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Research Article

Effect of Time-Limited Training on Endoscopic Submucosal Dissection in an Ex Vivo Porcine Stomach Model: A Prospective Randomized Controlled Study

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Abstract

Introduction Endoscopic submucosal dissection (ESD) is the first choice for superficial tumor resection. There is no report on whether the training effect is affected by limiting the operation time of each ESD operation. This study aimed to prospectively evaluate the efficiency of time-limited ESD training by using an ex vivo porcine stomach model.

Methods ESD was performed in accordance with the standard procedure on ex vivo porcine stomach model. The time-limited group required each operation time to be controlled within 30 minutes, and the nonlimited group did not limit the operation time. The en bloc resection rate, surface area of the resected specimen, procedure speed, and perforation rate were compared in the two groups.

Results Compared with the en bloc resection rate in the time-limited group, that in the nonlimited group was significantly higher in ESD-1 and ESD-2. In each ESD procedure, the median resection area in the nonlimited group was significantly larger than that in the time-limited group. The difference in median procedure speed between the two groups in ESD-1 to ESD-4 did not reach significance in the statistical analysis. The speed of ESD-5 in the time-limited group was significantly higher than that of the nonlimited group. The perforation rate of the time-limited group was similar to that of the nonlimited group.

Conclusion Limiting the training time does not help the trainees to complete large resection of lesions and reduce the perforation rate, but it may help to improve the operation speed.

Keywords
- endoscopic submucosal dissection
- ex vivo porcine stomach model
- time-limited
- en bloc resection rate
- procedure speed
- perforation rate

Introduction

In recent years, the detection rate of gastrointestinal tumors, especially precancerous lesions and early cancer, has been increasing. This condition is mainly due to the great attention devoted to tumor diseases and the development of new digestive endoscopy technology. The improvement in detection rate has also promoted the development of endoscopic submucosal dissection (ESD), which has many advantages, such as absence of laparotomy, organ preservation, and rapid recovery.[1]

In the late 1990s, Japanese scholar Gotoda and others first reported the successful dissection of early cancerous lesions larger than 2 cm in diameter by using ESD. ESD is an effective and safe method for the treatment of early gastrointestinal cancer.[2,3] However, compared with traditional endoscopic mucosal resection, ESD is more difficult, complicated, and time consuming; so the incidence of delayed bleeding,

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perforation, infection, and other complications is increased.[4–7] Although the amount of and experience in ESD development differ across countries,[8,9] great importance is attached to the prevention and treatment of ESD complications, especially in Western countries.[10–12] Therefore, endoscopists need systematic training before performing clinical ESD treatment procedures to reduce the incidence of complications, patient pain and costs.

Prior to ESD in the human body, we have trained on animal models, such as porcine stomach. Recently, the European Society of Gastroendoscopy provided guidelines for ESD and recommended that at least five ESD procedures be performed in animal models (in vivo or ex vivo) before the implementation of ESD in humans.[13–18]

Researchers have not determined how long ESD operators should be trained in porcine stomach model training and how many operations should be completed before they can implement the operation in human body independently. The coronavirus disease 2019 (COVID-19) pandemic in the past 3 years has severely challenged on-the-spot centralized learning.[19] The number of standardized ESD training institutions in many regions is still relatively limited. Full use of the limited training opportunities and time to achieve the training effect is important. Research on whether to limit ESD training time has not been performed. Therefore, this study aimed to investigate the differences between time-limited and nonlimited groups in the training of ESD in an ex vivo porcine stomach model to provide evidence for reasonable training methods.

Materials and Methods

Trainees

Twenty endoscopists with more than 10 years of experience in endoscopy and endoscopic mucosal resection, without ESD experience, were selected regardless of age and gender. Before using the ex vivo porcine stomach model for operation training, the trainees were introduced to ESD-related equipment and techniques online. The materials included the following contents (1) brief introduction of ESD equipment, such as endoscope and electric cutter; (2) basic steps of ESD in the stomach; (3) dual knife cutting techniques; (4) Insulated-tip diathermic knife (IT knife) cutting techniques; (5) common pitfalls to be avoided in ESD operation; and (6) complications in ESD and management. Then, the trainees reviewed videos of ESD procedures performed by experts with rich ESD operation experience. The trainees were randomly divided into two groups by using the random number table method with 10 participants each. The operation time for the time-limited group was 30 minutes, and the operation for the non-time-limited group ended with complete mucosal dissection. Each ex vivo porcine stomach model was used to train two trainees, and each group had five operation platforms. Each trainee underwent five procedures.

