—Original Article—

Technical feasibility and safety of one-step deployment of EUS-guided hepaticogastrostomy using an 8-mm diameter metal stent with a fine-gauge stent delivery system (with video)

Takeshi Ogura[1], Saori Ueno[1], Atsushi Okuda[1], Nobu Nishioka[1], Masanori Yamada[1], Jun Matsuno[1], Kazuya Ueshima[1], Yoshitaro Yamamoto[1], Kazuhide Higuchi[1]

[1]2nd Department of Internal Medicine, Osaka Medical College, Osaka, Japan

ABSTRACT

Background and Objectives: Adverse events (AEs) such as bile peritonitis or pneumoperitoneum might occur during procedural steps for EUS-guided hepaticogastrostomy (HGS), such as during device exchange and after fistula dilation until stent deployment. Reducing the steps to the EUS-HGS procedure might therefore be ideal to prevent the occurrence of AEs. Recently, a novel, fully covered self-expandable metal stent (FCSEMS) has become available. Because of the fine-gauge stent delivery system (5.9Fr), fistula dilation might not be needed before stent deployment during EUS-HGS. The aim of this pilot study was to evaluate the technical feasibility and safety of one-step EUS-HGS using a novel 8-mm diameter FCSEMS. **Patients and Methods:** The primary outcome in this study was technical success, and the secondary outcomes were procedure- and stent-related AEs and clinical success. The technical success of one-step EUS-HGS was defined as successful FCSEMS deployment without any fistula dilation. Procedure time was measured from scope insertion to successful FCSEMS deployment. **Results:** One-step EUS-HGS using the novel FCSEMS was attempted on 14 patients. Technical success with a short procedure time (median: 7 min) and clinical success were obtained in all patients. In addition, procedure-related AEs such as bleeding, bile peritonitis, and stent migration during the procedure were not observed in any patients. **Conclusions:** One-step EUS-HGS using the novel FCSEMS with a fine-gauge stent delivery system is technically feasible and shortens the procedure time with no requirement for additional fistula dilation, resulting in a potential reduction in procedure-related AEs.

Key words: ERCP, EUS-guided biliary drainage, EUS-guided hepaticogastrostomy, EUS-guided hepaticogastrostomy

Video Available on: www.eusjournal.com

Access this article online

Quick Response Code:

Website: www.eusjournal.com

DOI: 10.4103/EUS-D-20-00206

How to cite this article: Ogura T, Ueno S, Okuda A, Nishioka N, Yamada M, Matsuno J, *et al*. Technical feasibility and safety of one-step deployment of EUS-guided hepaticogastrostomy using an 8-mm diameter metal stent with a fine-gauge stent delivery system (with video). Endosc Ultrasound 2021;10:355-60.

Address for correspondence

Dr. Takeshi Ogura, 2nd Department of Internal Medicine, Osaka Medical College, 2-7 Daigakuchou, Takatsukishi, Osaka 569-8686, Japan. E-mail: oguratakeshi0411@yahoo.co.jp

Received: 2020-09-18; **Accepted:** 2021-05-06; **Published online:** 2021-08-21

INTRODUCTION

Malignant biliary obstruction is usually treated by biliary drainage (BD) under ERCP.[1-3] However, if the patient shows complications with malignant duodenal obstruction, such as that due to cancer of the pancreatic head, or surgically altered anatomy, the approach to the ampulla of Vater might be challenging. Percutaneous transhepatic biliary drainage (PTBD) has been performed as an alternative method. However, several disadvantages of PTBD, such as extra-drainage and cosmetic issues, have led to the development of EUS-guided biliary drainage (EUS-BD).[4-10] Among EUS-BD procedures, EUS-guided hepaticogastrostomy (HGS) is indicated for patients with duodenal obstruction or surgically altered anatomy. To date, various meta-analyses regarding EUS-BD have been published.[4,11,12] According to these reports, the technical success rate of EUS-HGS appears high; however, the rate of adverse events (AEs) is also high. Therefore, methods to prevent the occurrence of AEs, such as bile peritonitis or pneumoperitoneum, that might occur during the procedural steps for EUS-HGS, such as during device exchange and after fistula dilation until stent deployment, are needed.[13] Reducing the steps in the EUS-HGS procedure might therefore be ideal to prevent the occurrence of AEs.

Recently, a novel, fully covered self-expandable metal stent (FCSEMS) has become available in Japan. Due to the fine-gauge stent delivery system, fistula dilation might not be needed before stent deployment. The aim of this pilot study was to evaluate the technical feasibility and safety of one-step EUS-HGS using a novel FCSEMS.

