence after gastric EMR at 5 and 10 years surveillance was reported to be 30%, with the main risk factor being cases with obscured horizontal margins in the pathology results [7]. Therefore, reliable en bloc resection procedure is desired even if it is a small sized gastric tumor.

Compared with EMR, gastric ESD enables more reliable en bloc resection, but perforation and intraoperative bleeding rates are higher in ESD, and the operation time is longer than

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that in EMR [3]. Moreover, the required devices are expensive, which poses an economic problem.

To overcome both the problems of piecemeal resections and resulting local recurrence rates in EMR and the technical complexity, accident rates, and long operative times in ESD, a new technique called h-ESD has recently been developed and initially introduced for the resection of colorectal tumors [8].

Compared with conventional EMR, the incision line can be determined more accurately, and the underlying layer can be dissected more quickly than with ESD, making it a technique that combines the advantages of both EMR and ESD. In recent years, SOUTEN (Kaneka Medics, Tokyo, Japan), a multifunctional snare developed specifically for h-ESD, has become available. The SOUTEN has a knob-like tip that can be used as an ESD scalpel when the tip is brought out to a small size and can also be used as a snare for lesion resection when the entire unit is expanded (Figs 1a, 1b). It is inexpensive, being approximately one-third the price of conventional ESD devices, and can solve the cost problem of ESD. Furthermore, in Japan, gastric ESD can be reimbursed by insurance programs when early-stage gastric carcinoma is resected as en bloc specimen of 3 cm or more. In other words, ESD is not approved for small tumors, due to an economical issue.

Therefore, for gastric tumors with a lesion diameter of 15 mm (resected with a margin of 5 mm around the lesion) and a resection diameter of 3 cm or less, the h-ESD method is preferable because it is safe, inexpensive, and can be used to easily perform en bloc resection with few complications. In our previous investigation, our colleague reported a first-ever case in which h-ESD using a SOUTEN was efficacious for resecting small gastric neoplasms [9]. However, detailed outcomes including location remain unclarified.

In this study, we investigated the usefulness of h-ESD using a SOUTEN snare for small gastric tumors less than 15 mm in size in a larger number of cases.

METHODS

Patients who underwent h-ESD for gastric adenoma or differentiated intramucosal carcinoma less than 15 mm in diameter and without ulcer at Kagawa University Hospital between March 2019 and March 2021 were prospectively enrolled. The inclusion criteria were adults aged ≥ 20 years and provision of written informed consent. The exclusion criteria were lesions with mixed or poorly differentiated carcinomas, submucosal (SM) invasion, severe scar, gastric adenocarcinoma

of the fundic gland type, and neuroendocrine tumor (NET), which were predicted by preoperative endoscopy examination and histologically confirmed by biopsy samples. Lesion size was measured against the diameter of the endoscope tip hood.

The study was approved by the Clinical Ethics Committee of Kagawa University Hospital (Registration No.2018-190, approval date: 29/03/2018) in accordance with the Helsinki Declaration. The study was registered in the University Hospital Medical Network Clinical Trials Registry (Registration No. UMIN000034970, registration date: 21/11/2018). All patients provided written informed consent to undergo the procedures and participate in the study.

Outcomes

The primary endpoint was curative resection rate of h-ESD. A difficult snaring case due to unexpected poor submucosal lifting was rescued by conventional ESD (conversion to ESD rate). Secondary endpoints included procedure time, total (h-ESD + ESD) curative resection rate, use rate of knives other than a SOUTEN (excluding hemostats), intraoperative and postoperative perforation rate, intraoperative bleeding, and postoperative bleeding.

Definitions

The curative resection rate for h-ESD was defined as the percentage of all cases in which h-ESD was completed without conversion to conventional ESD and was deemed pathologically curative. The treatment time was from the start of the incision to the completion of the snaring resection. Pathological cure was defined as a differentiated intramucosal carcinoma with negative horizontal and vertical margins and negative lymphovascular invasion. For safety evaluation, intraoperative bleeding was defined as major bleeding that was difficult to control and could not be stopped within 5 minutes using hemostats or other devices. Postoperative bleeding was defined as hematemesis, melena, or a drop in hemoglobin of 2 g/dl or more requiring hemostasis.

