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Which Kind of Gastrointestinal Endoscopic Doctors Should Receive Endoscopic Submucosal Dissection (ESD) Training—ESD Training in The Affiliated Drum Tower Hospital from Single Center's Experience

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1. Abstracts

1.1. Objective: Our study aimed to investigate the prerequisites for those gastrointestinal endoscopic doctors who were suitably chosen to receive the ESD training.

1.2. Methods: Our study was enrolled in 41 ESD training fellows. The general information of fellows was collected in the datasheet including the name, age, gender, the cases of performed EGD (Esophagogastroduodenoscopy), the cases of colonoscopy, the applications of NBI, ME, EMR, ESD, EUS, and ERCP techniques.

1.3. Results: Among the 41 ESD fellows, 26 male fellows and 15 female fellows were included in our study. The average age was 36.07±4. 44-year-old ranging from 27 to 53 years old. The method of colonoscopy for 41 fellows was totally performed by single person without other assistant. According to linear regression analysis, the individual EGD cases (N>5000), the individual colonoscopy cases (N>3000), the detected early cancer cases in upper GI tract (N>30), the detected early cancer cases in lower GI tract (N>10), and the applications of ME, EMR and ESD techniques were statistically correlated with the performance speed of ESD fellows (P<0.05). Applications of NBI, ERCP and EUS techniques before ESD training were not statistically correlated with the performance speed of ESD fellows (P>0.05). The performing speed of ESD fellows was negatively correlated with the perforation rate of ESD fellows (P<0.01). However, according to multivariable linear regression model, EMR and ESD techniques were statistically correlated with the performing speed of ESD in a positive manner (P<0.05).

1.4. Conclusion: This study provided us with the enough theoretical bases to select the appropriate ESD training fellows in the future.

2. Introduction

Endoscopic Submucosal Dissection (ESD), as a safe and effective endoscopic minimally invasive therapy with advantages of small trauma, fast recovery and complete removal of larger lesions and with lower recurrence rate, has turned into the first choice for the treatment of early gastrointestinal cancer and precancerous lesions [1]. However, the performing difficulty limited the clinical

development of this technique. Therefore, the acquisition of more ESD-mastered endoscopic doctors and the popularization of ESD technology through effective ESD training has been a concern for those gastrointestinal endoscopic doctors. Moreover, researches on the selection of suitable endoscopic doctors for ESD training is worthwhile deserved in the future.

In Japan, the mode of ESD training varies from hospital to hospital. But generally speaking, the modes include: 1) accumulating basic knowledge and skills; 2) learning from the experts' live demonstration; 3) assisting the experts with their performance of ESD as an assistant; 4) performing on the model (animal model in ex vivo/in vivo); 5) completing ESD operation under the supervision of the mentor [2-5]. In China, specific research on the ESD training mode has not yet been reported. The expert consensus on the ESD treatment of gastrointestinal tract lesions in 2012, however, following the principles of evidence-based medicine, with reference to a large number of domestic and foreign literatures and experts' experiences and the actual situations over the country, indicated that the principal operators of ESD and their assistants must be technical trained [7] and then placed some requirements on the ESD training for lesions at different sites. For gastric ESD training, the personnel operating must be qualified after four stages' learning: 1) complete mastery of ESD related knowledge; 2) on-site observation; 3) animal experiments (in ex vivo or in vivo); 4) formal operation on the patients. For the beginners of ESD training, professor Fujita emphasized that at least 30 cases of operation experience could effectively improve the gastric ESD efficiency [6]. When entering the formal operation stage on the patients, we usually started with simple lesions, i.e. those located in the lower 1/3 of the stomach. For small and non-ulcerative lesions, we should complete at least 30 cases of gastric ESD under the guidance of a superior physician before we can operate independently [7, 8].

