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Original Article

Novel quantitative assessment indicators for efficiency and precision of endoscopic submucosal dissection in animal training models by analyzing an electrical surgical unit

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Objectives: Although endoscopic submucosal dissection (ESD) training is important, quantitative assessments have not been established. This study aimed to explore a novel quantitative assessment system by analyzing an electrical surgical unit (ESU).

Methods: This was an ex vivo study. Step one: to identify the novel efficiency indicators, 20 endoscopists performed one ESD each, and we analyzed correlations between their resection speed and electrical status. Step two: to identify the novel precision indicators, three experts and three novices performed one ESD each, and we compared the stability of the electrical status. Step three: three novices in step two performed 19 additional ESDs, and we analyzed the learning curve using novel indicators.

Results: Step one: the percentage of total activation time (AT) of ESU in the procedure time (β coefficient, 0.80; $P < 0.01$) and AT required for submucosal dissection (β coefficient, −0.57; $P < 0.01$) were significantly correlated with the resection speed. Step two: coefficient of variation of the AT per one pulse (0.16 [range, 0.13–0.17] vs. 0.26 [range, 0.20–0.41], $P = 0.049$) and coefficient of variation of the peak electric power per pulse during mucosal incision (0.14 [range, 0.080–0.15] vs. 0.25 [range, 0.24–0.28], $P = 0.049$) were significantly lower in the experts than in the novices. Regarding the learning curve, the percentage of total AT of ESU in the procedure time and AT required for submucosal dissection had a trend of improvement.

Conclusion: Novel indicators identified by analyzing ESU enable quantitative assessment for endoscopist's skill.

Key words: animal model, electrical surgical unit, endoscopic submucosal dissection, quantitative assessment, training

INTRODUCTION

IN ENDOSCOPIC SUBMUCOSAL dissection (ESD), an electrical surgical unit (ESU) is essential. An ESU constantly senses tissue impedance and generates power, depending on the degree of contacting of an electrosurgical knife and tissue, thereby allowing for mucosal incision and submucosal dissection with thermal effects.[1–5] A thermal effect can cause stenosis or post-ESD coagulation syndrome from an inflammatory response, or even perforation; therefore, efforts should be made to minimize thermal damage.[6–9] However, manipulating the electrosurgical knife consistently at a certain distance in a limited time with minimal thermal damage is difficult for novices (Fig. 1). It is important for novices to complete proper training before starting the actual procedure.

For training, an animal model is useful. It has been reported that resection speed, en bloc resection rate, and adverse event rate improve after training in animal model.[10–17] However, there are some difficulties with the set outcome when assessing skill. Resection speed is usually calculated by dividing the resection area by the total procedure time; thus, this indicator cannot accurately evaluate efficiency in ESD with various processes. En bloc resection and adverse events do not directly reflect a precise technique with minimal thermal damage to the tissue. More detailed, direct, and quantitative assessment indicators are required to establish an appropriate training system for each individual level.

We speculated that the efficiency of ESD could be evaluated in more detail by analyzing the activation time (AT) and value of the generated electric power (EP) of the ESU required for each process in ESD. The precise ESD

