

Ex vivo comparison of electrocautery-enhanced delivery of lumen-apposing metal stents matching electrosurgical workstations during EUS-guided gallbladder drainage

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ABSTRACT

Background and Objectives: EUS-guided gallbladder drainage (EUS-GBD) has become one of the recommended treatments for patients with high-risk acute cholecystitis. However, the gallbladder reportedly collapsed due to bile leakage, which was a disadvantage that affects the surgical success rate. Different electrocautery-enhanced delivery of the lumen-apposing metal stents (ECE-LAMSs) using suitable power levels in electrosurgical workstations can increase the surgical success rate and reduce trauma. Therefore, we proposed the use of the ECE-LAMSs and electrosurgical workstations for the first time through *ex vivo* experiments to adjust the different power levels and select the most suitable electrosurgical power for each ECE-LAMS type. **Methods:** We compared three types of ECE-LAMS (9Fr, 10.5Fr, and 10.8Fr) with three types of electrosurgical workstations during EUS-GBD. GBD was simulated *ex vivo* under the guidance of an ultrasound endoscope. We performed various power tests to elucidate the ideal electric power for different ECE-LAMS combined with the different types of electrosurgical workstations. **Results:** For the 10.8Fr ECE-LAMS matched with the Martin, Erbe, and Olympus electrosurgical workstations, the ideal power levels were 200 W, 200 W, and 250W. For the 10.5Fr and 9Fr ECE-LAMS matched with the Martin, Erbe, and Olympus electrosurgical workstations, the ideal power levels were 150 W, 200 W, and 200 W. **Conclusion:** During the operations, due to low-power levels in the electrosurgical workstations increased the number of cuts, the EUS images were obviously unclear, which affected the success rates of the operations. We suggested different power levels for the different types of LAMS and their matching electrosurgical workstations, which can increase the surgical success rates and reduce surgical injuries.

Key words: electrocautery-enhanced delivery of the lumen-apposing metal stents, EUS, EUS-guided gallbladder drainage

INTRODUCTION

EUS-guided interventional therapy is the main treatment method for many diseases including drainage of the bile duct, gallbladder, peripancreatic fluid

collections, or even the gastrointestinal tract through gastroenterostomy.^[1-4] In particular, EUS-guided

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gallbladder drainage (EUS-GBD) is increasingly becoming the recommended treatment for patients with high-risk acute cholecystitis.^[5,6] However, with the development of this treatment, gallbladder collapse due to bile leakage during the puncture process has become the main technical issue against surgical success, with bile leakage possibly causing adverse events such as acute peritonitis.^[7-14] This is especially relevant when cutting the gallbladder wall through electrocautery-enhanced delivery of the lumen-apposing metal stent (ECE-LAMS), making the number of cuts and the duration of cutting particularly important due to a great risk of gallbladder collapse and acute peritonitis due to bile leakage. Therefore, numerous ways of improving the surgical success rate are being explored.^[15-17] Based on our *ex vivo* study, we found that low-power levels in the electrosurgical workstations increased the number of cuts. During the operations, due to low-power levels in the electrosurgical workstations increased the number of cuts, the EUS images were obviously unclear, which affected the success rates of the operations [Figure 1]. Based on our *ex vivo* study, we also found that the use of different ECE-LAMSs and different power levels in the electrosurgical workstations affects the number of cuts