Both in China and Japan, the training modes underline practices on animal models, which may be isolated pig stomach or esophagus, living pig or computer simulator, etc. Studies have indicated that the application of these models in the early training improves students' operational skills. Early applications of simulation model in ESD training also contribute to acquire skills required for safe operation of ESD, especially in regions and hospitals with lower number of ESD cases [9]. Western scholars generally believe that real-world ESD operation shall be a significant part of structured ESD training [10]. ESD training had been undertaken in the Department of gastroenterology of Nanjing Drum Tower Hospital for more than 10 years and the cases of ESD operations during the past 3 years exceeded 1000 cases per year. More than 40 ESD training fellows who came from all over the country received ESD training in our center every year. For the sake of their skills acquisition, these ESD fellows are required to do systematic practices on isolated animal models in an ex vivo manner and then are arranged to begin practical ESD performing training before their real world operations, to perfect training efficiency and ESD learning curve.

Isolated pig stomach or esophagus, due to easier availability and lower price, has become an available simulator for early ESD training. Lots of practices on isolated pig's stomach or esophagus before formal operations on living pigs is feasible [11]. In one study from Korea, simulated ESD training with isolated pig's stomach showed preferable outcome. The outlet portion of the pig stomach model was closed by the operating forceps. The model was then placed in an airtight frame connected to electrodes. The inlet portion was connected to the outer cannula. Both of them were fixed together in the frame. The endoscope was inserted into the esophageal or gastric cavity through the outer cannula and inflated, followed by target positioning and marking. The mucosa was precut around the circumference of lesion and separated after submucosal injection before marking the mucosa. Animal models provided endoscopic doctors with more practical opportunities, more performing skills and preliminary practical experiences in a relatively short period under the guidance of ESD training experts. Our study thus included 41 fellows from various provinces who came to the Department of Gastroenterology, the affiliated Drum Tower Hospital of Nanjing University, Medical School for ESD training. They were assigned to complete the performance on the isolated pig esophagus model for 4 times before real operation on human body. By evaluating the quality of operation and analyzing the relevant indicators before the ESD training, this project aimed to explore how to select appropriate endoscopy doctor for ESD training, which could achieve better results and provide sufficient theoretical basis and technical supports for selecting the appropriate endoscopy doctors for ESD training in the future.

3. Material and Methods

3.1. Equipment and Material

Experimental conditions with isolated pig model in an ex vivo manner: Endoscope host (LUCERA CLV-260), electronic EGD (GIF-XQ240) and tip cap (D-201-1804) were all bought from Olympus Company, Japan. Dual scalpel (KD650L, Olympus, Japan) was used for both the mucosal incision and dissection. Entry needle (25ga-CE0086) for submucosal injection was provided by Boston Science (U.S.A.). The submucosal injection: methythioninium Chloride + epinephrine + normal saline mixture.

3.2. General Information of ESD Fellows

41 fellows were included in our study from various provinces of P.R. China who attended ESD training in our GI endoscopic center, the affiliated Drum Tower Hospital of Nanjing University, Medical School. The general information was collected in the datasheet including his or her name, age, gender, the individual performed EGD cases, the individual performed colonoscopy cases, the use of Narrow band image (NBI) technique, magnifying endoscopy (ME), Endoscopic Mucosal Resection (EMR), ESD, Endoscopic Ultrasonography (EUS), and Endoscopic Retrograde Cholangiopancreatography (ERCP), etc. Scores were calculated and then recorded by the trainer based on the proficiency of 41 fellows (as shown in the (Table 1).

Table 1: Proficiency-based Scores

	Never	Occasionally	Often
NBI	0	1	2
ME	0	1	2
EMR	0	1	2
ESD	0	1	2
EUS	0	1	2
ERCP	0	1	2

3.3. Isolated Animal Experiment

Separated esophagus of pigs with body weight of 50-100 kg was used as the objects of ESD operation. The outlet portion of the pig esophagus was closed with operating forceps. The model was placed in an airtight frame connected to electrode. The inlet portion was connected to the outer cannula and both of them were fixed together in the frame (as shown in (Figure1A and 1B)). The endoscope was inserted into the esophageal cavity through the outer cannula and inflated, followed by target positioning and marking. The mucosa was precut around the circumference and dissected after marking and submucosal injection. When the ESD operating finished, the integrity of the esophagus was detected for perforation by using immersion & insufflation method.