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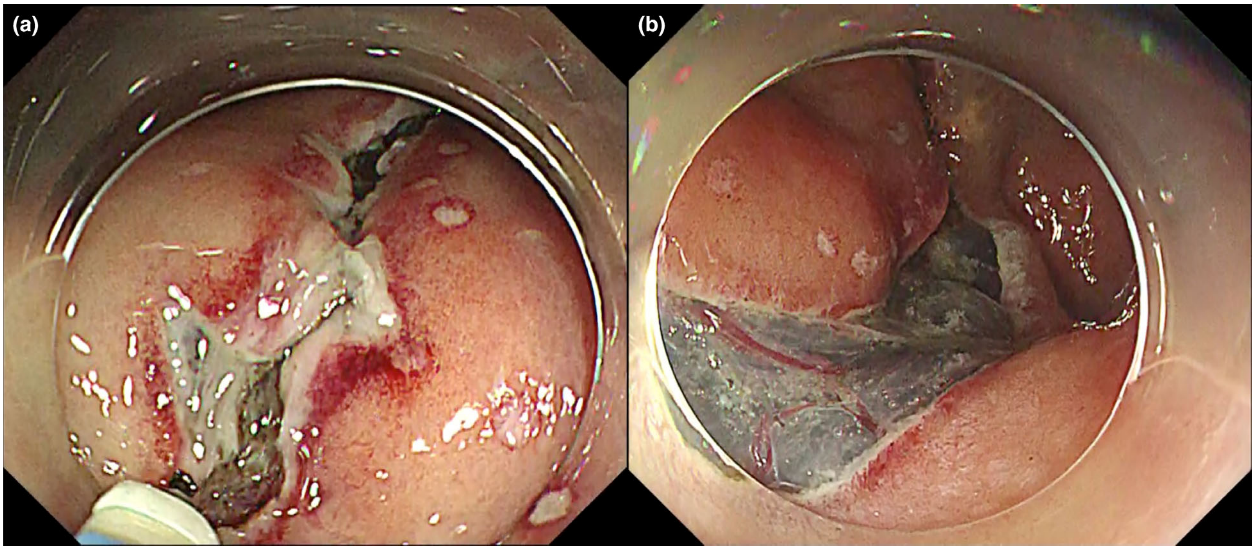

Figure 1 Example of the difference in mucosal incision between a novice and an expert. (a) Mucosal incision made by a novice. The incision line is zigzag, and thermal damage to the surrounding tissues is noticeable because of unstable electrosurgical knife manipulation. (b) Mucosal incision performed by an expert. The incision line is clean with minimal thermal damage to the surrounding area.

technique could be evaluated by analyzing the stability of the electrical status, thereby reflecting the stability of tissue and electrosurgical knife contacting. This study aimed to explore a novel assessment system for the efficiency and precision of ESD in animal training models by analyzing ESU.

METHODS

Study design

THIS EX VIVO study was conducted in three steps using an excised porcine stomach. Step one: to identify novel indicators reflecting the efficiency of ESD, 20 endoscopists performed one ESD each. We analyzed AT and the value of the generated EP required for each process in ESD and correlations between these values and their resection speed.

Step two: to identify novel indicators reflecting the precision of ESD, three experts with more than 100 clinical ESD experiences regardless of organs and three novices with fewer than five ESD experiences regardless of organs performed one clinical ESD each. We compared the stability of the electrical status between the experts and novices.

Step three: to explore a novel assessment system for the efficiency and precision of ESD, the three novices in step two performed 19 additional ESDs for training. Over time, we analyzed data change for the indicators identified in steps one and two.

Animal model

Porcine stomachs were used. In step one, a box with a side hole was used, and an overtube was ligated into the hole. One end of the overtube was attached to an isolated porcine stomach (Fig. 2a). A round lesion approximately 2 to 3 cm in size was made in the lesser curvature of the body. In steps two and three, the stomach was cut open from the side of the greater curvature to standardize technically difficult factors on the lesion and to simplify the procedure (Fig. 2b). The lesion was created by marking a 1.5 cm diameter plastic disk placed in the lesser curvature of the lower part.

Device and equipment

Endoscopic submucosal dissection was performed using a therapeutic endoscope (GIF-Q260J or GIF-H290T; Olympus Medical Systems, Tokyo, Japan). A transparent hood (D-201-11804; Olympus Medical Systems) was attached to the tip of the endoscope. We used a 2.0 mm DualKnife J (Olympus Medical Systems) and submucosal injection of saline solution.

Electrical surgical units and recording system

A VIO 300D (ERBE Elektromedizin, Tübingen, Germany) was used as the ESU. The VIO 300D is a voltage-control