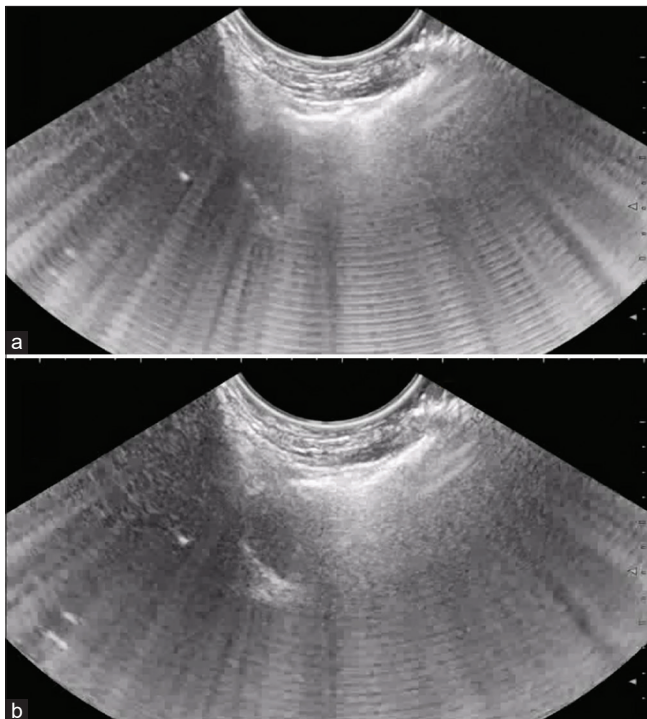


Figure 1. (a) During the operations, due to low-power levels in the electrosurgical workstations increased the number of cuts, the EUS images were obviously unclear (b) During the operations, due to low-power levels in the electrosurgical workstations increased the number of cuts, the EUS images were obviously unclear

and thus influences the puncture success rate. A longer period of electrical cutting, unclear EUS images, and gallbladder deformation can lead to further reduction of gallbladder space, which can then lead to failed stent delivery and the ultimate failure of EUS-GBD.^[17]

Presently, there are several types of LAMSs guided by gallbladder and gastric anastomosis that can be used under EUS guidance, which can shorten the surgery time and reduce surgical wound injury. Furthermore, these could also reduce leakage and injury in cavity organs and could improve discharge time after surgery. However, no studies have proven these hypotheses, and no objective data have yet been reported. Therefore, we performed *ex vivo* experiments for the first time using three common ECE-LAMSs and electrosurgical workstations. By adjusting the different power levels, we have selected the most suitable level for each type of ECE-LAMS with respect to their matching electrosurgical workstations. Our findings provide new ideas to improve the success rate of puncture for interventional therapy guided by EUS and provide a reference for improving the surgical success rate.

METHODS

An *ex vivo* study was performed using pig tissue to create a model of EUS-GBD using three different ECE-LAMSs to match three different electrosurgical workstations [Figure 2]. We adjusted the power levels separately, followed the same rhythm, and performed cutting in a short duration (intermittently cutting at the same frequency at 0.3 s intervals). The starting power was 100 W, which was increased in 50 W increments until the ideal power level was obtained. The ideal power was defined as the power level that allowed breaking through the gallbladder and stomach wall (*i.e.*, the head of the ECE-LAMS can be seen as fully entering the gallbladder) within five attempts of continuous cutting. Different LAMSs had been selected to match the appropriate electrosurgical workstation and power level.

A pig's isolated esophagus, stomach, and liver were prepared before surgery [Figure 3a and b]. We selected 5 cm of the pig's small intestine. Then, we injected 5 mL of physiological saline, and both sides were tightened to simulate the gallbladder. We then placed this model in the gallbladder fossa [Figure 3c and d]. We used the three most common electric ECE-LAMS, 10.8Fr ECE-LAMS (Hot AXIOS/