3.4. ESD Performance

ESD performance on isolated esophagus of pig followed standard ESD operating steps: marking, injection, incision,

and dissection, etc. Indexes below were observed and then recorded: ESD specimen size of the isolated esophagus, auxiliary needed instruments, mucosa incision time (thereafter to be referred as circumferential incision time, the time spent from the completion of marking to the completion of circummucosal incision, min), submucosal dissection time (thereafter to be referred as separation time, the time spent from the completion of circummucosal incision to the completion of submucosal dissection, min); total operating time (circumferential incision time + dissection time, min), size of the specimen (its length and width were recorded), the competition of dissection (complete en bloc resection, complete piecemeal resection, or incomplete resection); complications (perforation), etc. The specimen size (cm2) was calculated as the results of length (cm) multipled width (cm). ESD on isolated esophagus operation for four times were assigned for each fellow. The percentage of perforation (perforation number/total number×100%) was recorded accordingly if perforation actually occurred.

Figure 1A: Establishment of ESD isolated pig esophagus model;
Figure 1B: ESD fellows operating in vitro pig esophagus experiments;
Figure 1C: Establishment of ESD isolated pig esophagus and stomach model;
Figure 1D: ESD fellows operating in vitro pig esophagus experiments;
Figure 1E: ESD fellows operating in vitro pig esophagus and stomach experiments;
Figure 1F: ESD specimen of pig esophagus

3.5. Performing Speed of ESD on Isolated Esophagus of Pig Model

The average performing speed (specimen area per operation time) was used to evaluate the students' operative efficiency. The calculation method: area of the en-bloc specimen (cm2)/ the total performing time (min).

3.6. Statistical Analysis

All the data were analyzed by SPSS22.0 statistical software and measurement data expressed in Mean±Standard deviation (MEAN±SD). As for the individual EGD and colonoscopy cases, their performing methods of colonoscopy (single-person or double-person's operation), the detected early cancer cases in upper/lower GI tract, the use of NBI, ME, EMR, ESD, EUS, ERCP, etc.; the correlation between them and the performing speed (cm2/min) was analyzed by single factor linear regression. Multiple linear

regression method was used for the correlation of multiple factors (mastering those techniques) with the performing speed. P<0.05 was considered as statistical differences.

4. Results

4.1. General Statistics of ESD Fellows

Among the 41 ESD fellows, the male fellows were 26 doctors and the female covered about 15. And the average age was 36.07±4. 44-year-old ranging from 27 to 53 years old. The cases of EGD performance were ranging from 200 to 20000 and the cases for colonoscopy performance varied within 10 to 10000. The performing method of colonoscopy was by single person without assisting. The number of cases of early upper gastrointestinal tract cancer ranged from 0 to 200, and that of early lower digestive tract cancer ranged from 0 to 40. Their applications of techniques before the ESD training were summarized in (Table 2). Among the 41 participants, the average performing speed of ESD was calculated with the performing time and specimen size for the evaluation of quality of ESD operation. All the fellows completed the whole ESD performing. In terms of perforated percentage, there were 16 cases (16/41, 39.02%) without perforation, 15 fellows (15/41, 36.59%) with perforation rate of 25%, and 10 fellows with perforation rate of 50% (10/41, 24.39%).