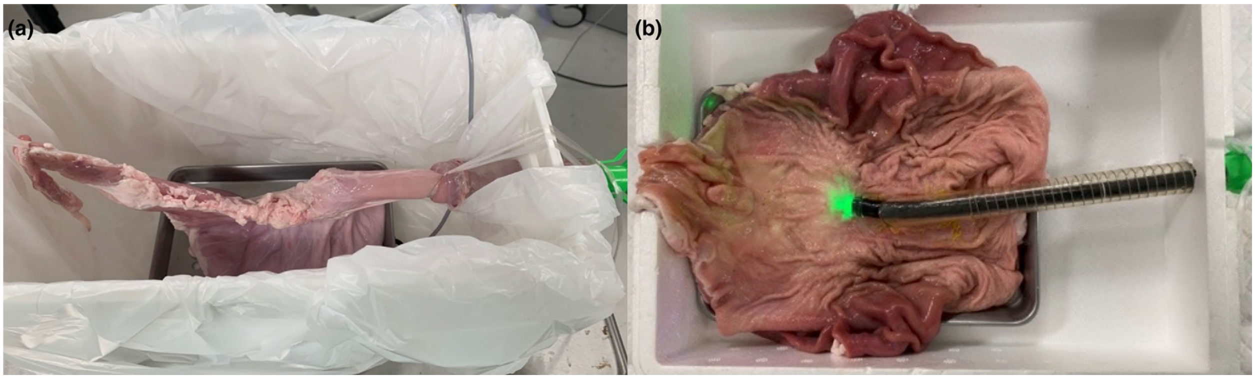

Figure 2 (a) Animal model for step one. (b) Animal model for steps two and three.

type of ESU that maintains the set voltage value and adjusts the generated EP automatically within a set range, depending on the sensed impedance.[18] To make differences in the generated EP depending on the amount of tissue contact, the effect and maximum watt value were set higher than usual (dry cut, effect 4 150 W; swift coagulation, effect 4 150 W). In this setting, the larger the contacting between the tissue and electrosurgical knife, the clearly larger the generated EP (Fig. S1).

We used a data recording program (VIO DOKU; ERBE Elektromedizin) to analyze the electrical status of the ESU. The ESU is activated only when pedaling the ESU footswitch. The VIO DOKU records the generated EP every 40 ms while the ESU is activating. In one pedaling of the ESU footswitch, one electrical pulse was observed, including the increasing, stable, and decreasing phases (Fig. 3a). As shown in Figure 3b, when all pulses of the generated EP in one ESD are described, the electrical status in one ESD is observed.

Endoscopic procedure

A mucosal incision was performed in the cut mode, and submucosal dissection was performed in the coagulation mode. The ESD was performed using the following procedure: first, a partial mucosal incision and mucosal flap were made; second, a full circumferential incision was made; and, finally, the remaining submucosal layer was dissected.

Measured outcomes

Step one: identification of indicators reflecting the efficiency of ESD

We collected data on characteristics of the enrolled endoscopists, including age, years since graduation from a medical university, whether they were board-certified fellows of the Japan Gastroenterological Endoscopy Society, number of esophagogastroduodenoscopy experiences, number of colonoscopy experiences, and number of ESD experiences. Data on the following treatment outcomes and electrical status were collected: en bloc resection rate, perforation rate, major axis of the resected specimen, area of the resected specimen, circumference of the resected specimen, procedure time, resection speed, AT of ESU during ESD, percentage of total AT in the procedure time, AT and EP required for mucosal incision, and AT and EP required for submucosal dissection. The resected specimen area was calculated using the following formula: A = semi-major axis (cm), B = semi-minor axis (cm), and area (cm^2) = $A \times B \times \pi$. The circumference of the resected specimen was calculated using the following formula: $h = (A - B)^2/(A + B)^2$, circumference (cm) = $\pi\ (A + B)\ [1 + (3\ h)/(10 + \sqrt{(4 - 3\ h)})]$. Procedure time was defined as the time from the initiation of mucosal incision to completion of lesion removal. Resection speed was defined as the area of resected specimen divided by the procedure time. AT was defined as the time the ESU was activated by pedaling the ESU footswitch. EP was defined as the value of EP generated by the ESU. The AT and EP required for mucosal incision were defined as the AT and EP generated during mucosal incision divided by the circumference of the resected specimen. The AT and EP required for submucosal dissection were defined as the AT and EP generated during submucosal dissection divided by the area of the resected specimen.