Statistical Analysis

Simple descriptive statistics were used to state proportions and characteristics of the outcomes. Categorical variables were expressed as absolute and relative frequencies. Differences in continuous variables were examined by the Kruskal–Wallis test and the chi square test. A *p* value less than 0.05 was considered statistically significant. GraphPad Prism 9.2.0 was used to perform the statistical analysis. The required sample size was

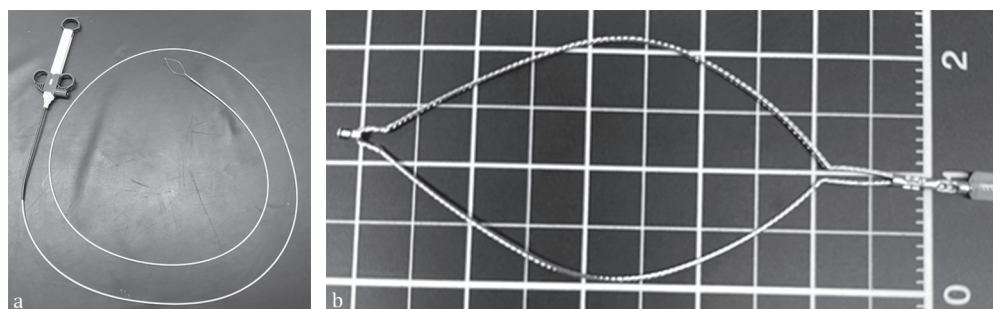


Fig. 1. a) SOUTEN snare; b) SOUTEN: a multifunctional snare with a 1.5mm needle knife of the snare tip.

determined using 95% power, alpha value of 0.05 (one-sided), and binomial test, with an expected en bloc resection rate of 70% for EMR and 90% for h-ESD, and a target sample size of at least 50 patients, assuming 5% ineligibility.

Procedure of h-ESD using SOUTEN

All patients were treated under sedation with propofol.

The h-ESD method using a SOUTEN was as follows: 1) the snare tip was protruded by 1.5 mm, and an area 5 mm outside the tumor was marked (Fig. 2a); 2) a mixture of half hyaluronic acid and half glycerol was injected to lift the submucosal layer of the lesion (Fig. 2b); 3) the 1.5 mm snare tip was used as a needle knife to incise and trim the entire circumference of the tumor (Figs. 2b, 2c); 4) the tip of the snare was inserted under the normal mucosa on the contralateral side where the entire circumference had been dissected and that point was used as a fulcrum to open the snare completely. A snaring resection of the entire lesion was performed along the line of excision. If snaring the lesion en bloc was difficult, the size of the lesion was reduced by performing submucosal dissection on the lesion side (Fig. 2d).

The high-frequency power unit (VIO3 [ERBE, Tübingen, Germany]) was set up as below: 1) marking: Forced Coag

0.8; 2) incision: Endo Cut I, effect 2, duration 4, interval 3; 3) submucosal dissection and snaring: Swift coag 4.8

Conventional ESD was performed when it was determined that the lesion could not be safely and appropriately incised and dissected around the lesion. Hemostatic forceps were used as appropriate for bleeding during the treatment. The procedure was performed by an endoscopist with more than 50 cases of gastric ESD experience.

RESULTS

During the 2-year study period, there were 71 cases of gastric tumors less than 15 mm in size. Fourteen cases that met the exclusion criteria were excluded, and 57 cases were finally included in the study (Fig. 3).

Forty-two patients (73%) were male, and the mean age was 75.0 ± 8.9 (standard deviation) years. The lesions were located in the upper stomach in 13 cases (23%), the middle stomach in 14 cases (25%), and the lower stomach in 30 cases (53%). The mean tumor diameter was 10.3 mm, and the mean resection diameter was 21.4 mm. Other details of antithrombotic therapy, dialysis, macroscopic type, and histological type are shown in Table I.