Table 2: ESD Fellows' mastery of different endoscopic techniques before the ESD training

	Never(-person)	Occasionally(-person)	Ofte(-person)
NBI	2	24	15
ME	14	26	1
EMR	9	22	10
ESD	36	5	0
EUS	30	7	4
ERCP	33	2	6

4.2. Linear-Regression Analysis of ESD Fellows' Independent Operation Cases of EGD Before ESD Training and The Performing Speed

The ESD fellows' individual operation of EGD before ESD training was closely related with the performing speed. When performing EGD cases of fellows before ESD training were more than 5000, the performing speeds of the ESD training fellows were more stable above the linear regression analysis curve, indicating significant effects. P=0.0018 indicated the statistical significance (as shown in (Figure 2)).

4.3. Linear-Regression Analysis of ESD Fellows' Independent Operation Cases of Colonoscopy Before ESD Training and The Performing Speed

The ESD fellows' independent operation cases of colonoscopy before ESD training were closely correlated with the performing speed. Those whose individual performing cases of colonoscopy before ESD training were more than 3000 might have more stable performing speeds of ESD above the linear regression analysis curve, indicating remarkable effects. P=0.0001 showed significant statistical differences (as shown in (Figure 3)).

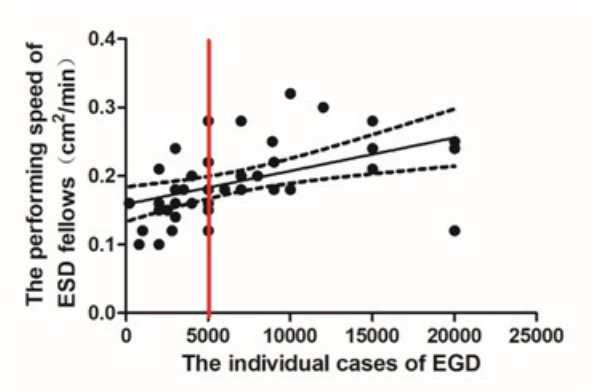

Figure 2: The ESD fellows' independent operation cases of EGD before training were closely related to the operating speed (N>5000 more remarkable) （P=0.0018）

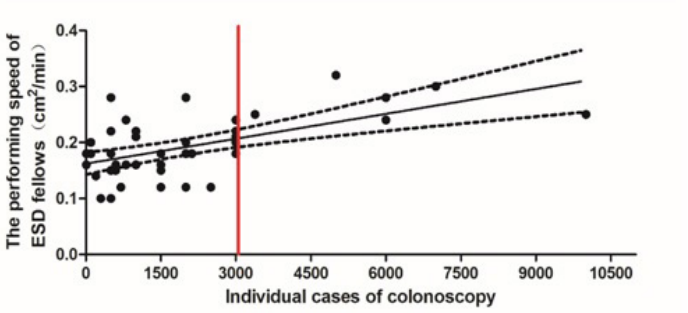

Figure 3: The ESD fellows' independent operation cases of colonoscopy before ESD training were closely related to the operating speed (N>3000 more remarkable) （P=0.0001）

4.4. Linear-Regression Analysis of the Detected Upper GI Early Cancer Cases Before ESD Training and The Performing Speed

The detected early cancer cases in upper GI tract before ESD training were positively related with the performing speed. When the fellows detected more than 30 cases, their performing speeds of ESD were more stable above the linear regression analytic curve, indicating remarkable effects. P=0.0003 means significant statistical differences (as shown in (Figure 4)).

4.5. Linear-Regression Analysis of the Detected Early Cancer Cases in Lower GI Tract Before ESD Training and The Performing Speed

The detected early cancer cases in lower GI tract before training were related with the performing speed in a positive manner. Those who detected more than 10 cases might have their more stable performing speeds above the linear regression analytic curve, indicating remarkable effects. P=0.0197 means statistical significance (as shown in (Figure 5)).

