A Newly Designed Polyvinyl Alcohol Hydrogel-Based Gastric ESD Simulator for Trainees: A Pilot Study

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Abstract

Background

Endoscopic submucosal dissection (ESD) is a useful option for the treatment of a variety of digestive diseases but has the disadvantage of difficulty in acquiring skills. We developed a new polyvinyl alcohol hydrogel (PVA-H)-based gastric ESD simulator and evaluated its usefulness for training with a group of experts.

Methods

A new gastric ESD simulator was constructed with three modules (esophagus, gastric wall, and electric). The expert group tested ten ESD sessions and evaluated the simulator with questionnaires on eight items related to ESD procedures using a 7-point Likert scale.

Results

Compared with the real human stomach, the new ESD simulator showed no inferior success rate in lifting of the submucosal layer (5.00 [4.00–6.00]), cutting of the submucosal layer (6.00 [5.00–6.00]), visibility by bubble (4.00 [4.00–6.00]), thickness of the muscle layer (4.00 [4.00–5.00]), combination of the three layers (6.00 [6.00–7.00]), size of the ESD sheet (6.00 [5.00–6.00]), and connectivity of the electrode (6.00 [6.00–7.00]).

Conclusion

A new PVA-H-based gastric ESD simulator can be helpful for training before performing real human gastric ESD.

Background

Endoscopic submucosal dissection (ESD) is a widely used endoscopic technique for the treatment of gastrointestinal diseases such as early gastric cancer, esophageal cancer, colon cancer, and achalasia [1–5]. However, ESD requires a long time to acquire a high level of technical experience, and the complications and prognoses of patients are dependent on the skill level of the operator [6].

Some simulators that mimic gastric ESD have been introduced to reduce the burden on endoscopists and improve patient safety. However, there are several limitations compared with real gastric ESD in a human model. Animal models, such as *ex vivo* and *in vivo* porcine models, differ in elasticity from humans and are expensive to prepare [7, 8]. In addition, there are ethical concerns and limitations in regards to reusability. To overcome these limitations, an ESD simulator using artificial tissue was introduced, but it was impossible to lift the submucosal layer [9].

Recently, a new artificial ESD simulator, Endogel (Sunarrow, Japan), was developed for ESD/ Peroral Endoscopic Myotomy (POEM) training [7, 10]. Endogel is a composite plate laminated with three different types of polyvinyl alcohol hydrogel (PVA-H) sheets. The PVA-H sheets contain a lot of moisture, so it is easy to control the stiffness. Different types of PVA-H sheets can be laminated with different elasticity. It is possible to simulate procedures such as mucosal incision, submucosal dissection, and muscle layer myotomy with PVA-H sheets mimicking the mucosa and submucosa [10]. However, there are some limitations to the Endogel. First, the Endogel is quite expensive and not available in some countries. Therefore, we have developed a new gastric ESD simulator that is inexpensive and easily accessible and evaluated its usefulness for training with a group of experts.

Methods

Participants

The study was approved by the SMG-SNU Boramae Medical Center Institutional Review Board (IRB No. 07-2020-17). Five experts in ESD were recruited to assess the validity of the ESD simulator in June 2020 at Seoul National University Boramae Medical Center, Seoul, Korea. The expert group members were experienced with gastric ESD in more than 500 human models and 50 animal models.