PATIENTS AND METHODS

This retrospective study analyzed consecutive patients in whom one-step EUS-HGS was attempted between January and March 2020. The indications for one-step EUS-HGS were as follows: (1) advanced malignancy; (2) inaccessible papilla due to duodenal obstruction or surgically altered anatomy such as Roux-en-Y anastomosis; (3) consent from the patient to undergo the procedure; and (4) refusal of PTBD at the time of obtaining informed consent before ERCP. The exclusion criteria were (1) refusal to undergo the procedure, (2) uncontrolled coagulopathy, (3) pregnancy, (4) age <18 years, and (5) presence of ascites between the hepatic parenchyma and stomach wall. All analyzed patients provided written, informed consent to undergo all procedures associated with this study. This study was approved by the institutional review board at Osaka Medical College.

Details of the novel fully covered self-expandable metal stent and technical tips for one-step EUS-hepaticogastrostomy

Figure 1 shows the novel FCSEMS (HANAROSTENT® Biliary Full Cover Benefit™: HANARO Benefit; M.I. Tech, Seoul, Korea). The tip of this stent is extremely tapered and stiff. Compared with a standard ERCP catheter (7 Fr, MTW; Endoskopie, Wesel, Germany), the stent delivery system is thinner (5.9 Fr). Two stent diameters (6 or 8 mm) are available, and lengths of 10 cm and 12 cm can also be selected. In this study, an 8-mm diameter and 12-cm long EUS-HGS stent were used.

Figure 2 shows technical tips for one-step EUS-HGS [Video 1]. The intrahepatic bile duct (B3) was punctured using a 19-G needle (EZ Shot 3 Plus; Olympus Medical Systems, Tokyo, Japan), and bile juice was aspirated. Contrast medium was injected to obtain images of the hepatic bile duct [Figure 2a]. After a 0.025-inch guidewire (VisiGlide 1; Olympus Medical Systems) was inserted into the biliary tract [Figure 2b], the fine needle aspiration needle was removed [Figure 2c]. Next, using the stent delivery system, the novel FCSEMS was inserted into the left hepatic bile duct [Figure 2d] without any dilation devices such as balloon or electrocautery dilators (EDs). Finally, stent deployment from the left hepatic bile duct to the stomach was performed using the intrascope channel release technique, as previously

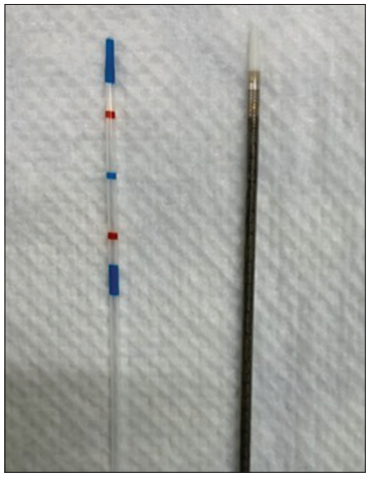

Figure 1. The novel fully covered self-expandable metal stent with a fine gauge stent delivery system (5.9Fr) and standard ERCP catheter

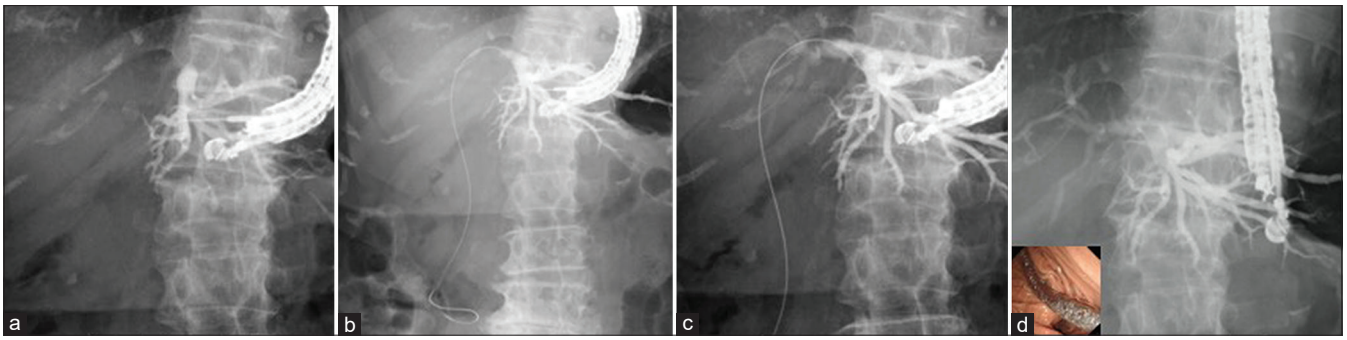

Figure 2. (a) The intrahepatic bile duct is punctured using a 19-G needle, and contrast medium is injected to obtain images of the hepatic bile duct. (b) A 0.025-inch guidewire is inserted into the biliary tract. (c) The needle is removed. (d) The stent delivery system for the novel fully covered self-expandable metal stent is inserted into the left hepatic bile duct without any dilation devices, and successfully deployed

described.[14] After EUS-HGS, all patients underwent computed tomography to detect early AEs such as stent migration.