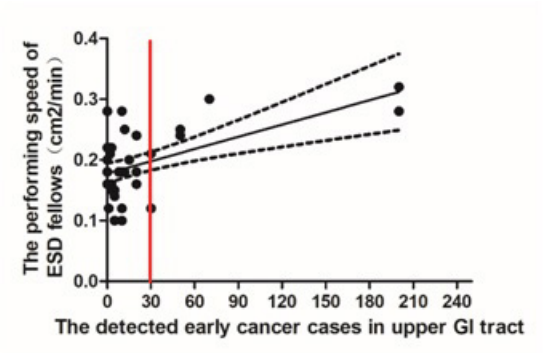

Figure 4: The detected early cancer cases in upper GI tract before ESD training were closely related to the operating speed (N>30 more remarkable) (P=0.0003)

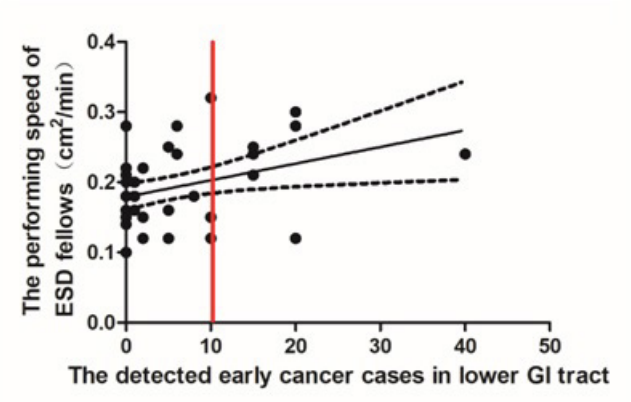

Figure 5: The detected early cancer cases in lower GI tract before training were closely related to the operating speed (N>10 more remarkable) (P=0.0197)

4.6. Linear-Regression Analysis of ESD Fellows' Application of NBI Technique and The Performing Speed

Linear-Regression analysis of ESD fellows' mastery of NBI and the performing speed showed that previous application of NBI was not significantly correlated with the performing speed, and P=0.5329 showed that there was no statistical significance (as shown in (Figure 6)).

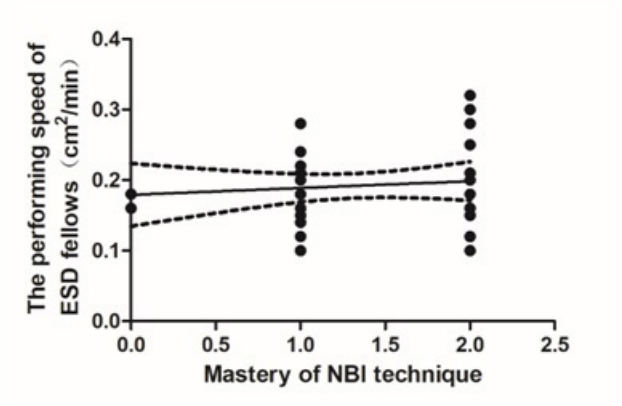

Figure 6: ESD fellows' mastery of NBI was not significantly correlated with the performing speed without statistical significance (P>0.05)

4.7. Linear-Regression Analysis of ESD Fellows' Previous Application of ME Technique and The Performing Speed

Linear-Regression analysis of ESD fellows' previous application of ME and the performing speed showed that previous application of ME technique was closely correlated with the performing speed, and P=0.0478 showed statistical differences (as shown in (Figure 7)).

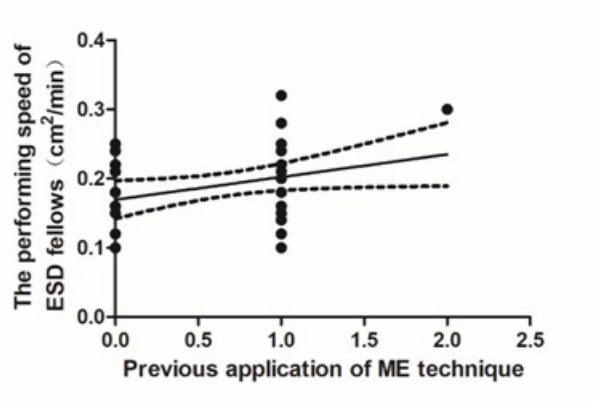

Figure 7: Previous application of ME was closely related to the performing speed with differences statistically significant (P=0.0478)

4.8. Linear-Regression Analysis of ESD Fellows' Previous Application of EMR Technique and The Performing Speed

Linear-Regression analysis of ESD fellows' previous application of EMR and the performing speed showed that previous application of EMR was significantly correlated with the performing speed, and P=0.0196 showed significant difference (as shown in Figure 8).