Step two: identification of indicators reflecting the precision of ESD

We collected the same data as in step one for the characteristics of the enrolled endoscopists. The following

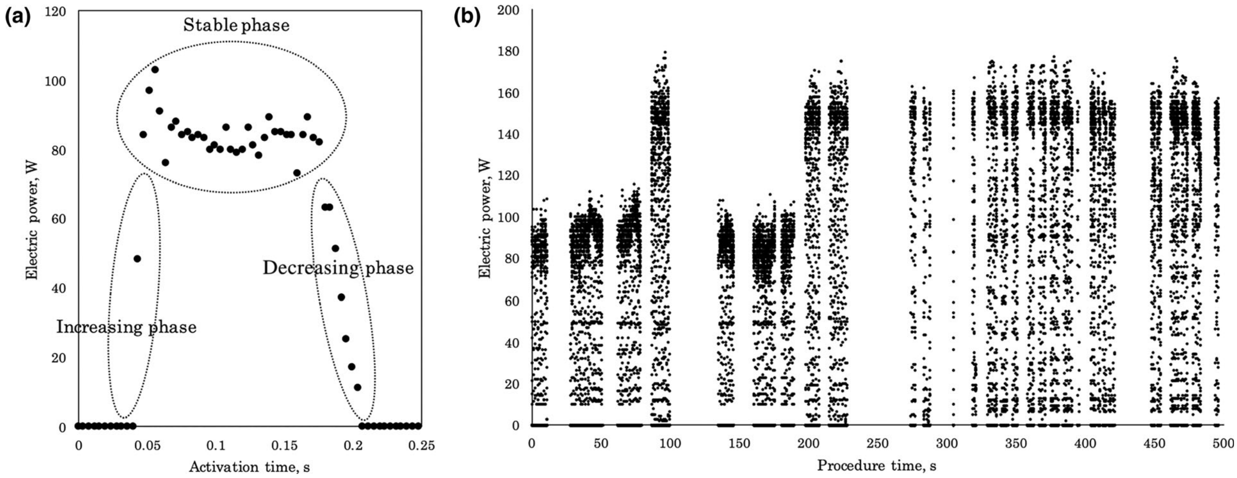

Figure 3 Electrical status. (a) One electrical pulse in one pedaling of the electrical surgical unit footswitch, including the increasing, stable, and decreasing phases. (b) Electrical status in one endoscopic submucosal dissection.

treatment outcomes and electrical status were also collected: en bloc resection rate, perforation rate, coefficient of variation (CV) of the AT per electrical pulse during ESD, and CV of the peak EP per electrical pulse during mucosal incision and submucosal dissection. The peak EP was defined as the mean of the stable phase of one electrical pulse (Fig. 3a).

Step three: exploration of a novel assessment system for the efficiency and precision of ESD

We described the data change over time in the statistical significance indicators identified in steps one and two. Furthermore, the proficiency line, defined as the range of the experts' values measured in step two, was also described for comparison.

Statistical analysis

In step one, simple and multiple regression analyses of the resection speed were performed. Beta coefficients and *P*-values were calculated for each item. For multiple regression analysis, factors that were statistically significant during the simple regression analysis were used. In step two, Fisher's exact test was used to analyze categorical data. Quantitative data were compared using the Mann–Whitney *U*-test. Statistical significance was set at $P < 0.05$. All statistical analyses were performed using JMP software (version 17.0.0; SAS Institute, Cary, NC, USA).

RESULTS

Step one: identification of indicators reflecting the efficiency of ESD

Characteristics of the endoscopists

THE CHARACTERISTICS OF the 20 endoscopists are listed in Table 1. Eleven endoscopists were board-certified fellows. The median number of ESD procedures was 73.

Treatment outcomes and electrical status

The treatment outcomes and electrical status of ESD by the 20 endoscopists are presented in Table 2. En bloc resection was achieved in all cases without perforation.

Regression analysis of resection speed

Regression analysis results of the resection speed are presented in Table 3. Simple regression analysis showed that the number of EGD (β coefficient, 0.60; $P = 0.0056$), colonoscopy (β coefficient, 0.53; $P = 0.016$), and ESD (β coefficient, 0.54; $P = 0.013$) experiences were significantly correlated with the resection speed, respectively. Additionally, the percentage of total AT in the procedure time (β coefficient, 0.80; $P < 0.0001$) and AT required for submucosal dissection (β coefficient, −0.57; $P = 0.0083$) were significantly correlated with the resection speed. Multiple regression analysis of the resection speed using these five factors showed that the percentage of total AT in the procedure