Ex Vivo Porcine Stomach Model

The porcine stomach of 6 to 9-month-old samples was used to make the training model, and a complete esophageal connection was required. On the night before the training, the frozen stomach was thawed at room temperature. The stomach sample was washed thoroughly with warm water before use, and food residue was removed from the stomach. The stomach was fixed in a $25 \times 15 \times 10$ cm plastic box, and the open part of the stomach was tightly clamped with hemostatic forceps. The esophagus protruded through a hole at the top of the box and was fixed with a tube that could pass through the gastroscope. A metal plate connected with the electrotome was placed under the stomach as an electrode for the operation (►**Fig. 1**).

Endoscopes and Attachments

The Olympus GIF-h190 upper endoscope (Olympus, Center Valley, Pennsylvania, United States) and ERBE VIO 300 D electric generator (ERBE, Tübingen, Germany) were used in all the training courses. The following settings were adopted for all operations: Endo-Cut effect 3 and 130 Watts. Coagulation settings were not needed because no bleeding occurred in the ex vivo porcine stomach. Dual knife (KD-650U; Olympus, Tokyo, Japan) was used for each phase of ESD. Olympus distal attachments (D-201–11804; Olympus, Tokyo, Japan) were utilized in all operations. All operations were performed with normal saline and methylene blue as the lifting solution.

ESD Operation Process

ESD was performed in accordance with the standard procedure. The dual knife was used to mark the circumference around the target area. Normal saline and methylene blue were injected to lift the lesion. The initial mucosal incision was performed at 12 and 6 o'clock by using the dual knife. The dual knife was also used to cut the mucosa around the mark. Submucosal dissection was performed after circumferential cutting of the mucosa. When necessary, additional injections were made to lift and expose the submucosa sufficiently to ensure complete dissection. ESD should be performed in the proximal–middle part of the stomach (►**Fig. 2**). Gastric antrum with thick mucosa should be avoided. The size of the resected area was determined by

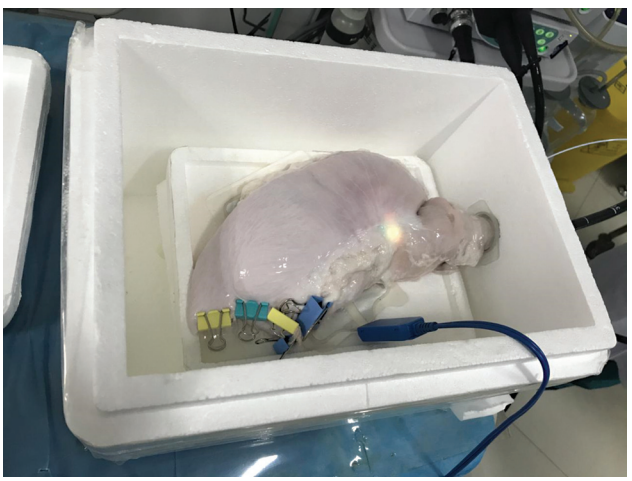

Fig. 1 Ex vivo porcine model used for endoscopic submucosal dissection training.