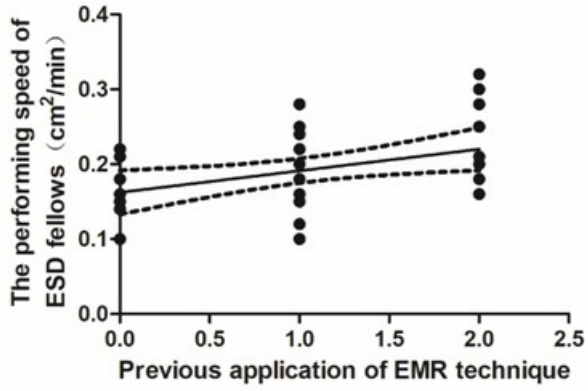

Figure 8: Previous application of EMR was closely related to the performing speed with differences statistically significant (P=0.0196)

4.9. Linear-Regression Analysis of ESD Fellows' Previous Application of ESD Technique and The Performing Speed

Linear-Regression analysis of ESD fellows' previous application of ESD and the performing speed showed that previous application of ESD was significantly correlated with the performing speed, and

P=0.0003 showed differences statistically significant (as shown in Figure 9).

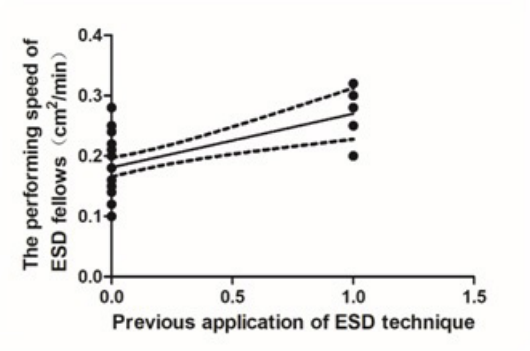

Figure 9: Previous application of ESD was closely related to the performing speed with differences statistically significant (P=0.0003)

4.10. Linear-Regression Analysis of ESD Fellows' Previous Application of EUS Technique and The Performing Speed

Linear-Regression analysis of ESD fellows' previous application of EUS and the performing speed showed that previous application of EUS has no obvious relations with the performing speed. P=0.7668 showed that there was no statistical significance (as shown in Figure 10).

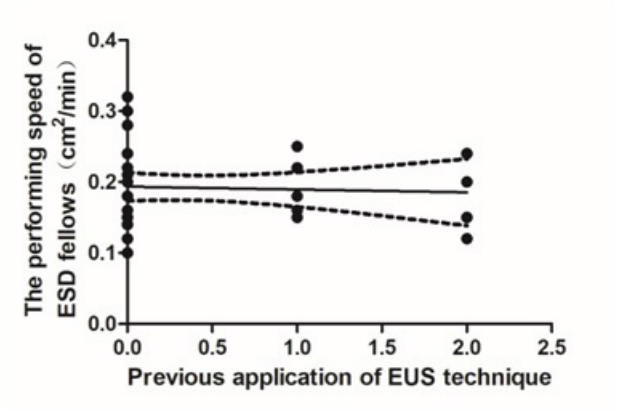

Figure 10: Previous application of EUS has no relations with the performing speed. The differences were not statistically significant (P=0.7668)

4.11. Linear-Regression Analysis of ESD Fellows' Previous Application of ERCP Technique and The Performing Speed

Linear-Regression analysis of ESD fellows' previous application of ERCP and the operating speed showed that previous application of ERCP has no apparent relations with the performing speed. P=0.5007 showed that there was no statistical significance (as shown in (Figure 11)).