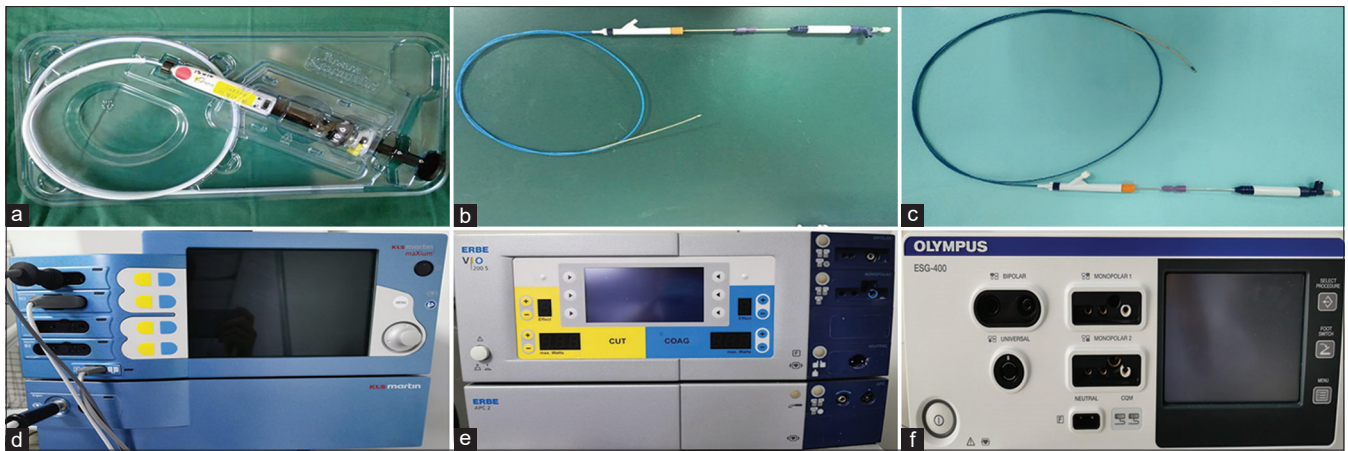


Figure 2. (a) 10.8Fr electrocautery-enhanced delivery of the lumen-apposing metal stent (Hot AXIOS/Boston Scientific; Marlborough, United States) (b) 10.5Fr electrocautery-enhanced delivery of the lumen-apposing metal stent (Micro-Tech/Nan Jing Co, Ltd; Nanjing, China) (c) 9Fr electrocautery-enhanced delivery of the lumen-apposing metal stent (Micro-Tech/Nan Jing Co, Ltd; Nanjing, China) (d) Martin electrocautery workstation (ME 402 maxium; Martin, Germany) (e) Erbe electrocautery workstation (VIO 200S; Erbe, Germany) (f) Olympus electrocautery workstation (ESG-400; Olympus, Japan)

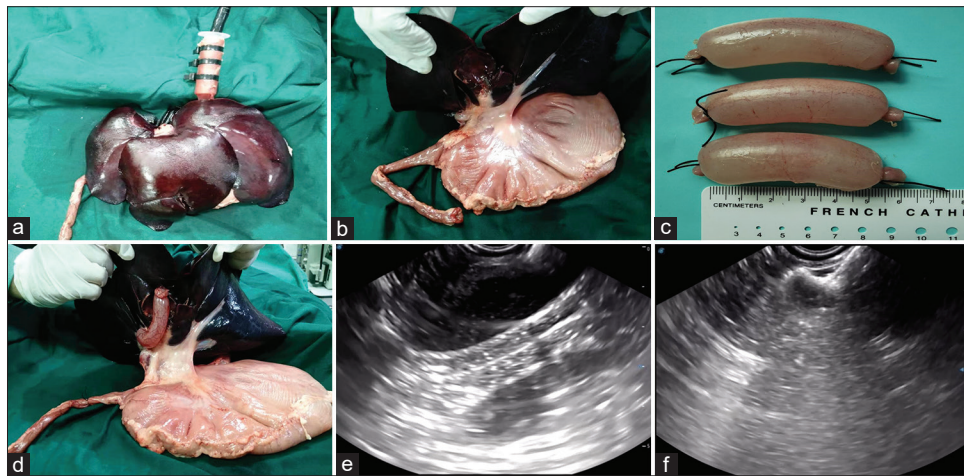


Figure 3. (a) The pig's isolated esophagus, stomach, and liver have been prepared before surgery. (b) The pig's isolated esophagus, stomach, and liver have been prepared before surgery. (c) We selected 5 cm of the pig's small intestine. Then, 5 mL of physiological saline was injected, and both sides were tightened to simulate the gallbladder. (d) The gallbladder model was placed in the gallbladder fossa. (e) We started cutting when the gallbladder model started being deformed through EUS. (f) The electrocautery-enhanced delivery of the lumen-apposing metal stent completely entered the gallbladder and the stent was successfully released

Boston Scientific; Marlborough, United States), 10.5Fr ECE-LAMS (Micro-Tech/Nan Jing Co, Ltd; Nanjing, China), and 9Fr ECE-LAMS (Micro-Tech/Nan Jing Co, Ltd; Nanjing, China), and the three most common electrocautery workstations, Martin (ME 402 maxium; Martin, Germany), Erbe (VIO 200S; Erbe, Germany), and Olympus (ESG-400; Olympus, Japan).