New Pva-h Based Gastric Esd Simulator

New PVA-H based gastric ESD simulator is composed of three modules: the esophagus module for endoscopic insertion, gastric wall module for injection and cutting, and electric module for radiofrequency current conduction and return function (Fig. 1A). The esophagus module was produced using stereolithography 3D printing (OMG SLA 660 3D printer, XIAMEN ZHISEN ELECTRO. EQUIP., Quanzhou, China) and silicone molding technique (EchoFlex 0030, Smooth-On Inc., PA, USA) [11, 12]. The gastric wall module was produced using a 3-layered PVA-H (PVA 98-98.8% hydrolyzed, MW 146,000-186,000, Thermo Fisher Scientific, Inc., MA, USA) sheet (Fig. 1D). The size of the gastric wall module is 17 cm × 12 cm × 1.7 cm and is composed of a 3-layered PVA-H sheet. The first layer is the mucosa layer, the second layer is the submucosa layer, and the third layer is the proper muscle layer. Different concentrations of PVA and additives were used to achieve the appropriate mechanical properties (elongation and tensile strength) of each layer. Each layer was tightly attached together to avoid detachment during lifting and incision. PVA-H layers were polymerized by 1–2 cycles of freeze–thaw technique. The final material properties and thickness of each layer were optimized based on the lifting thickness of the mucosal layer and the incision of the submucosal layer. The electric module has dual electrodes (KODE plate, KODE medical, Ind., Seoul, Korea) connected to the gastric wall module that conduct the electric current and monitor tight attachment (Fig. 1). Our tests of the gastric ESD simulator were conducted with a standard single-channel endoscope (GIF-H290; Olympus Optical), ITknife 2 (KD-611L; Olympus, Japan), electrosurgical unit (ERBE VIO 300D; Erbe, Germany), dual knife (KD-655Q; Olympus, Japan), soft transparent hood (D-201-13404; Olympus, Japan), and injection of glycerol (10 % glycerol and 5 % fructose; Chugai Pharmaceutical, Japan) with a small amount of indigo carmine and 0.1 % epinephrine.

Outcome Measures

Participants assessed the new PVA-H-based gastric ESD simulator with a newly developed score sheet. A score sheet is a self-administered questionnaire using a 7-point Likert scale and contain the following topics: (1) lifting of the submucosal layer; (2) cutting of the submucosal layer; (3) visibility by bubble; (4) thickness of the muscle layer; (5) combination of the three layers; (6) size of the ESD sheet; and (7) connectivity of the electrode.

Statistical analysis

Statistical analysis was conducted using SPSS software, version 21 (IBM Corp., Armonk, NY, USA). Continuous variables are reported as the medians with interquartile ranges.

Results

All participants finished gastric ESD successfully without malfunctions. Five gastroenterologists estimated the performance of the new ESD simulator.

Outcomes

Compared with the real human stomach, the new simulator showed similar performance in lifting of the submucosal layer (5.00 [4.00–6.00]), cutting of the submucosal layer (6.00 [5.00–6.00]), visibility by bubble (4.00 [4.00–6.00]), thickness of the muscle layer (4.00 [4.00–5.00]), combination of the three layers (6.00 (6.00–7.00)), size of the ESD sheet (6.00 [5.00–6.00]), and connectivity of the electrode (6.00 [6.00–7.00]) (Table 1). All participants agreed that the new PVA-H-based gastric ESD simulator provided reasonable results for human gastric ESD training.

Table 1
Evaluation scores of the newly designed polyvinyl alcohol hydrogel-based gastric ESD simulator

Index	Score
Lifting of the submucosal layer	5.00 (4.00–6.00)
Cutting of the submucosal layer	6.00 (5.00–6.00)
Visibility by bubble	4.00 (4.00–6.00)
Thickness of the muscle layer	4.00 (4.00–5.00)
Combination of the three layers	6.00 (6.00–7.00)
Size of the ESD sheet	6.00 (5.00–6.00)
Connectivity of the electrode	6.00 (6.00–7.00)
Scores were assigned using a 7-point Likert scale (scale: 1 = strongly disagree; 7 = strongly agree).	
Values are presented as the median (range).	

Discussion

ESD is an effective option to treat a variety of gastrointestinal diseases. However, it requires a lot of experience and time to minimize ESD-related complications such as bleeding and perforation. Various ESD simulators have been introduced to provide ESD-related training opportunities. Live porcine models are the most commonly used models for gastric ESD training. However, there are many complex issues with ESD training using porcine models, such as animal ethics, cost, endoscopic room, and infection. In addition, the gastric mucosa of pigs has a large amount of oil, is thick, and the size and anatomical structure are different from those of humans. Recently, an artificial ESD simulator was introduced. However, the Endogel is difficult to purchase and since the incised PVA-H sheet is not curled, continuous resection of the lesion is difficult.

The advantages of the new PVA-H-based ESD simulator are as follows. First, any conventional endoscopic equipment is fully compatible with this new PVA-H-based ESD simulator. Second, the esophageal module is more effective in practicing gastric ESD. Third, since the angle of the ESD sheet can be adjusted, the trainee can practice gastric ESD with lesions in various locations. Because the size of the ESD sheet is wide enough, the trainee can create multiple lesions and practice gastric ESD several times. Fourth, since the gastric ESD process can be viewed directly and through the monitor, it can help improve the proficiency of the practitioner. Fifth, the process of mucosal lifting and cutting are very similar to human gastric ESD. Sixth, the amount of foam generated from the PVA-H sheet does not interfere with the procedure. Seventh, during gastric ESD, electric circuit connection and shock problems related to operator safety do not occur to the trainee. Ninth, the new gastric ESD simulator is inexpensive. The approximate price of the simulator is $270 and recycled ESD-related accessories can be used. The new gastric ESD simulator may be a good alternative to not using Endogels due to price and availability.