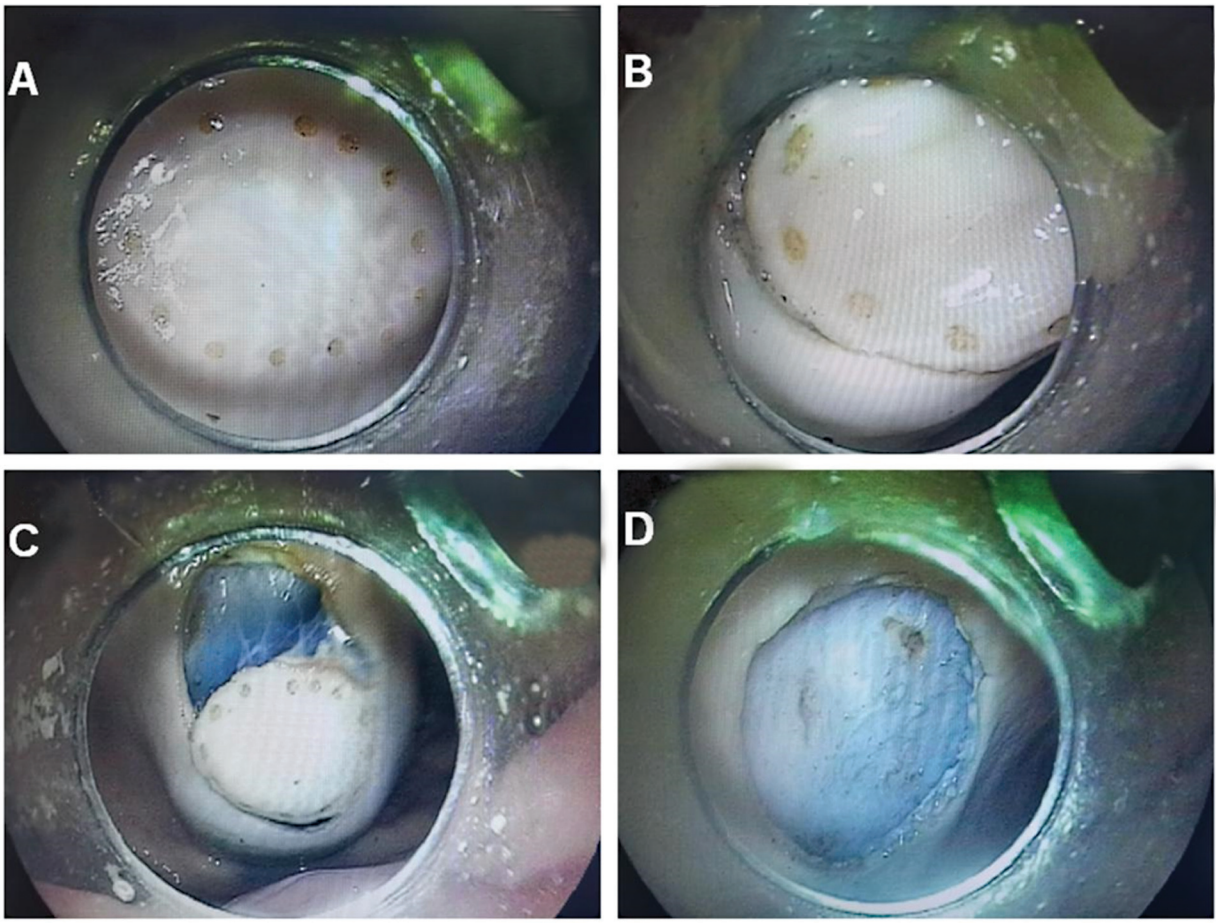

Fig. 2 Application of endoscopic submucosal dissection in the ex vivo model. (**A**) Confirmation of the mark. (**B**) Circumferential cut after submucosal injection. (**C**) Submucosal dissection of the lesion. (**D**) Postinterventional site of the resection.

the trainees. Direct or inverted ESD operation was optional for the trainees. Clamping was required for perforation and obstruction, such as air leakage.

Outcome Parameters

The following variables were recorded: (1) time of ESD operation, which is the time from the first circumferential marking to the complete dissection of the marked gastric mucosa; (2) completeness of the ESD resection (en bloc, incomplete), which refers to whether all the premarkers around the mucosal lesions are included in the resected specimens; (3) perforation, which refers to whether an obvious defect occurs on the muscle wall of the porcine stomach during operation; and (4) resection area. The dissected specimen was removed from the stomach and nailed to a cork board, and the area was measured. When the specimen had an ellipse shape, the two largest diameters of the resected specimen were measured, and the area was calculated as area (mm^2) = small diameter (mm) /2 × large diameter (mm) / 2 ×π. When the specimen was circular, the diameter of the resected specimen was measured, and the area was calculated as area (mm^2) = π × (diameter (mm)/2). Procedure speed was calculated in mm^2 per minute by using the formula procedure speed = area (mm^2)/time (minute).

Statistical Analysis

The data were expressed as mean ± standard deviation (SD). Chi-squared and paired *t*-tests were performed for statistical analyses. All statistical analyses were performed in StataCorp, College Station, Texas, United States. A *p*-value less than 0.05 was considered statistically significant.