4.12. Multiple Linear Regression Analysis Suggested That The EMR and ESD Techniques Were Closely Related to The Performing Speed with Statistical Significance (P<0.05)

As demonstrated in Table 3, it can be analyzed that the EMR and ESD techniques were closely related to the performing speed with statistical significance according to multiple linear regression analysis.

4.13. Correlation Analysis of ESD Fellows' Performing Speed and Perforation Rate

Correlation analysis of ESD fellows' performing speed and perforation rate showed that the former was negatively correlated with the latter with significant statistic difference (P<0.0001) (as shown in Figure 12). In addition, as for the cases of ESD fellows' performing EGD, the cases of individual colonoscopy, the detected early cancer cases in upper/lower GI tract, and previous use of NBI, ME, EMR, ESD, ERCP, EUS, etc. the correlation analysis of them with the perforation rate showed no statistical significance (P<0.05).

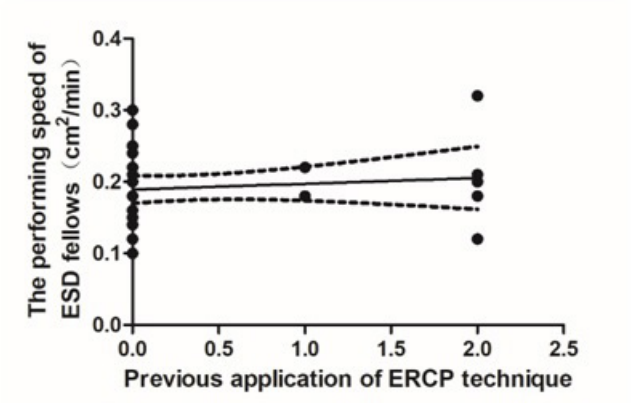

Figure 11: Previous application of ERCP has no relations with the performing speed. The differences were not statistically significant (P=0.5007)

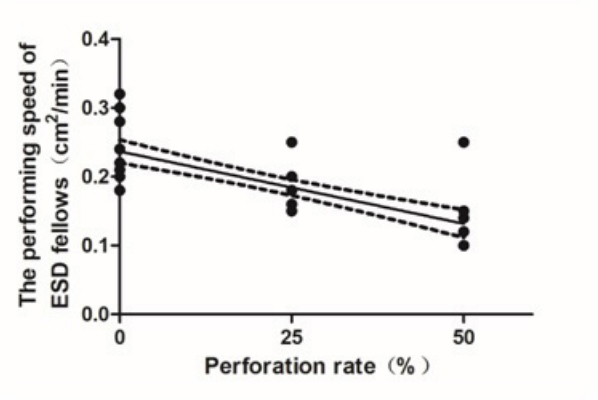

Figure 12: The performing speed of ESD was negatively correlated with the perforation rate with significant statistic differences (P<0.0001)

5. Discussion

The development of ESD technology enabled the early GI cancer and precancerous lesions treatment by endoscopic therapy and the complete resection of large-sized lesions [13]. The complicated operation steps, however, made it a difficult technique which could only be handled by well-trained endoscopic doctors, limiting its

clinical development. Further investigation is needed to select suitable endoscopic doctors for ESD training aiming to benefit the patients.