The disadvantages of the new PVA-H-based ESD simulator are as follows. First, when electrical stimulation is applied to the PVA-H, smoke is emitted, so sufficient ventilation is required when practicing gastric ESD. All materials used in the gastric wall modules are made of edible grade materials or ingredients that are harmless to the human body. Because moisture is contained in the PVA-H sheet, sufficient sealing and refrigeration are required when storing the PVA-H sheet. As the PVA-H sheet is not culled like a gastric wall, it is necessary to attach a cap to the end of the endoscope during practice.

Limitations Of The Study

This study has some limitations. First, selection bias could be present due to the single-center focus and small number of participants. Second, our simulator was compared to only human gastric ESD and not compared to other simulators, such as animal models. Third, because only the expert group participated in the evaluation, no evaluation was made by trainees; therefore, further evaluation with participants of different skill levels is necessary. Fourth, it is difficult to practice ESD for a lesion located on a curved surface because the ESD sheet is made only on a flat surface.

Conclusions

The new ESD simulator has several advantages, such as improved realism and affordable cost. We believe that a new gastric ESD simulator will help improve the practitioner's skills, and ultimately improve patient safety and prognosis.

Abbreviations

ESD
endoscopic submucosal dissection
PVA-H
polyvinyl alcohol hydrogel

Declarations

Acknowledgements

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Competing interests

The authors declare that they have no competing interests.

Authors’ contributions

DSL and JHL made the concept and design. DSL, JWK, and JHL wrote the first draft of the manuscript, which was edited and revised by JHL and JWK. DSL, JWK, BGK, JBJ and JHL undertook a data collection and analysis. All authors have read and approved the manuscript.

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Availability of data and materials

The dataset used in the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the SMG-SNU Boramae Medical Center Institutional Review Board (IRB No. 07-2020-17). All participants who were included gave written consent.

Consent for publication

All included participants gave written consent.

Competing interests

The authors declare that they have no competing interests.

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References

1. Kang KJ, Kim KM, Min BH, et al. Endoscopic submucosal dissection of early gastric cancer. Gut Liver. 2011;5:418–26.
2. Gotoda T, Yamamoto H, Soetikno RM. Endoscopic submucosal dissection of early gastric cancer. J Gastroenterol. 2006;41:929–42.
3. Ohkura Y, Iizuka T, Kikuchi D, et al. Endoscopic submucosal dissection for early esophageal cancer associated with achalasia. Turk J Gastroenterol. 2013;24:161–6.
4. Holmstrom AL, Aadam AA, Hungness ES. Submucosal endoscopy. Techniques in Gastrointestinal Endoscopy. 2018;20:211–7.
5. Pasricha PJ, Hawari R, Ahmed I, et al. Submucosal endoscopic esophageal myotomy: a novel experimental approach for the treatment of achalasia. Endoscopy. 2007;39:761–4.
6. Odagiri H, Yasunaga H. Complications following endoscopic submucosal dissection for gastric, esophageal, and colorectal cancer: a review of studies based on nationwide large-scale databases. Ann Transl Med. 2017;5:189.
7. Mizuno K, Sato H, Hashimoto S, et al. A novel training model composed of nonbiological materials for endoscopic submucosal dissection. Gastrointest Endosc. 2016;84:373–4.
8. Ohata K, Nonaka K, Misumi Y, et al. Usefulness of training using animal models for colorectal endoscopic submucosal dissection: is experience performing gastric ESD really needed? Endosc Int Open. 2016;4:E333–9.
9. Chen MJ, Wang HY, Chang CW, et al. A novel artificial tissue simulator for endoscopic submucosal resection training - a pilot study. BMC Gastroenterol. 2016;16:112.
10. Sato H, Mizuno KI, Sato Y, et al. Development and use of a non-biomaterial model for hands-on training of endoscopic procedures. Ann Transl Med. 2017;5:182.
11. XIAMEN ZHISEN ELECTRO. EQUIP. CO. LTD. Product brochure [Internet]. c2020[cited 2020 Dec 30]. Available from: http://www.zero-tek.com/en/SLA660Lite.html. In.
12. Smooth-On. Inc., Product brochure [Internet]. c2020[cited 2020 Dec 30]. Available from: https://www.smooth-on.com/products/ecoflex-00-30/. DOI.