Results

In the time-limited and nonlimited groups, 100 endoscopic procedures (50 time-limited and 50 nonlimited) were performed in the ex vivo porcine model. An overview of the data is presented in ►**Tables 1** and **2**.

Rate of En Bloc Resection

In ESD-1 and ESD-2, the time-limited group achieved an en bloc resection rate of 50 (5 of 10) and 60% (6 of 10), respectively. In ESD-3 to ESD-5, the values were 100 (10 of 10), 80% (8 of 10), and 90% (9 of 10), respectively. In ESD-1 to ESD-5, the nonlimited group had an en bloc resection rate of 100% (10 of 10). Compared with the en bloc resection rate of the time-limited group, the rate of the nonlimited group was significantly higher in ESD-1 (100 vs. 50%, $p < 0.05$) and ESD-2 (100 vs. 60%, $p < 0.05$) (►**Fig. 3**).

Table 1 Date of the time-limited group

	Number	1	2	3	4	5	6	7	8	9	10
ESD-1	En bloc resection	Y	Y	N	Y	Y	N	N	Y	N	N
	Perforation	N	N	Y	N	N	Y	Y	Y	N	N
	Resection area(mm^2)	80	125	130	75	160	410	490	165	240	205
	Dissection time(min)	28	28	N[a]	25	20	N[a]	N[a]	22	N	N[a]
	Procedure speed(mm^2/min)	2.86	4.46	4.33	3	8	13.67	16.35	7.5	8	6.83
ESD-2	En bloc resection	N	Y	Y	N	N	Y	N	Y	Y	Y
	Perforation	N	N	N	N	N	Y	N	Y	Y	Y
	Resection area(mm^2)	240	225	320	210	380	520	645	350	430	450
	Dissection time(min)	N[a]	28	29	N[a]	N[a]	28	N[a]	25	29	29
	Procedure speed(mm^2/min)	8	8.04	11.03	7	12.67	18.57	21.5	14	14.83	15.52
ESD-3	En bloc resection	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Perforation	N	N	N	Y	N	N	N	N	N	N
	Resection area(mm^2)	430	395	520	490	420	650	750	450	620	680
	Dissection time(min)	28	28	N[a]	27	28	28	30	27	29	28
	Procedure speed(mm^2/min)	15.36	14.11	17.33	18.15	15	23.21	25	16.67	21.38	24.29
ESD-4	En bloc resection	Y	Y	Y	Y	Y	N	N	Y	Y	Y
	Perforation	N	N	N	N	N	N	N	N	N	Y
	Resection area(mm^2)	650	768	765	683	815	1080	920	670	815	890
	Dissection time(min)	26	28	30	25	29	N[a]	N[a]	26	30	28
	Procedure speed(mm^2/min)	25	27.43	23.23	27.32	28.1	36	30.67	25.77	27.17	31.79
ESD-5	En bloc resection	Y	Y	Y	N	Y	Y	Y	Y	Y	Y
	Perforation	N	N	N	N	N	N	Y	N	N	N
	Resection area(mm^2)	830	938	1078	1120	1086	1312	1190	910	1050	1216
	Dissection time(min)	28	27	29	N[a]	28	29	28	27	30	28
	Procedure speed(mm^2/min)	29.64	34.74	37.17	37.33	38.79	45.24	42.5	33.7	35	43.43

Abbreviation: ESD, endoscopic submucosal dissection.
[a]En bloc resection was not performed in 30 minutes. The time is counted in 30 minutes.

Resection Area

The median resection area in the time-limited group for ESD-1 was 208 mm^2 (SD: 138.47). In ESD-2 to ESD-5, the value was 377 mm^2 (SD: 139.11), 540.5 mm^2 (SD: 125.04), 805.6 mm^2 (SD: 131.81), and 1073 mm^2 (SD: 148.33) for the time-limited group, respectively. In each ESD procedure, the median resection area was significantly larger in the nonlimited group than in the time-limited group. In ESD-1, the median resection area was 383.3 mm^2 for the nonlimited group (SD: 188.65, $p < 0.05$). The median resection area was 604.2 mm^2 (SD: 181.56, $p < 0.01$) in ESD-2, 826.5 mm^2 (SD: 237.28, $p < 0.01$) in ESD-3, 1332.8 mm^2 (SD: 249.54, $p < 0.01$) in ESD-4, and 1787.8 mm^2 (SD: 296.86, $p < 0.01$) in ESD-5 for the nonlimited group (►**Fig. 4**).