Table 3: Multiple linear regression analysis of multiple factors and the performing speed

Models	Nonstandardized Coefficients		Standardized Coefficients	t	Significance	Colinearity statistics	
	B	Standard error	Beta			Tolerance	VIF
Constants	0.184	0.019		9.889	0		
EGD	3.13E-06	0		1.661	0.107	0.359	2.783
	4.77E-06	0		0.694	0.493	0.168	5.96
Earlu Upper GI Cancer	0	0		0.796	0.432	0.274	3.645
Earlu Lower GI Cancer	0	0		0.335	0.74	0.187	5.355
ME	0.018	0.016		1.135	0.265	0.527	1.897
EMR	-0.35	0.015		-2.289	0.029	0.489	2.046
ESD	0.071	0.032		2.222	0.034	0.32	3.123
NBI	0.001	0.012		0.057	0.955	0.527	1.897
EUS	-0.014	0.01		-1.374	0.18	0.775	1.29
ERCP	0.001	0.009		0.1	0.921	0.847	1.181

Effective training is crucial to ESD fellows. Beginners must be able to operate ESD independently through systematic theories learning and, under the experts' supervision and guidance, real-world ESD operation observation, and lots of practice on simulated ESD ex vivo or vivo animal models. Specifically, the training should be determined on the basis of historical training, training device, surroundings, funds, learning phase, and fellows' will and other factors for the sake of the best outcome [8, 14]. The Endoscopy Center of the affiliated Drum Tower Hospital of Nanjing University, Medical School received over dozens of endoscopic doctors for ESD training each year. Based on theoretical teaching and clinical cases/pathology discussion, they are required to observe live demonstration, to practice on the ex vivo animal models and to perform real-world ESD operations on the patients. It could be expected to improve their ESD theories and operation levels from those above several aspects.

This study found that the cases of individual performing EGD were closely related to fellows' speeding speed with statistical significance. When historical EGD cases of the ESD fellow were more than 5000, their performing speeds were more stable, so was related with historical cases of individual performing colonoscopy more than 3000. In terms of the early upper and lower GI tract cancers, the cases they found over 30, 10, resulted more stabilized performing speed. In addition, previous applications of ME, EMR and ESD also were strongly correlated with the performing speed. Previous applications of NBI, ERCP and EUS techniques, however, had no relations with it. We could see that more standardized completion of EGD and colonoscopy performances are conductive to the acquiring of basic skills and the perfection of handling ESD. Being skilled in using the ME and EMR techniques contributed to the operational basis of ESD technology. Our research confirmed that there was no significant correlation between previous applications of ERCP and EUS techniques and the ESD performing speed. Most ESD fellows have, to a certain degree, solid basis on EMR (32/41), few fellows have ERCP (8/41) or EUS (11/41) technique application experiences. There was certain bias in the statistical results. While the large-sized ESD participants contributed to reducing the occurrence of bias. The multiple linear regression analysis suggested that previous applications of EMR and ESD techniques were closely related with the performing speed with statistically significant differences. Hence the ME and EMR technique constituted a part of the technological base for enhancement of the ESD training. In terms of perforation rate, there were 16 fellows (16/41, 39.02%) with their perforation rate of 0, 15(15/41, 36.59%) with their perforation rate of 25%, and 10 (10/41, 24.39%) with perforation rate of 50%. Correlation analysis showed that the performing speed was negatively correlated with the perforation rate, showing the statistical significance to a certain extent ($P<0.0001$). The performing speed suggested that it did not mean fast operation within a short period of time, but at an effective evaluation index for high-quality completion of ESD in ex vivo animal model tests. It represented the fellows' performing capacity with high quality. The higher the index went, the stronger the fellows' operational capabilities were, and surely the lower of the perforation rate was, which indicated the negative correlations between each other.

On the basis of our study, requirements on the selection of ESD fellows including over 5000 cases of historical single-person EGD operation, more than 3000 cases of single-person colonoscopy operation, at least 30 cases of upper GI early cancers, and 10 cases

of lower GI early cancers detected respectively, and previous use of ME, EMR and ESD techniques before the training were obviously helpful to ESD training. The performing speed was negatively related to the perforation rate during ESD performance. This study provided sufficient theoretical basis and support with us for the appropriate selection of endoscopic doctors for ESD training in the future.

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