The curative resection rate for h-ESD was 89.5% (51/57). Of these, 100% (11/11) were for adenomas and 87% (40/46) were for adenocarcinomas. The details of the unsuccessful cases are shown below. Three cases were rescued after conversion to ESD because the submucosal lifting by injection was poor in the session before snaring. However, these cases were completed with ESD using only SOUTEN. There were also three pathologically non-curative cases: one had a positive horizontal margin, and two had an X horizontal margin. The positive horizontal margin was due to an error in range diagnosis; the actual lesion extended further outward.

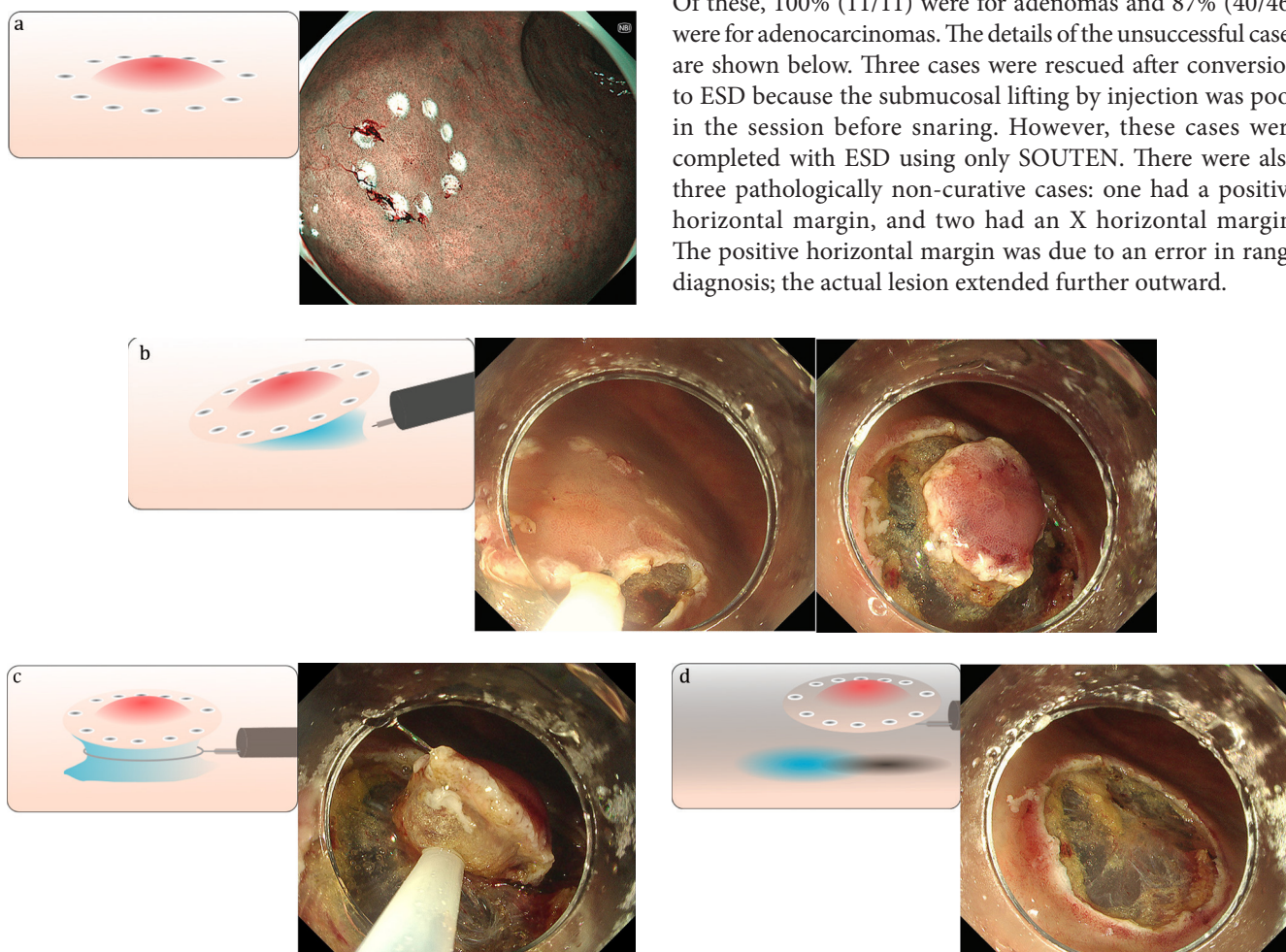


Fig. 2. h-ESD procedure: a) an area 5 mm outside the tumor was marked; b) a mixture of half hyaluronic acid and half glycerol was injected to swell the submucosal layer of the lesion and incised using the 1.5-mm snare tip as a needle knife; c, d) after performing the incision and trimming the entire circumference of the tumor, a snaring resection of the lesion along the line of excision was performed.

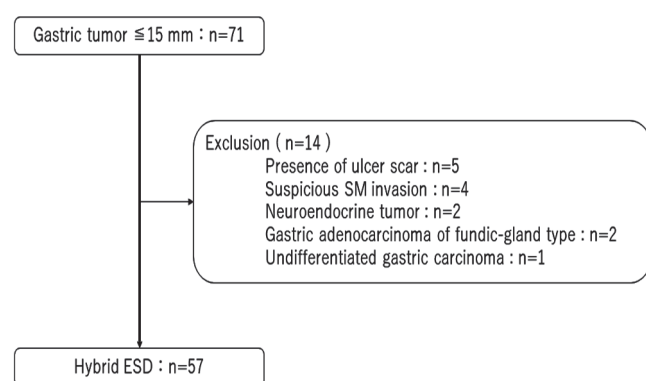


Fig. 3. Flow chart of enrolled patients.

Table I. Patient characteristics

Characteristic	n=57
Age, mean ($\pm$ SD)	75.0 ($\pm$ 8.9)
Sex (male/female)	42/15
Location, n (%)	
Upper	13 (23)
Middle	14 (25)
Lower	30 (53)
Macroscopic type, n (%)	
I	5 (9)
IIa	34 (60)
IIb	3(5)
IIc	15(26)
Use of antithrombotic drugs, n (%)	14(25)
Hemodialysis, n (%)	4(7)
Lesion diameter, mean ($\pm$ SD) (mm)	10.3 ($\pm$ 4.0)
Resection diameter, mean ($\pm$ SD) (mm)	21.4 ($\pm$ 5.4)
Histological type, n (%)	