Table 1 Characteristics of the enrolled endoscopists

Step one	*N* = 20
Years since graduation, median (range)	11 (5–21)
Board-certified fellow, yes, *N*	11
Number of EGD experiences, median (range)	5500 (1000–15,000)
Number of CS experiences, median (range)	1600 (400–10,000)
Number of ESD experiences, median (range)	73 (0–2130)
Step two, expert	*N* = 3
Years since graduation, median (range)	13 (8–21)
Board-certified fellow, yes, *N*	3
Number of EGD experiences, median (range)	10,000 (5000–15,000)
Number of CS experiences, median (range)	6000 (2000–10,000)
Number of ESD experiences, median (range)	500 (100–2000)
Step two, novice	*N* = 3
Years since graduation, median (range)	5 (4–5)
Board-certified fellow, yes, *N*	0
Number of EGD experiences, median (range)	600 (500–700)
Number of CS experiences, median (range)	300 (200–700)
Number of ESD experiences, median (range)	1 (0–4)

CS, colonoscopy; EGD, esophagogastroduodenoscopy; ESD; endoscopic submucosal dissection.

Table 2 Treatment outcomes and electrical status in step one

Major axis of the resected specimen, cm, median (range)	2.6 (1.8–3.7)
Area of the resected specimen, cm^2, median (range)	4.2 (1.8–7.5)
Circumference of the resected specimen, cm, median (range)	7.3 (4.9–9.7)
Procedure time, min, median (range)	14 (5–37)
Resection speed, cm^2/h, median (range)	16 (6.1–33)
AT of ESU, s, median (range)	
Total	70 (33–229)
Mucosal incision	29 (12–161)
Submucosal incision	46 (15–70)
Percentage of total AT in procedure time, %, median (range)	9.2 (3.9–21)
AT required for mucosal incision, s/cm, median (range)	4.1 (1.8–21)
EP required for mucosal incision, $\times 10^5$ W/cm, median (range)	0.41 (0.15–0.89)
AT required for submucosal dissection, s/cm^2, median (range)	10 (5.1–27)
EP required for submucosal dissection, $\times 10^5$ W/cm^2, median (range)	1.4 (0.6–2.1)

AT, activation time; EP, electric power; ESU, electrical surgical unit.

time and AT required for submucosal dissection were significantly correlated with the resection speed, independent of the number of EGD, CS, and ESD experiences.

Step two: identification of indicators reflecting the precision of ESD

Characteristics of the endoscopists

The characteristics of the endoscopists are presented in Table 1. All three experts were board-certified fellows with more than 100 ESD experiences. In contrast, none of the novices was a board-certified fellow, and the number of ESD experiences ranged between 0 and 4.

Treatment outcomes and electrical status

En bloc resection without perforation was achieved in all patients. Comparisons of the electrical pulse stability between experts and novices are presented in Figure 4. Representative situations of analyzing an ESU during ESD are presented in Video S1. The median CV of the AT per one pulse was significantly lower in the expert group than in the novice group (0.16 [range, 0.13–0.17] vs. 0.26 [range, 0.20–0.41], $P = 0.049$). Although the median CV of the peak EP per pulse during mucosal incision was significantly lower in the expert group than in the novice group (0.14 [range, 0.080–0.15] vs. 0.25 [range, 0.24–0.28], $P = 0.049$), there were no significant differences between the groups during submucosal dissection (0.24 [range, 0.10–0.33] vs. 0.31 [range, 0.18–0.35], $P = 0.51$).

Step three: exploration of a novel assessment system for the efficiency and precision of ESD

Learning curve of the three novices

In addition to the resection speed, the statistically significant indicators identified in steps one and two were evaluated in the learning curve (Fig. 5). All the novices improved their resection speed, and two of them finally reached the proficiency line. Although all the novices improved and finally reached the proficiency line in percentage of total AT in procedure time, only novice B improved and constantly reached the proficiency line in the late phase of AT for submucosal dissection. In all the novices, 20 practice sessions