Figures

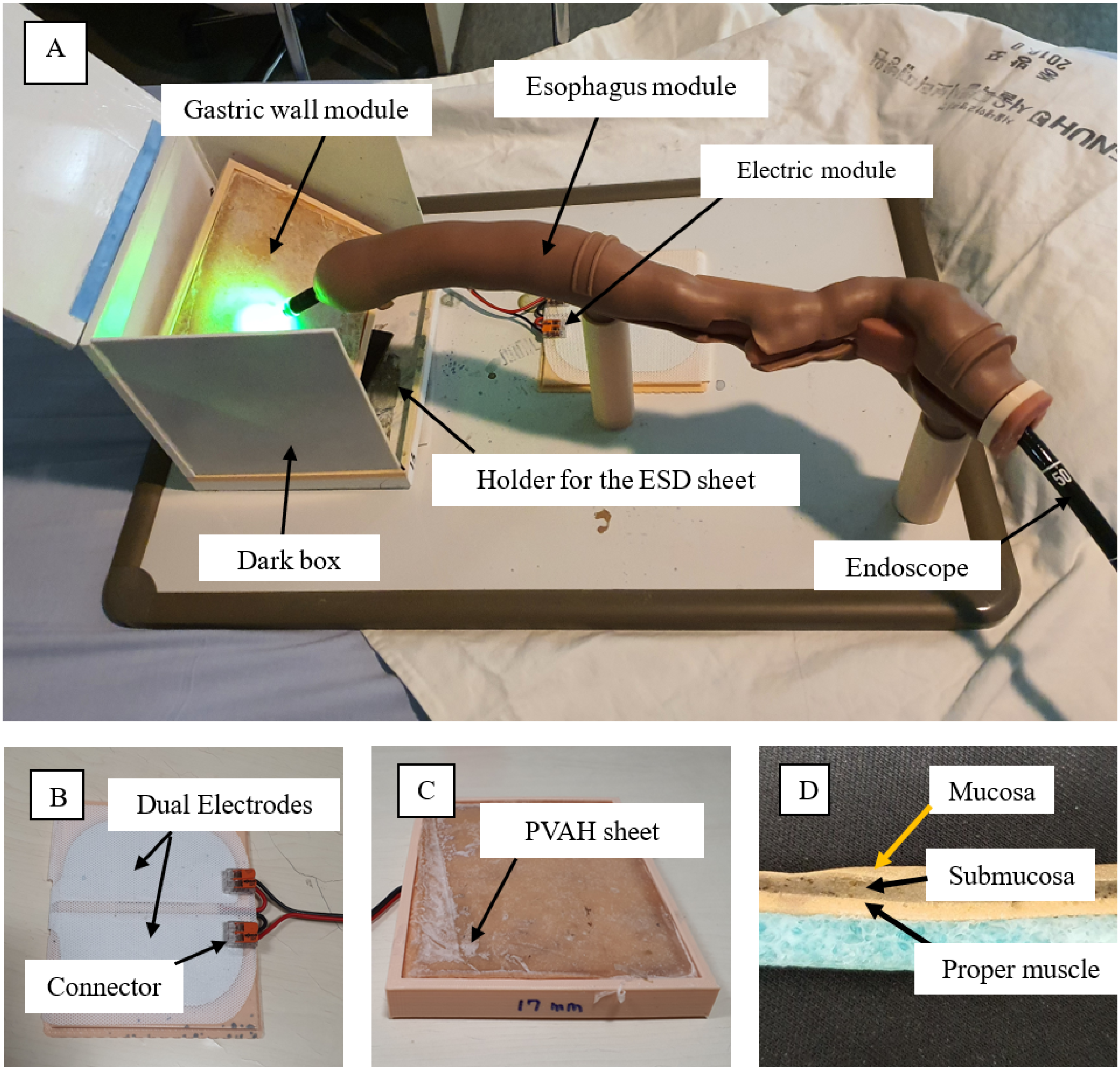

Figure 1

(A) The gastric endoscopic submucosal dissection (ESD) simulator is composed of three modules: the esophagus module for endoscopic insertion, gastric wall module for injection and cutting; and electric module for electric signal. (B) Electric current is supplied to the simulator through the electric module. (C) The gastric wall module is connected to electric module (D) The gastric wall module was produced with three layers of different type of polyvinyl alcohol hydrogel (PVA-H) sheets.

