

## Role of observation of live cases done by Japanese experts in the acquisition of ESD skills by a western endoscopist

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### Abstract

**AIM:** To evaluate the role of observation of experts performing endoscopic submucosal dissection (ESD) in the acquisition of ESD skills.

**METHODS:** This prospective study is documenting the learning curve of one Western endoscopist. The study consisted of three periods. In the first period (pre-observation), the trainee performed ESDs in animal models in his home institution in the United States. The second period (observation) consisted of visit to Japan and observation of live ESD cases done by experts. The observation of cases occurred over a 5-wk period. During the third period (post-observation), the trainee performed ESD in animal models in a similar fashion as in the first period. Three animal models were used: live 40-50 kg Yorkshire pig, explanted pig stomach model, and explanted pig rectum model. The outcomes from the ESDs done in the animal models before and after observation of live human cases (main study intervention) were compared. Statistical analysis of the data

included: Fisher's exact test to compare distributions of a categorical variable, Wilcoxon rank sum test to compare distributions of a continuous variable between the two groups (pre-observation and post-observation), and Kruskal-Wallis test to evaluate the impact of lesion location and type of model (*ex-vivo* vs live pig) on lesion removal time.

**RESULTS:** The trainee performed 38 ESDs in animal model (29 pre-observation/9 post-observation). The removal times post-observation were significantly shorter than those pre-observation ( $32.7 \pm 15.0$  min vs  $63.5 \pm 9.8$  min,  $P < 0.001$ ). To minimize the impact of improving physician skill, the 9 lesions post-observation were compared to the last 9 lesions pre-observation and the removal times remained significantly shorter ( $32.7 \pm 15.0$  min vs  $61.0 \pm 7.4$  min,  $P = 0.0011$ ). Regression analysis showed that ESD observation significantly reduced removal time when controlling for the sequence of lesion removal ( $P = 0.025$ ). Furthermore, it was also noted a trend towards decrease in failure to remove lesions and decrease in complications after the period of observation. This study did not find a significant difference in the time needed to remove lesions in different animal models. This finding could have important implications in designing training programs due to the substantial difference in cost between live animal and explanted organ models. The main limitation of this study is that it reflects the experience of a single endoscopist.

**CONCLUSION:** Observation of experts performing ESD over short period of time can significantly contribute to the acquisition of ESD skills.

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**Key words:** Endoscopic submucosal dissection; Training; Animal models; Early gastric cancer; Learning curve

**Core tip:** Endoscopic submucosal dissection is complex procedure which and requires intense and lengthy training. There is a consensus that an essential component of the training is observation of experts performing endoscopic submucosal dissection (ESD). In this study, we prospectively evaluated the impact of observation of experts performing ESD on the acquisition of ESD skills. Our data show a decrease in time needed to remove the lesion and a decrease in complication rate after the period of observation, which confirm that observing experts while performing ESD has significant impact in acquiring ESD expertise. Interestingly, there was no significant difference in the time needed to remove lesions in different animal models, which has implications in designing training courses or programs due to the substantial difference in cost between live animals and explanted organs.

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## INTRODUCTION

Endoscopic submucosal dissection (ESD) was developed in Japan in the late 1990s as an advanced, minimally invasive technique for endoscopic removal of early gastric cancers<sup>[1]</sup>. In Japan, ESD quickly gained popularity and has become the preferred modality for the management of superficial lesions containing early cancer or high grade dysplasia throughout the gastrointestinal tract<sup>[2-5]</sup>. The use of ESD instead of endoscopic mucosal resection (EMR) is supported by the well-documented higher *en-bloc* and curative resection rates as well as decreased local recurrence<sup>[4,6]</sup>. As a result, the technique of ESD has been disseminated to other Asian countries but has not been widely accepted in the United States, where superficial neoplastic lesions are still largely managed by EMR or laparoscopic resection. There is a number of reasons for this slow dissemination of ESD in the United States including the complexity of the procedure, long procedure times, higher complication rates and the lack of dedicated reimbursement code. However, the main obstacle to the wide availability of ESD in the West has been and remains the very flat learning curve and lack of training resources<sup>[7,8]</sup>.

A number of investigators have evaluated the learning curve of acquiring ESD skills but no definitive conclusions could be reached due to the differences among studies as far as the type of lesions included, degree of trainee supervision, type of training system, trainee exposure to animal models, definition of outcomes and, in the case of colonic ESD, the degree of prior experience with

gastric ESD<sup>[9-24]</sup>. Although in Japan, training approaches vary among institutions, typically ESD skills are acquired over the course of few years in the traditional time honored apprenticeship model. This approach is not applicable to Western endoscopists trying to learn ESD and, as a result, even greater variability in training pathways exists. Despite the significant variations in ESD training models around the world, there is a consensus that observation of experts performing ESD is an essential component of training<sup>[7,25,26]</sup>. Thus, observation of ESD cases is routinely recommended as part of any training algorithm yet its role has never been formally evaluated<sup>[7,25]</sup>. Therefore, we prospectively evaluated the impact of observation of Japanese experts performing ESD on the acquisition of ESD skills.