Adenoma	10 (18)
Well-differentiated adenocarcinoma	47 (82)

SD: standard deviation.

In the two cases with a horizontal X edge, the burning effect of the circumferential incision affected the edge, resulting in an unknown margin.

As a secondary endpoint, the mean $\pm$ SD procedure time was 21.2 ± 16.5 minutes. The rates of conversion to ESD and total curative resection rate were 5.3% and 94.7% respectively.

Additional devices were required in two cases (IT knife 2™ was used). There were no perforations, and no intraoperative bleeding that was difficult to control was observed. Posterior bleeding was observed in one patient (1.8%). The results of each endpoint are summarized in Table II.

Table II. Results

Primary outcomes	n=57
Curative resection rate of h-ESD, n (%)	51 (89.5)
Secondary outcomes	
Procedure time, mean ($\pm$ SD) min	21.2 ($\pm$ 16.5)
Conversion to ESD, n (%)	3 (5.3)
Total (h-ESD + ESD) curative resection rate, n (%)	54 (94.7)
Use of additional device, n (%)	2 (3.5)
Rates of complications, n (%)	1 (1.8)
Perforation	0 (0)
Intraoperative bleeding	0 (0)
Postoperative bleeding	1 (1.8)

ESD: endoscopic submucosal resection; h-ESD: hybrid ESD; SD: standard deviation.

The characteristics and outcomes on each location of the stomach (upper, middle, lower stomach) were additionally analyzed (Table III). Although there was no significant difference, there was a trend toward shorter procedure times in the lower region of the stomach. There was no significant difference in the curative resection rate, conversion to ESD rate, or complication rate in each location.