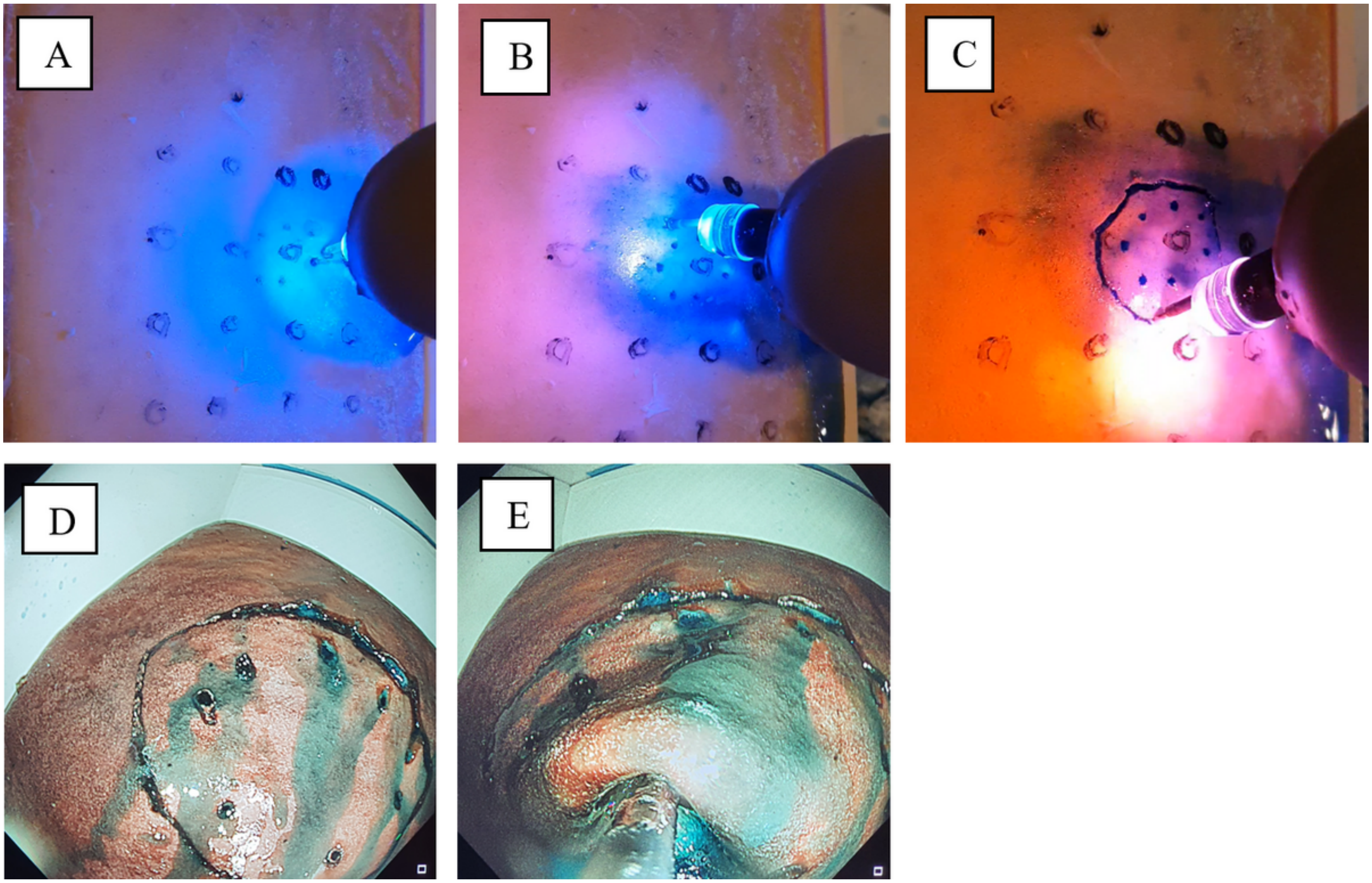

Figure 2

(A) Marking, view from above the simulator (B) submucosal injection, view from above the simulator (C) mucosal incision, view on the monitor (D) mucosal layer dissection, view on the monitor and (E) submucosal dissection, view on the monitor.