During the surgery, the gallbladder model was scanned using an ultrasound endoscope (EG-UC5T; SonoScape, Shenzhen, China), and the puncture site was marked. An ECE-LAMS was used to pass the working tube of the EUS and was connected to the electrocautery workstation. We started cutting when we found that the

gallbladder model started being deformed through the EUS. Then, we tested the power level. When several attempts of regular continuous cutting allowed the ECE-LAMS to completely enter the gallbladder and successfully release the stent, we recorded the power level as the ideal power level [Figure 3e and f]. Then, we replaced the electrocautery workstations.

RESULTS

Based on our *ex vivo* study, we found that low-power levels in the electrocautery workstations increased the number of cuts. During the operations, due to low-power levels in the electrocautery workstations

increased the number of cuts, the EUS images were obviously unclear, which affected the success rates of the operations. Based on our *ex vivo* study, we also found that the use of different ECE-LAMSs and different power levels in the electrosurgical workstations affects the number of cuts and thus influences the puncture success rate.

The ideal power level for the 10.8Fr ECE-LAMS (Hot AXIOS/Boston Scientific; Marlborough, United States) when matched with the Martin (ME 402 maxium; Martin, Germany) electrosurgical workstation was 200 W (Pure Cut). When matched with the Erbe (VIO 200S; Erbe, Germany) and the Olympus (ESG-400; Olympus, Japan) electrosurgical workstations, the ideal power levels were 200 W (Automatic Cut Effect 6) and 250 W (Pure Cut Effect 3), respectively [Table 1].

For the 10.5Fr ECE-LAMS (Micro-Tech/Nan Jing Co, Ltd; Nanjing, China) matched with the Martin (ME 402 maxium; Martin, Germany), Erbe (VIO 200S; Erbe, Germany), and Olympus (ESG-400; Olympus, Japan) electrosurgical workstations, the ideal power levels were 150 W (Pure Cut), 200 W (Automatic Cut Effect 6), and 200 W (Pure Cut Effect 3), respectively [Table 1].

For the 9Fr ECE-LAMS (Micro-Tech/Nan Jing Co, Ltd; Nanjing, China) matched with Martin (ME 402 maxium; Martin, Germany), Erbe (VIO 200S; Erbe, Germany), and Olympus (ESG-400; Olympus, Japan) electrosurgical workstations, the ideal power levels were 150 W (Pure Cut), 200 W (Automatic Cut Effect 6), and 200 W (Pure Cut Effect 3), respectively [Table 1].

DISCUSSION

Due to the technical difficulties associated with EUS-GBD, many methods have been clinically

proposed to improve the surgical success rate, including implantation with different pulling and fixing aids to ensure organ displacement and leakage problems. In 2002, Fritscher-Ravens *et al.* described a new suture method under elastic EUS control.^[15] This way, the gallbladder or small intestine can be fixed to the stomach, and a stent and a device for forming an anastomosis can be delivered. In 2011, Binmoeller and Shah. reported a new type of lumen fixation stent designed for intestinal drainage of nonadherent lumens and demonstrated significant effects through survival experiments on four pigs.^[16] In 2018, Zhang *et al.* confirmed that 16 pigs could be used as controls to assist puncture through retrievable puncture anchors to improve the success rate of EUS-GBD.^[17] They also proposed that although the pig gallbladder is relatively small, prolonged electrical cutting and gallbladder deformation can lead to further reduction of gallbladder space, which can ultimately lead to failed stent delivery. These studies show that improvements in the equipment are necessary to avoid gallbladder collapse caused by bile leakage. Through another perspective, we found that during the process of stent implantation, the time it takes for the ECE-LAMS to penetrate the stomach wall and gallbladder also played an important role. Considering the different power levels of the electrosurgical workstations, the time it takes to penetrate the stomach wall and adjacent cavities also differ. When the power level is too low, the penetration time becomes prolonged, and this prolonged electrocautery may cause leakage, deformation of the cavity organs, and unclear EUS images, further reducing the space for surgery, and eventually leading to stent implantation failure. At the same time, these adverse events may also occur due to the long puncture time, the number of cuts, unclear ultrasound images, the incomplete penetration of the gallbladder during the cutting process, and the penetration of organs, which could lead to the

Table 1. The ideal power levels for ECE-LAMSs matching electrosurgical workstations