## MATERIALS AND METHODS

### Study design

This is a prospective study documenting the learning curve of one Western physician training in ESD. The trainee is an experienced endoscopist with background in advanced therapeutic endoscopy including endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound (EUS) and EMR but no prior experience with ESD.

The study consisted of three time periods. In the first period (pre-observation), the trainee performed ESDs in animal models in his home institution in the United States. The second period (observation) consisted of visit to Japan and observation of live ESD cases done by experts. The observation of cases occurred over a 5-wk period in 3 Japanese major referral centers. During the observation period, the trainee observed live ESD cases performed by expert Japanese endoscopist. The trainee observation involved the pre-procedure evaluation, the room set-up, the diagnostic and therapeutic portions of the procedure. During the third period (post-observation), the trainee performed ESD in animal models in a similar fashion as in the first period. The outcomes from the ESDs done in the animal models before and after observation of live human cases (main study intervention) were compared. The study protocol was approved by the Institutional Animal Care and Use Committee.

### ESD equipment and procedure

One of three animal models were used: (1) live 40-50 kg Yorkshire pig, (2) explanted pig stomach model; and (3) explanted pig rectum model. ESDs in the animal models were done using the Dual (KD-650L) and IT 2 (KD-612L) knives (Olympus America Inc., Center Valley, PA, United States). A "lesion" was first created by placing marks on the mucosa using the tip of the Dual knife. Injection of the submucosal space with mixture of normal saline and indigo carmine was then carried out to lift the lesion using a 25 g injection needle (NM-200U-0525, Olympus America Inc., Center Valley, PA, United States). That was followed by circumferential incision and sub-

**Table 1** Lesion characteristics

	Pre-observation	Post-observation	P value
Location	(n = 29)	(n = 9)	
Antrum/body	14	1	
Incisura/lesser curve	10	2	
Cardia	5	3	
Rectum	0	3	
Type of Model	(n = 29)	(n = 9)	0.08 <sup>1</sup>
Ex-vivo	20	9	
Live pig	9	0	
Size (mm <sup>2</sup> )	(n = 25)	(n = 9)	0.86 <sup>2</sup>
mean ± SD	1143.2 ± 515.8	1280.9 ± 882.4	
Median	1044.6 (452.4, 2277.7)	804.2 (510.5, 2777.2)	
(min, max)			

<sup>1</sup>Fisher's exact test; <sup>2</sup>Wilcoxon rank sum test.

mucosal dissection. Injection of saline was repeated as needed to maintain adequate submucosal cushion.

### Study outcomes

The main study outcome was lesion removal time in the animal model. The time for lesion removal was measured from the time the first mucosal mark was placed until the completion of the submucosal dissection. Secondary outcomes included successful lesion removal, *en-bloc* resection rate and complications.

### Statistical analysis

We performed Fisher's exact test to compare distributions of a categorical variable and the Wilcoxon rank sum test to compare distributions of a continuous variable between the two groups (pre-observation and post-observation). We used the Spearman coefficient to evaluate the correlation between the two continuous variables. We performed the Kruskal-Wallis test (a non-parametric alternative to one-way analysis of variance) to evaluate the impact of lesion location and type of model (*ex-vivo* vs live pig) on lesion removal time. Since physician's skill is expected to improve with cumulative experience, we used a regression model to assess the impact of training on lesion removal time while controlling for the sequence of lesion removal in addition to the comparison of lesion removal times without adjustment. All data analyses were performed using the SAS software version 9.3. (SAS Institute Inc., Cary, NC, United States).

## RESULTS

### Observation of live human cases

The trainee observed a total of 43 human ESD cases done by Japanese experts in three large volume Japanese academic centers over a period of 5 wk. The lesion location included 10 in the esophagus, 21 in the stomach and 12 in the colorectum (7 rectal and 5 colonic).