Procedure Speed

In ESD-1 to ESD-5, the median procedure speeds in the time-limited group were 7.50 mm^2/min (SD: 4.45), 13.12 mm^2/min (SD: 4.75), 19.05 mm^2/min (SD: 4.07), 28.25 mm^2/min (SD: 3.70), and 37.75 mm^2/min (SD: 4.85), respectively.

The difference in median procedure speed between the nonlimited and time-limited groups in ESD-1 to ESD-4 did not reach significance in the statistical analysis (7.22 mm^2/min [SD: 2.44] vs. 7.50 mm^2/min [SD: 4.45], $p = 0.65$; 12.93 mm^2/min [SD: 3.35] vs. 13.12 mm^2/min [SD: 4.75], $p = 0.26$; 18.38 mm^2/min [SD: 3.99] vs. 19.05 mm^2/min [SD: 4.07], $p = 0.18$; 26.13 mm^2/min [SD: 4.08] vs. 28.25 mm^2/min [SD: 3.70], $p = 0.31$). By contrast, the procedure time in ESD-5 was significantly lower in the nonlimited group compared with that in the time-limited group (33.89 mm^2/ min [SD: 2.80] vs. 37.75 mm^2/min [SD: 4.85], $p < 0.05$) (►**Fig. 5**).

Perforations

In ESD-1 and ESD-2, four perforations were observed in the time-limited group. In ESD-3 to ESD-5, one perforation occurred. In ESD-1 to ESD-5, three perforations, two perforations, two perforations, no perforations, and one perforation occurred in the nonlimited group, respectively. No

Table 2 Date of the nonlimited group

	Number	1	2	3	4	5	6	7	8	9	10
ESD-1	En bloc resection	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Perforation	N	N	Y	N	Y	Y	N	N	N	N
	Resection area(mm^2)	160	140	420	280	545	650	320	258	390	670
	Dissection time(min)	45	29	59	55	49	65	51	37	52	69
	Procedure speed(mm^2/min)	3.56	4.83	7.12	5.09	11.12	10	6.27	6.97	7.5	9.71
ESD-2	En bloc resection	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Perforation	N	N	N	Y	N	N	N	N	N	Y
	Resection area(mm^2)	560	390	570	412	768	910	510	672	430	820
	Dissection time(min)	60	32	42	45	42	56	55	47	41	50
	Procedure speed(mm^2/min)	9.33	12.19	13.57	9.16	18.29	16.25	9.27	14.3	10.49	16.4
ESD-3	En bloc resection	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Perforation	N	Y	N	N	N	N	Y	N	N	N
	Resection area(mm^2)	520	660	1060	610	975	1180	690	680	760	1130
	Dissection time(min)	42	45	50	36	46	60	40	45	40	43
	Procedure speed(mm^2/min)	12.38	14.67	21.2	16.94	21.2	19.67	17.25	15.2	19	26.28
ESD-4	En bloc resection	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Perforation	N	N	N	N	N	N	N	N	N	N
	Resection area(mm^2)	862	1160	1550	1128	1446	1656	1270	1248	1376	1632
	Dissection time(min)	45	50	60	52	50	60	45	56	48	60
	Procedure speed(mm^2/min)	31.37	33.64	32	36.15	32.8	40.33	34.67	30.79	32.5	34.67
ESD-5	En bloc resection	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Perforation	N	N	N	N	N	N	Y	N	N	N
	Resection area(mm^2)	1412	1682	1920	1880	1640	2420	1560	1724	1560	2080
	Dissection time(min)	45	50	60	52	50	60	45	56	48	60
	Procedure speed(mm^2/min)	31.37	33.64	32	36.15	32.8	40.33	34.67	30.79	32.5	34.67

Abbreviation: ESD, endoscopic submucosal dissection.