	Martin (ME 402 maxium/ Martin, Germany)	Erbe (VIO 200S/ Erbe, Germany)	Olympus (ESG-400/ Olympus, Japan)
10.8Fr ECE-LAMS (Hot AXIOS/Boston Scientific, Marlborough; United States)	200 w Pure cut	200 w Automatic cut Effect 6	250 w Pure cut Effect 3
10.5Fr ECE-LAMS (Micro-Tech/Nan Jing Co, Ltd; Nanjing, China)	150 w Pure cut	200 w Automatic cut Effect 6	200 w Pure cut Effect 3
9Fr ECE-LAMS (Micro-Tech/Nan Jing Co, Ltd; Nanjing, China)	150 w Pure cut	200 w Automatic cut Effect 6	200 w Pure cut Effect 3

ECE-LAMS: Electrocautery-enhanced delivery of the lumen-apposing metal stents

leakage of bile into the abdominal cavity, causing the gallbladder to collapse and deform, thereby increasing the surgical difficulty and the occurrence of retroperitonitis. However, if the power level is too high, severe organ damage can occur. Based on our *ex vivo* study, we found that low-power levels in the electrosurgical workstations increased the number of cuts. During the operations, due to low-power levels in the electrosurgical workstations increased the number of cuts, the EUS images were obviously unclear, which affected the success rates of the operations. We also found that more than five attempts of cutting caused excessive fluid outflow, unclear EUS images and gallbladder collapse, making it difficult to deliver the ECE-LAMS and ultimately leading to surgical failure.

In our *ex vivo* experiments, three different types of LAMSs have been used to match three different types of electrosurgical workstations. By adjusting the powers levels, when ECE-LAMS is inserted into the gallbladder within five cutting attempts, the stent could be successfully released. The power level wherein this was achieved was recorded as the ideal power level. Based on our experiments, we propose nine different matching situations. Different ECE-LAMSs match the different power levels of the electrosurgical workstations. The ideal power level for the 9Fr ECE-LAMS was the same as that for 10.5Fr ECE-LAMS. However, the 9Fr ECE-LAMS was thinner and had less friction with the pipe; hence, it was more controllable. The 9Fr ECE-LAMS could have a larger pipeline space and is convenient for use with other devices and could therefore be the next development trend for ECE-LAMSs.

The current research also has some limitations. First, due to the use of an *ex vivo* model, the fixation of the mold had been more stable than in actual practice, which could have reduced the technical requirements for the EUS-guided surgery to a certain extent. The resistance of isolated organs and living organs may be different. Therefore, there may still be a gap in our findings and the setting of an actual clinical surgery, and our data should hence be used for clinical reference only. Second, the anastomosis process depends on various parameters, including the type of organ, collagen content, blood flow, anastomosis method, ischemia, and tension.^[18] We used the same intestinal tube to avoid the effects of organs of varying sizes. It should be noted that the tissues of the gallbladder and intestine are different. We can only achieve similar

shapes; nevertheless, the materials of the organs are actually different, which could have caused some discrepancies in our experimental data.

Through *ex vivo* experiments, we propose for the first time that the power levels of electrosurgical workstations can significantly affect stent release during transluminal surgery guided by EUS. During the operations, due to low-power levels in the electrosurgical workstations increased the number of cuts, the EUS images were obviously unclear, which affected the success rates of the operations. Our findings could provide a reference for clinical EUS-GBD and improve the surgical success rate. In addition, this study is not only applicable to EUS-GBD but could also be applicable to other ultrasound-guided interventional procedures. During EUS-guided gastroenterostomy, intestinal leakage could also occur, leading to bowel collapse, unclear EUS images, and stent release failure, as a result of frequent cutting and a long cut time. Double balloon and single balloon methods have also been proposed to ensure a clear positioning between the stomach and intestines.^[18-22] We suggest that future studies on EUS interventional therapy focus as well on cutting power.

CONCLUSION

During the operations, due to low-power levels in the electrosurgical workstations increased the number of cuts, the EUS images were obviously unclear, which affected the success rates of the operations. We suggested different power levels for the different types of LAMS and their matching electrosurgical workstations, which can increase the surgical success rates and reduce surgical injuries.

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Conflicts of interest

Siyu Sun is a consultant of SonoScape and Nan Jing Micro-tech Company as well as the Editor-in-Chief of the journal. This article was subject to the journal's standard procedures, with peer review handled

independently of this editor and his research group. The other authors have no conflicts of interests to declare.

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