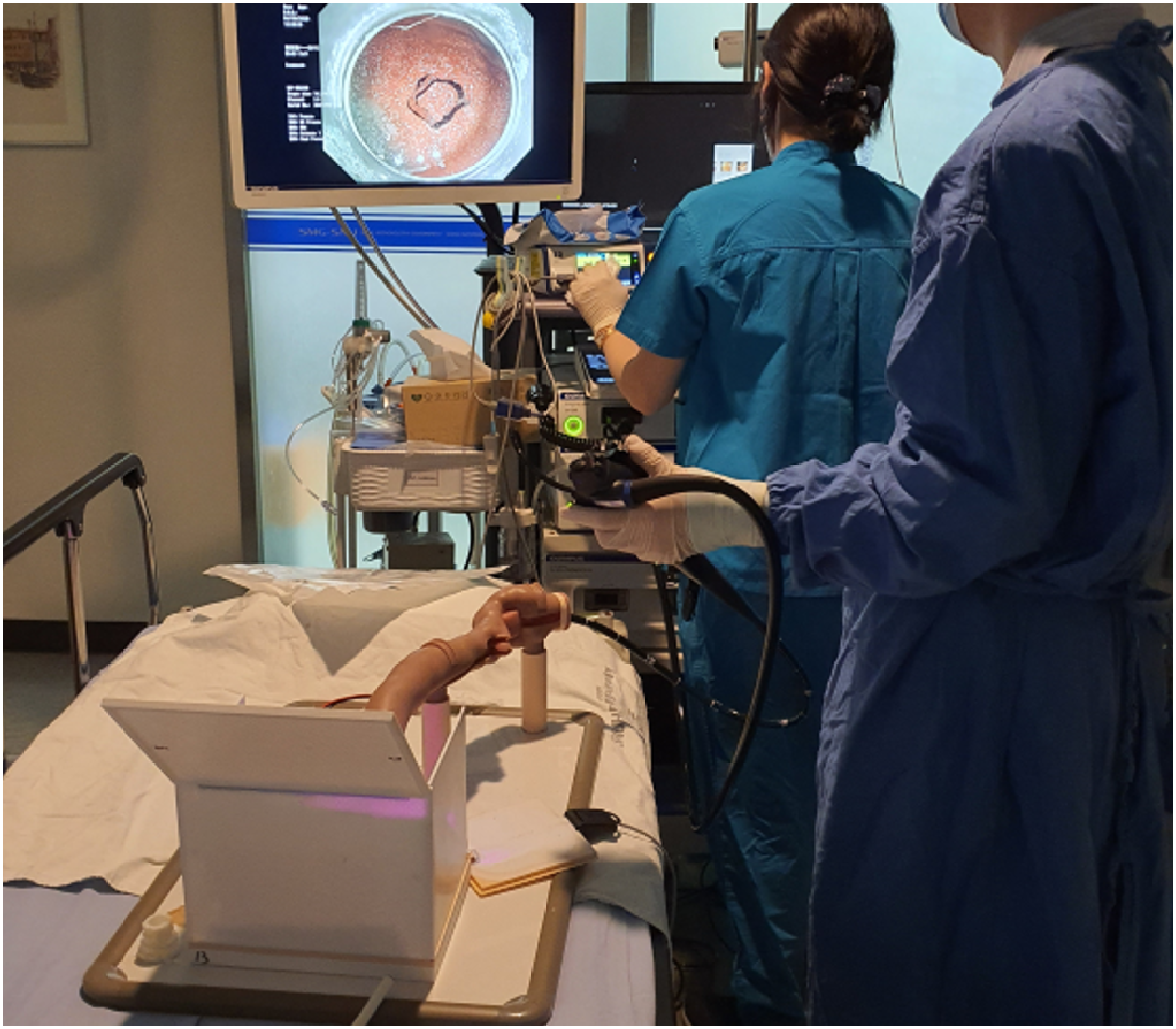

Figure 3

Demonstration of the gastric endoscopic submucosal dissection simulator.

Supplementary Files

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- Evaluationscoressheets.docx