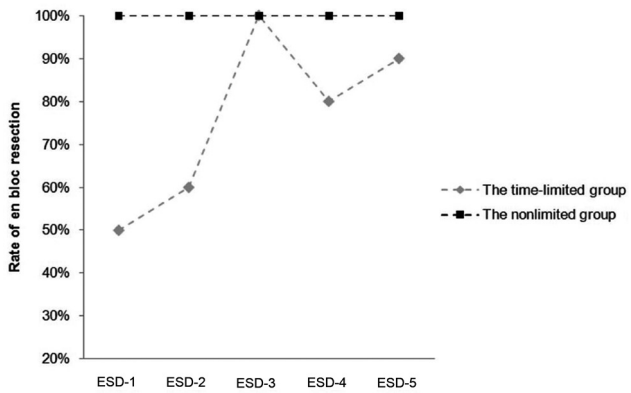

Fig. 3 Rate of en bloc resection. ESD, endoscopic submucosal dissection.

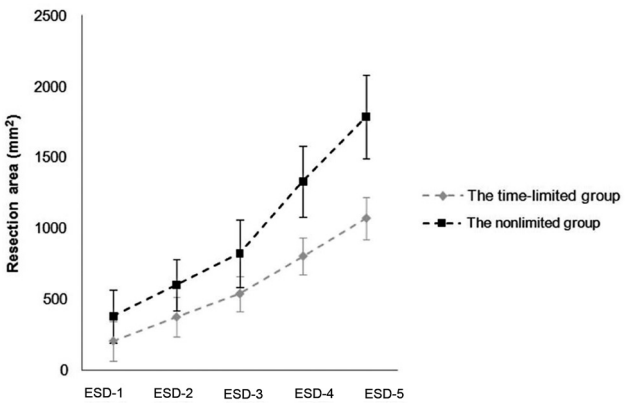

Fig. 4 Resection area. ESD, endoscopic submucosal dissection.

significant difference in the perforation rate was observed in each ESD between two groups (4/10 vs. 3/10, 4/10 vs. 2/10, 1/10 vs. 2/10, 1/10 vs. 0/10, 1/10 vs. 1/10; $p > 0.05$) (►**Fig. 6**).

Discussion

The value of the ex vivo porcine stomach model in ESD training has been widely recognized.[20,21] Given the wide

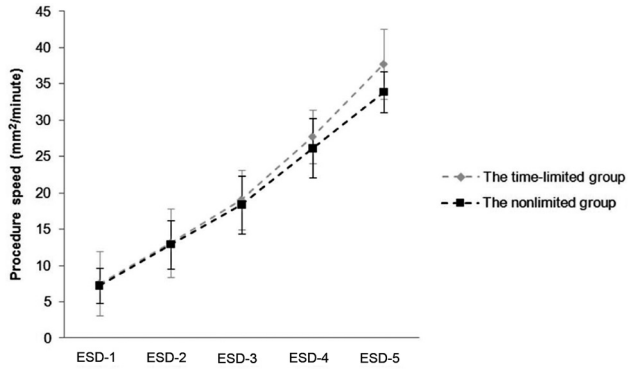

Fig. 5 Procedure speed. ESD, endoscopic submucosal dissection.

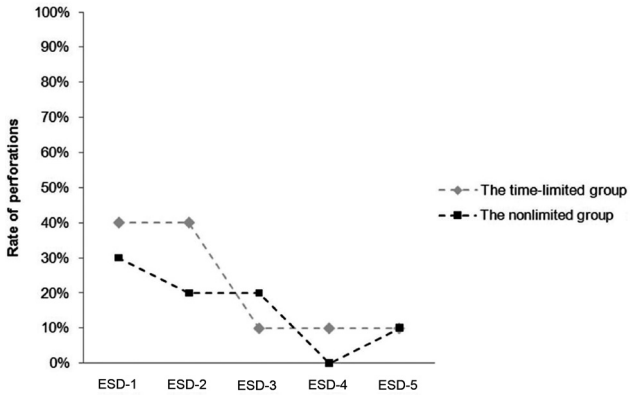

Fig. 6 Perforation rate. ESD, endoscopic submucosal dissection.