### ESD in animal models

The trainee attempted ESD in 38 lesions in animal

model. Twenty nine of the lesions were done in the pre-observation and nine in the post-observation period. Lesion characteristics and the type of animal model used are summarized in Table 1. We found that there was no significant difference in lesion sizes between pre- and post-observation cases (mean  $1143.2 \pm 515.8$  mm<sup>2</sup> vs  $1280.9 \pm 882.4$  mm<sup>2</sup>,  $P = 0.86$ ). Furthermore, lesion location and the type of model did not significantly affect lesion removal time ( $P = 0.31$  and  $P = 0.17$ , respectively by Kruskal-Wallis test). There was a significant negative correlation between removal time and the sequence of lesion removal (Spearman coefficient =  $-0.67$ ,  $P < 0.01$ ), indicating that the physician's skill was improving with cumulative experience.

The removal times post-observation were significantly shorter than those pre-observation (mean  $32.7 \pm 15.0$  min vs  $63.5 \pm 9.8$  min,  $P < 0.001$ ). To minimize the impact of improving physician skill, we compared removal times in the 9 lesions post-observation to the last 9 lesions pre-observation, and found that the removal times post-observation remained significantly shorter than those in pre-training (mean:  $32.7 \pm 15.0$  min vs  $61.0 \pm 7.4$  min,  $P = 0.0011$ ). Furthermore, we performed regression analysis with removal time as the response variable and sequence of lesion removal and observation (pre- vs post-observation) as explanatory variables. We found that the ESD observation significantly reduced the lesion removal time when controlling for the sequence of lesion removal ( $P = 0.025$ ). For all successful ESDs the lesion was removed *en-bloc*. There was a trend towards decreased rate of failure of lesion removal (4/29 pre-observation versus 0/9 post-observation) and decreased rate of complications (4/29 pre-observation versus 0/9 post-observation), although the difference did not reach statistical significance ( $P = 0.55$ ). All complications consisted of perforation.

## DISCUSSION

ESD is a technically demanding procedure requiring a high level of endoscopic skill. The ESD learning curve is very flat and, in the typical Japanese training program, the trainees will acquire the background knowledge and the manual skill to perform ESD over a period of 3-4 years<sup>[7,8,25]</sup>. Although in Japan there is no universally accepted training algorithm, most programs follow the traditional apprentice/mentor model<sup>[25]</sup>. Trainees will progress in stepwise fashion starting with the accumulation of basic knowledge for lesion evaluation and procedure indications. That is followed by a lengthy period of observation of experts in action. The trainees will then assist in procedures and finally start performing ESD under supervision<sup>[25]</sup>. Unfortunately, the extensive Japanese experience in ESD training cannot be directly applied in the West due to a number of substantial differences. Importantly, in the West, there is only a handful of highly qualified experts in ESD. Therefore, observing large number of cases over long period of time is not feasible

in the home country<sup>[8,9,25]</sup>. As such, the typical Western approach to ESD training follows the steps outlined in our study: (1) self-study and hands-on training in animal models to consolidate the theoretical knowledge and augment the acquisition of technical skills; (2) brief visit to expert Japanese to observe experts performing ESD. At this time, it is well accepted that most highly experienced endoscopists performing ESD are located in Japan. In the West, there are very few experts and high-volume centers, which limit the opportunities to pursue ESD training. Our trainee spent 5 wk in Japan, observing a total of 43 live ESD procedures. Based on this experience, we encourage at least 4-5-wk visit to a high volume ESD center in Japan. We recommend this visit to occur after the endoscopist has already trained on animal models and acquired basic ESD skills; (3) further hands-on training in models to continue practice of newly acquired skills; and (4) start performing “easier” ESD cases in humans and then gradually expanding the degree of difficulty<sup>[7,8]</sup>.

Despite outlined differences, observation of experts in action is routinely recommended in both Japanese and Western training environments<sup>[7,25]</sup>. The belief that observation of live cases would be beneficial in ESD training is purely based on the time honored approach of learning procedures in Medicine: “see one, do one, teach one”. Our data, for the first time confirm that observing live cases done by experts, indeed, significantly contributes to the acquisition of ESD technical skills. Furthermore, we noted a trend towards decrease in failure to remove lesions and decrease in complications after the period of observation.

Importantly, there was no significant difference in the time needed to remove lesions in different animal models. This finding can have important implications in designing training programs due to the substantial difference in cost between live animal and explanted organ models. The main perceived advantage of the live models is that they may provide more realistic environment and may allow the trainee to treat ESD related bleeding which significantly contributes to the procedure complexity in humans<sup>[11]</sup>. It is our subjective impression, confirmed by our objective measurements (*e.g.*, time needed to remove the lesion), that the use of live pigs does not significantly enhance the training experience because bleeding is a rare occurrence and tends to be of a small magnitude compared with that in humans. Finally, we demonstrate that short period of observation of live cases can have significant impact on ESD technical skills. That makes the training algorithm described by us feasible because it requires a relatively short time period to be spent away from the trainee home institution thus minimizing problems related to clinical workload coverage and financial constraints related to an extended stay in Japan.