Table 3 Regression analysis of resection speed in step one

Variables	Simple		Multiple	
	β coefficient	*P*-value	β coefficient	*P*-value
Number of EGD experiences	0.600	0.0056*	0.013	0.9600
Number of CS experiences	0.530	0.0160*	0.360	0.2100
Number of ESD experiences	0.540	0.0130*	−0.220	0.3900
Percentage of total AT in procedure time, %	0.800	<0.0001*	0.620	0.0004*
AT required for mucosal incision, s/cm	−0.070	0.7700	–	–
EP required for mucosal incision, $\times 10^5$ W/cm	0.062	0.7900	–	–
AT required for submucosal dissection, s/cm^2	−0.570	0.0083*	−0.380	0.0058*
EP required for submucosal dissection, $\times 10^5$ W/cm	−0.380	0.0970	–	–

*Statistically significant.
AT, activation time; EP, electric power; ESD, endoscopic submucosal dissection.

did not clearly improve the CV of the AT per pulse or the CV of the peak EP per pulse during mucosal incision.

DISCUSSION

THIS STUDY REVEALED that the percentage of total AT in the procedure time and AT for submucosal dissection were independently and significantly correlated with resection speed. We also successfully showed that the median CV of the AT per pulse and CV of the peak EP per pulse during the mucosal incision were significantly lower in the expert group than in the novice group.

There are several reports on the usefulness of animal models for ESD.[10–17] However, all the reports used resection speed as the main outcome, which cannot accurately evaluate the efficiency of ESD using various processes. In this study, the evaluation of AT by ESU analysis allowed for measuring the true incision and dissection time accurately, and we successfully divided the resection speed into percentage of total AT in procedure time and AT for submucosal dissection. In other words, we could evaluate the efficiency separately from the process of preparing the dissection, such as creating the field of view, and the process of actually manipulating the knife.

Furthermore, the median procedure time was 14 min, whereas the median total AT was 70 s, resulting in a median percentage of total AT in procedure time of only 9.2%. This result reminded us of the importance of the process of preparing the dissection without the electrosurgical knife as well as actual submucosal dissection.

In ESD, only performing the procedure quickly is insufficient. A precise and stable technique is essential for ensuring a safe and reliable procedure. In this study, the results of step two showed that AT per pulse was more stable in the expert group than in the novice group. In other words, novices cannot step on the ESU footswitch in a certain rhythm, which means that novices sometimes energize too long, which is dangerous, or too short, which is meaningless. It is important for novices to be aware of duration of stepping on the footswitch during training.

Peak EP per pulse during mucosal incision also varied more widely in the novice group with less experience of using the electrosurgical knife than in the expert group in step two. This means that novices cannot maintain precise scope movement, and knife and tissue contact is unstable, which is one of the key skills in ESD as shown in Figure 1. In contrast, the CV of the peak EP per pulse during submucosal dissection was not significantly different between the novices and experts; expert waveforms also varied widely. This might be because the degree of contact between the knife and the tissue is smaller when the edges are dissected even by experts, as shown in Video S1. Because this study targeted small lesions, the submucosal dissection of edges was relatively more frequent, which could result in the unstable waveform of the submucosal dissection.

The results of the learning curve for the novices in step three confirmed that the resection speed gradually increased, even after only 20 sessions of training. Detailed evaluation showed a marked improvement in percentage of total AT in procedure time over AT for submucosal dissection, which means that the time of creating a field of view was especially shortened because of the training. The AT for submucosal dissection varied depending on the individual, suggesting that efficiently using the knife may be a more advanced technique. As for the indicators reflecting precision, there was no improvement despite preparing an easy and simple target lesion. Twenty sessions might not be enough to acquire precise scope control techniques, and we found further training was needed for novices.