application of the model, many problems need to be considered about how to create a highly standardized training process to obtain improved effects. Most of the endoscopists participating in such training are in-service doctors, and taking a few weeks or days off to complete the training on animal models is difficult with the limited number of standardized ESD training institutions. In the particular case of COVID-19, staff aggregation is highly restricted. Therefore, animal model training should be arranged efficiently. Operation time is often used as an indicator to measure operator proficiency in animal model training,[22–26] and limiting the operating time may be beneficial for improving training efficiency. In our study, each trainee had a time limit of 30 minutes based on good criteria in the skill assessment of participants according to the consensus of the National Cancer Centre of Japan and Western supervisory endoscopy experts with experience in ESD.[27] Through the experiment, we found that most of the trainees in the time-limited group completed the operation within 30 minutes in the third implementation. Although some of the trainees in the time-limited group failed to resect the lesions completely in the first two operations, the training period was shortened, and training efficiency was improved by limiting the operation time for each case. However, in the nonlimited group, the time for the 10 trainees to complete five operations was 206 to 301 minutes, with an average of 248 minute. Limiting the operation time and improving the efficiency of training may be conducive to solving the problem of time for participating trainees.

In addition, we recorded and analyzed the en bloc resection rate, resection area, procedure speed, and perforations of the two groups. From our records, we found that the en bloc resection rates of the first two operations in the time-limited group (5/10 and 6/10) were significantly lower than those in the nonlimited group (10/10). By the third operation, both groups could almost complete the operation. The resection area of the time-limited group was significantly smaller than that of the nonlimited group in each ESD procedure. We speculate that sufficient operation time can help trainees achieve successful en bloc resection and remove large lesions. After five operations, the procedure speed of all trainees increased. The speed in the fifth operation of the time-limited group was significantly higher than that of the non-limited group. Limiting the operation time could make the trainees pay attention to the training, and the resection speed was improved significantly. The perforation rate of the time-limited group was similar to that of the nonlimited group and gradually decreased with the increase in the number of operations. No significant correlation was observed between perforation and limited operation time, which can be reduced only by improving operation skills. Therefore, according to the data above, the benefits of improving the procedure speed cannot be viewed as the main basis for limiting the operation time in ESD training requirements.

After communicating with the trainees in the two groups, we found that the psychological pressure of the trainees in the time-limited group was higher than that of the trainees in the nonlimited group because of the time requirement. Psychological quality training is important for surgeons, but it is often ignored or no good training method is available.[28–30] By limiting the time, this study increased the psychological pressure on the participants, resulting in some psychological quality training before the actual operation on the human body, which is also unexpected.

However, limiting operation time is also an additional pressure for actual clinical surgeries. In practical cases, the difficulty of ESD such as complex surgical sites, abundant blood vessels, large lesion areas, and fibrosis cannot be measured solely by the operating time to determine the success of the surgery. Therefore, limit operation time may be more beneficial for the psychological quality training of trainees during animal models training. In actual operations on human cases, senior doctors with ESD experience need to timely replace junior doctors who lack operation experience in performing actual procedures to ensure the success and safety of the operation.[31,32] However, the specific replacement time is usually determined by experience. Although a limited time set cannot represent the specific situation of human surgery, if the primary operator fails to achieve effective dissection within 30 minute or if perforation is possible, then the need for replacement is not guaranteed. This information can be confirmed by further clinical study.

This study has several limitations. This study focused on a small sample of endoscopists. The ex vivo porcine stomach model was used, and this model does not involve the

treatment of intraoperative blood vessels and bleeding. Therefore, the conclusions still need to be confirmed using large samples and large-scale, live porcine stomach models.

In this study, endoscopists were trained in ex vivo porcine stomach models for the first time to limit the operation time. The results showed that limiting the training time did not help the trainees complete large resection lesions, but it was beneficial for improving the procedure speed. Perforation control, which requires endoscopists to have superb operation skills, was not related to operation time. However, this study also puts forward new opinions on limiting the operation time for the exploration of trainers' psychological quality training, and team cooperation in clinical practice. In short, limiting the operation time should be adopted depending on the actual situation of the training institution.

Data Availability Statement

All data generated or analyzed during this study are included in this published article.

Statement of Ethics

This study does not involve ethical approval.

Authors' Contributions

X.L. proposed the study and performed research and wrote the first draft. X.L. and Y.L. collected and analyzed the data. All authors contributed to the design and interpretation of the study and to further drafts.

Conflict of Interest

None declared.

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