DISCUSSION

To our knowledge, this is the first study to show the prospective outcomes of h-ESD using a SOUTEN for small gastric tumors. This study demonstrated that h-ESD for small gastric tumors ≤ 15 mm in diameter had favorable outcomes in terms of procedural completion rate, curative resection rate, complication rate, and operative time.

Conventional gastric EMR has a problem of an insufficient resection margin owing to slippage of the snare and high local recurrence rate (2,7). The h-ESD method, in which a peripheral incision and dissection similar to that in ESD are performed followed by snaring, allows for a planned and reliable margin. Furthermore, the submucosal layer can be removed in a short time using a snare, which is more time-efficient than

Table III. Characteristics and outcomes on each location of the stomach

Gastric location	Upper N=13	Middle N=14	Lower N=30,	p
Lesion diameter (mm)	8.5	11.1	10.7	0.254
Resection diameter (mm)	20.8	21.8	21.4	0.908
En bloc resection, n (%)	13 (100)	13 (92.9)	29 (96.7)	0.600
Conversion to ESD, n (%)	0 (0)	0 (0)	3 (10)	0.241
Curative resection of h-ESD, n (%)	12 (92.3)	13 (92.9)	26 (86.7)	0.766
Total (h-ESD + ESD) curative resection, n (%)	12 (92.3)	13 (92.9)	29 (96.7)	0.788
Procedure time (min)	26.8	21.4	18.4	0.096

For abbreviations see Table II.

conventional ESD [10, 11]. The h-ESD method can simplify such delicate submucosal dissection procedures, especially for lesions where the knife is perpendicular to the mucosa, which tends to be difficult to perform with conventional ESD owing to the high risk of perforation.

A retrospective comparison of 29 cases of h-ESD had a median procedure time of 20 minutes, compared with 40 minutes for the conventional method, indicating that h-ESD can be performed in a shorter time [10]. Although the study showed favorable outcomes with a 100% en bloc resection rate, there were issues in terms of a possible bias in the selection of lesions that were easily performed for h-ESD and sample size. In this study, we conducted a prospective observational study with a larger number of consecutive cases according to the inclusion/exclusion criteria to further validate the points to be considered in the application of h-ESD.

In this study, h-ESD for small gastric tumors using SOUTEN showed a curative resection rate of 89.5%, and a satisfactory curative resection rate of 94.7% for all cases combined (h-ESD + ESD conversion case). The average procedure time was 21.2 minutes. No perforation or intraoperative hemorrhage was observed, and postoperative hemorrhage occurred in 1.8% of cases, indicating that h-ESD has acceptable safety.

The SOUTEN can perform two roles; it can be used as a needle scalpel for incision and dissection of the peripheral area when it is retracted and as a snare for snaring and resection of lesions when it is expanded. The tip of the device has a knob-like shape that allows it to be used as a hook for cutting. The protruding length of the device may change as the endoscope moves; therefore, it is necessary to pay attention to the changes. The price of a SOUTEN is approximately 8,000 yen, which is roughly one-third the price of conventional ESD devices (20,000–40,000 yen), making it a device with excellent medical economic benefits.

Currently, h-ESD is already being introduced and widely used for colorectal tumors, where its efficacy has been demonstrated [8, 12, 13]. A recent meta-analysis comparing conventional ESD and h-ESD for colorectal tumors showed significantly shorter procedure times (mean difference 18.45 min; $p=0.003$) and lower complication rates but lower en bloc resection rates ($p < 0.001$) for h-ESD [13]. This suggests that it is important to determine the indications for h-ESD in the stomach to increase the en bloc resection rate and to improve the technique. The appropriate lesion diameter for h-ESD with a SOUTEN is ≤ 15 mm in diameter, with an expected margin of 5 mm around the lesion, and a maximum resection area of 25 mm in diameter. The SOUTEN snare width is 15 or 20 mm, and when pressed against the mucosa, it expands to a circular shape approximately 30 mm in diameter. Even when using an even larger snare other than SOUTEN, it may be technically difficult to apply larger h-ESD due to field of view and snaring difficulties. By sufficiently dissecting the surrounding area, the lesion size can be reduced to a smaller size and fit within the snare. The snare may not fit properly in narrow spaces, such as the cardia and pylorus, making it difficult to apply. In addition, because the submucosa cannot be seen during snaring, it is not indicated in cases where SM invasion or fibrosis of the submucosa is suspected, and it was excluded from this study.