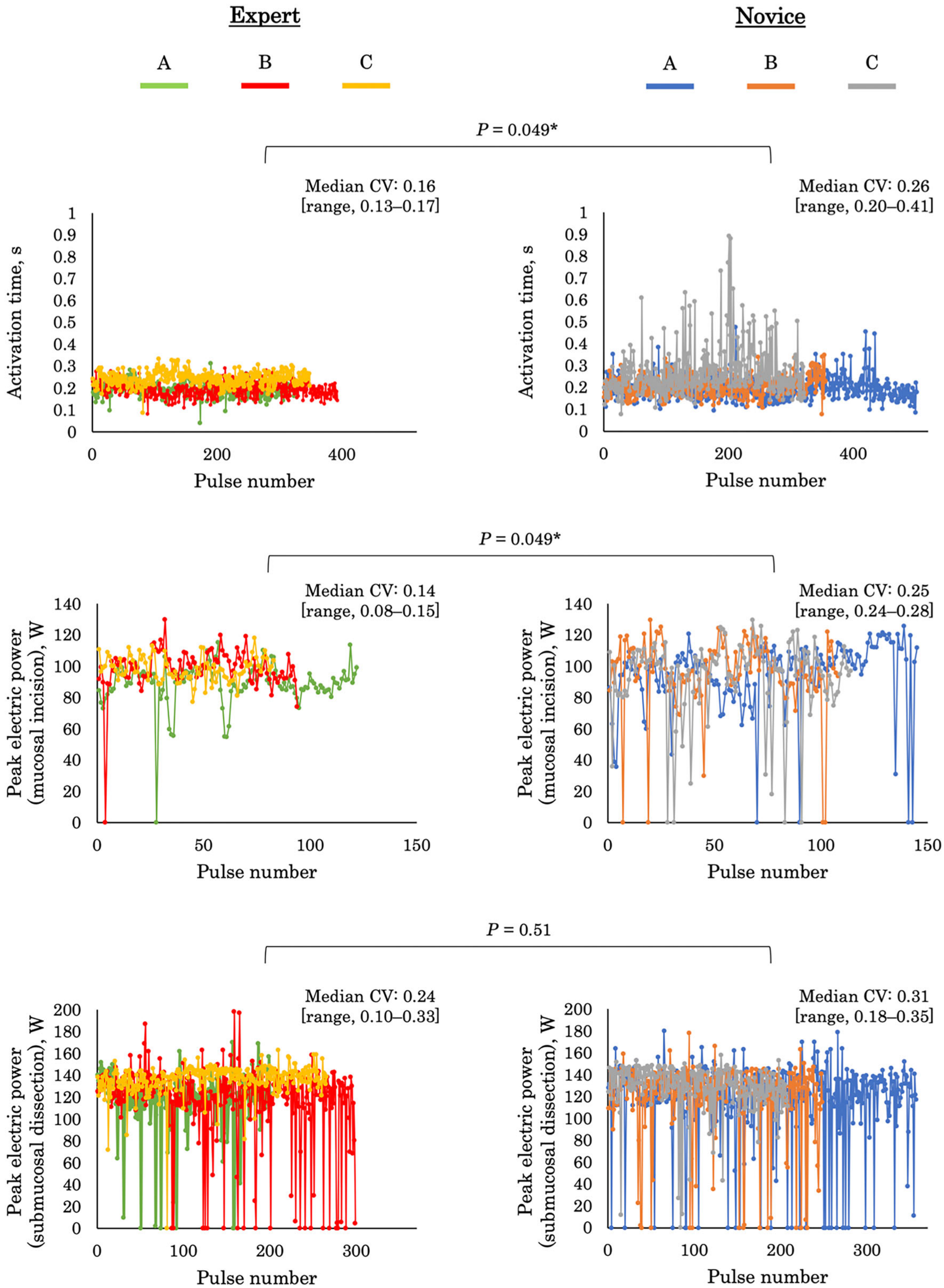

Figure 4 Comparisons of the stability of electrical pulse between experts and novices in step two. CV, coefficient of variation.