Our study is not without limitations. It is based on a single trainee experience and the findings may not be applicable to all trainees, specifically to trainees in the East. The technical expertise and background of endoscopists embarking on ESD in the West differ significantly than

those of their Eastern counterparts. At present, in Japan, the typical trainee learning ESD is a GI fellow. On the other hand, in the West, physicians embarking on ESD tend to be otherwise more mature and well experienced therapeutic endoscopists typically with background in ERCP and EUS. From that perspective, our Western trainee matches well with the prototypical Western endoscopist perusing ESD training. In our study, we used animal models to evaluate pre- and post-observation evaluation of technical skills. This brings some limitations including the different magnitude of procedure related bleeding and, most importantly, the need to create virtual lesions in the animal model. Nevertheless, training in models is an essential part of the Western training experience and since the mentor/apprentice approach will not be feasible in the foreseeable future, the use of models will remain a key component in ESD training in the West. Finally, our post-observation sample size is relatively small which did not allow us to apply a multivariate regression model. After completing the 9 post-observation cases, our trainee started performing ESD cases in humans. Since the performance of ESD in humans can directly impact on the acquisition of ESD skills we could not enroll additional post-observation animal cases. Nevertheless, we believe that our experience is representative of the number of animal model ESDs that most Western endoscopists will perform as part of their training.

In summary, we found that observation of Japanese experts performing ESD over relatively short period of time can significantly contribute to the acquisition of ESD skills. A trend toward decreased rate of complications and decreased failure to remove lesions was also noted. Performing ESDs in explanted organ model appears to provide adequate environment for training which can decrease the cost related to the use of live animal models.

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## COMMENTS

### Background

Endoscopic submucosal dissection (ESD) represents an important advancement in the therapy of early GI cancers, offering the potential for *en-bloc* removal of mucosal and submucosal tumors, with high curative rates. Despite these advantages, ESD is a challenging procedure, requiring advanced endoscopic skills and focused training to acquire these skills. Thus, there has been a recognized need for a structured training system for ESD to enhance trainee experience and to reduce the risks of complications and inadequate treatment. A number of training algorithms has been proposed in Japan with the goal to standardize ESD training. These algorithms however cannot be directly applied in the West due to substantial differences including the availability of highly qualified mentors, the trainee's background and the type of pathology seen.

### Research frontiers

An important part of the training is watching and learning from experts performing live ESD cases. This is easily accomplished in Asian country where ESD



is performed in many hospitals and ESD experts are readily available. In the West, where ESD has had a slower dissemination and acceptance, only very few medical centers perform ESD cases routinely. Thus, at this time, as the most highly experienced endoscopists performing ESD are in Japan, a visit to a specialized Japanese center will most likely remain, for some time, an essential component of ESD training in the West. The use of animal models in ESD training is a highly debated topic and, while not a requirement in Japan, these models can be a valuable resource when training in the West. Studies showed that practicing on animal models can augment the acquisitions of skills in low-volume centers.

### Innovations and breakthroughs

The study made two important observations which can have significant consequences for the Western endoscopist embarking in ESD training. First, as expected, there was a significant improvement in reducing operative time and complications after observing ESD experts performing live cases. The novelty of this finding consists in the significant improvement in ESD skill even after only a short observation period of several weeks. In addition, this study showed that there is no difference in the time needed to remove lesions when using live animal models versus harvested organs. This finding has implications in designing training courses or programs due to the substantial difference in cost between live animals and explanted organs.

### Applications

Following the traditional Japanese algorithm, the ESD training spans over the course of 3-4 years. This experience cannot be directly applied in the West, as the gastroenterologist embarking on learning ESD is usually a well-established advanced endoscopist. The algorithm proposed in this manuscript, which includes a 4-6-wk visit to Japan, appears to be a more feasible and realistic approach to ESD training in the West because it requires a relatively short time period to be spent away from the trainee home institution thus minimizing problems related to clinical workload coverage and financial constraints related to an extended stay in Japan.

### Terminology

Early gastric neoplasms are malignant tumors which involve only the mucosa and submucosal space, thus being amenable to endoscopic removal. An animal model is a living animal or harvested organ from an animal used during the research and investigation of human disease, for the purpose of better understanding the disease process without the added risk of harming an actual human.

### Peer review

The manuscript entitled "The Role of Observation of Live Cases Done by Japanese Experts in the Acquisition of Endoscopic Submucosal Dissection Skills by a Western Endoscopist" by Draganov *et al* reported the usefulness of hospital visit to learn the skill of ESD.

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