Of the 57 cases reviewed in this study, h-ESD was discontinued in three cases and converted to conventional ESD. In all cases, the lesion diameter was approximately 15 mm in diameter, which is the limit of the indication, and the lesion did not fit into the snare at the stage of snaring after circumferential incision, resulting in prompt transition to ESD and curative resection. In this case, the SOUTEN alone was sufficient to complete the ESD and could be used as an ESD device. As described above, the h-ESD method using SOUTEN can be used to achieve a reliable en bloc resection by shifting to ESD flexibly according to the lesion site and size.

Of the 57 cases, one had a positive horizontal margin, and two had an X horizontal margin. The positive horizontal margin was due to an error in range diagnosis; the actual lesion extended further outward. h-ESD technique was not compromised. This case was subsequently treated surgically. In the two cases with a horizontal X edge, the burning effect of the circumferential incision affected the edge, resulting in an unknown margin. There were no residual lesions or recurrence in the follow-up. The problem is that h-ESD tends to have a narrow surgical margin because the difficulty of snaring increases as the resection area increases. As a result, a burning effect is caused in the lesion, making it difficult to evaluate horizontal margins. Therefore, h-ESD should be applied only to small lesions ≤ 15 mm with an appropriate margin of at least 5 mm around the lesion; if snaring is judged to be difficult, it is important to switch to conventional ESD.

In two cases, tissue was left behind at the margins after snaring resection. The remnant tissue was healthy mucosa at the margins, and although the lesions themselves were resected en bloc, this is an event that requires attention. In both cases, the remnant tissue was on the distal side of the scope, and it was thought to be caused by the difficulties with visibility during snaring. To prevent this, it is important to dissect the distal side sufficiently before snaring. It is also important to set an appropriate margin in case residual tissue is left behind.

In addition to the SOUTEN, additional devices were required in only two out of 57 cases, and it was possible to complete the procedure using the SOUTEN alone in most cases, thus realizing a low-cost treatment. Both cases were lesions in the U region. One of the cases was a bleeding lesion in the upper gastric lesser curvature, and an IT knife 2 (KD-611L, Olympus, Tokyo, Japan) was additionally used as an incision scalpel with high hemostatic capacity during full circumferential incision. In another case, the lesion was in the fornix and the risk of perforation using the SOUTEN tip knife was high owing to respiratory variability, therefore an IT knife 2 was used for full circumferential incision, and h-ESD was completed in both cases. The submucosal dissection of the fornix was difficult to perform, and as a result, h-ESD was able to reduce the difficulty relative to that with conventional ESD.

Our study has limitations. It was an observational study with a single arm. A prospective randomized control trial is required to establish h-ESD using a SOUTEN as a standard procedure. In order to ensure a certain level of safety, ESD trainees were excluded. Although h-ESD is not more difficult than conventional ESD because it can greatly shorten the process of submucosal dissection, whether h-ESD can be performed safely and efficiently by beginners needs to be examined in the future.

CONCLUSIONS

Overall, h-ESD with a SOUTEN is a safe and effective treatment for small gastric tumors. The SOUTEN is an inexpensive device that can be used alone for incisional dissection and snaring, and h-ESD with a SOUTEN is a cost-effective procedure.

Conflicts of interest: None to declare.

Authors' contribution: T.C. performed all data analysis and drafted the paper. H.K., N.N. supervised the study and structured the paper. K.N., N.T., K.K., T.M. collected and analyzed the data. N.K., S.F., T.Y. assisted in figures' creation and statistical analysis. T.M. proofread the paper. All the authors read and approved the final version of the manuscript.

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