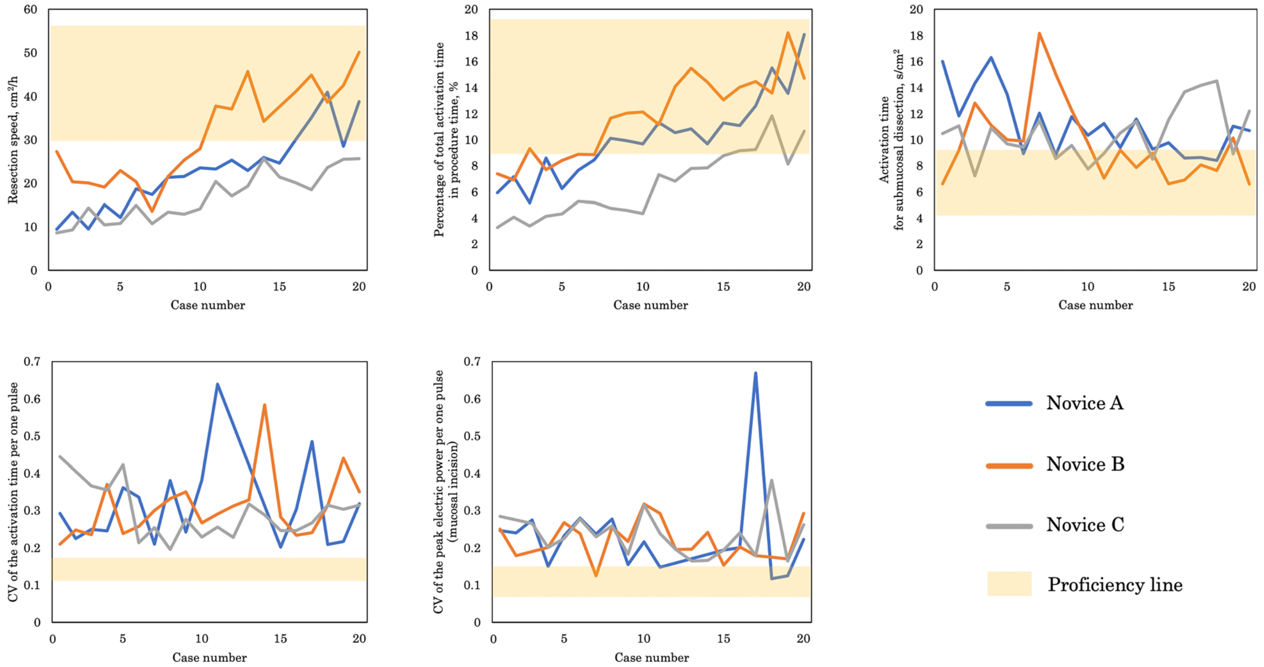

Figure 5 Learning curves of the three novices in step three. Proficiency line defined as the range of the experts' values measured in step two. CV, coefficient of variation.

In the future, the collection of a large amount of ESU data in real time in clinical ESD would enable safer and higher quality ESD by clarifying not only the relationship with the level of ESD skill but also with specimen quality and clinical outcomes such as symptoms, adverse events, and recurrence rate.

This study has several limitations. First, the ESU setting was set to an extraordinarily high value to observe variations in EP. Because of the safety assurance, we did not conduct research on humans in this ESU setting. Therefore, it was unclear at this stage whether the results of this study could reflect ESD skills in clinical settings. Second, the number of cases was small. Furthermore, in the learning curve analysis, improvement in the data was not observed to reach a plateau. Third, the results of this study were based on the needle-type electrosurgical knife DualKnife J. Thus, it is unclear whether this result would be adopted for other types of devices. Because of these limitations, the results of our study should be interpreted with caution. Based on the results of this pilot study, further prospective studies in clinical settings will be needed.

In conclusion, we found that the electrical status of ESU during a procedure directly and objectively indicates the endoscopist's skill. Although further validation is needed, the novel quantitative assessment may be helpful in establishing effective training methods.

CONFLICT OF INTEREST

AUTHORS DECLARE NO conflict of interest for this article.

FUNDING INFORMATION

NONE.

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SUPPORTING INFORMATION

ADDITIONAL SUPPORTING INFORMATION may be found in the online version of this article at the publisher's web site.

Figure S1 Difference in generated power according to the various conditions. (a) A VIO 300D (ERBE Elektromedizin, Tübingen, Germany) was activated 10 times in each of the following three situations: left, the knife was not contacting the tissue (no contact); center, only the tip of the knife was contacting the tissue (tip contact); and right, the entire knife was contacting the tissue (overall contact). (b) In the setting of dry cut, effect 3, 30 W. The graph was presented by overlaying the electrical pulse 10 times. After the generated electric power (EP) was adjusted up to 30 W, there was no significant difference in the mean generated power depending on the degree of contacting the tissue (P = 0.07). (c) In the setting of dry cut, effect 4, 150 W. The larger the contacting between the electrosurgical knife and tissue, the larger the generated EP (P = 0.0002).

Video S1 Representative situation of analyzing an electrical surgical unit during endoscopic submucosal dissection.