Definitions and statistical analysis

The physical condition of patients before EUS-HGS was evaluated according to the American Society of Anesthesiologists (ASA) Physical Status Classification system.[15] The primary outcome in this study was technical success, and the secondary outcomes were procedure- and stent-related AEs and clinical success. Technical success was defined as successful FCSEMS deployment without any fistula dilation, and clinical success was defined as a decrease in serum bilirubin levels to <50% of the pretreatment value within 14 days. Procedure time was measured from scope insertion to successful stent deployment. Follow-up days were measured from the day of EUS-HGS to the patient's death or last follow-up. Stent patency was also measured from stent deployment to dysfunction, such as cholangitis, occlusion, or dislocation. Descriptive statistics are presented as median (interquartile range [IQR]) and frequency for continuous and categorical variables, respectively. AEs associated with the procedures were evaluated according to the severity grading system of the American Society for Gastrointestinal Endoscopy lexicon.[16]

RESULTS

In total, 14 patients (8 males, 6 females; median age: 76 years; IQR: 62–89 years) were enrolled in this study. Table 1 shows the patients' demographic characteristics. The median number of comorbidities was three (IQR: 1.0–6.0), and the ASA classification was III (n = 9) or IV (n = 3). Pancreatic cancer was the most common disease causing obstructive jaundice in 64.3% (n = 9), followed by gastric cancer in 21.4% (n = 3), and bile duct cancer in 14.3% (n = 2). Among 14 patients, EUS-HGS was attempted because of duodenal obstruction (78.6%, n = 11) and surgically altered anatomy (21.4%, n = 3).

Table 2 shows technical outcomes from this study. Technical success with a short procedure time (median: 7 min) and clinical success were obtained in all patients. In addition, no procedure-related AEs such as bleeding, bile peritonitis, and stent migration during the procedure were observed. The median stent patency was 101 days. During follow-up, stent dysfunction was observed in one patient; this patient successfully underwent one-step EUS-HGS without experiencing any procedure-related AEs [Figure 3a]. However, after 7 days, inflammatory and liver markers were elevated. On computed tomography, biliary dilatation was observed in the B2 segment [Figure 3b]. This patient was considered to be complicated by focal cholangitis in the B2 segment because of biliary obstruction by FCSEMS. We tried to exchange this stent for a plastic stent. First, the mesh of the EUS-HGS was broken using the ERCP catheter, through which the guidewire was inserted into the biliary tract [Figure 4a]. Next, the EUS-HGS stent was removed using a forceps biopsy device [Figure 4b]. By doing so, the guidewire was still placed after stent removal [Figure 4c]. If no fistula had been created, we could safely perform reintervention using this guidewire.[17] Finally, stent exchange was successfully performed [Figure 4d]. After this procedure, clinical symptoms and laboratory findings improved.

DISCUSSION

Risk factors associated with AEs from EUS-BD have been evaluated in several studies.[18-20] In a study of dilation devices, Honjo *et al.* compared an ultra-tapered mechanical dilator (MD) with an ED.[18]

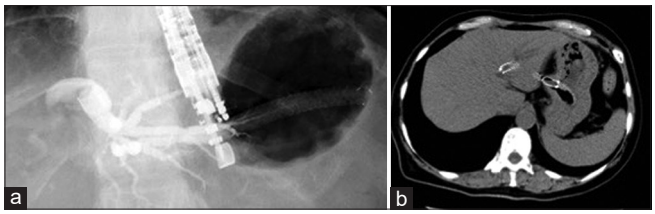

Figure 3. (a) EUS-guided hepaticogastrostomy using a novel fully covered self-expandable metal stent is successfully performed. (b) Biliary dilatation is observed in the B2 segment (focal cholangitis)

Table 1. Demographic and patient characteristics and technical results in the entire cohort

Variable	% (*n*)
Total number of patients	14
Age (year), median (IQR)	76.00 (62.00-89.00)
<75	35.7 (5)
≥75	64.3 (9)
Gender	
Female	42.9 (6)
Male	57.1 (8)
Number of comorbidity, median (IQR)	3 (1.00-6.00)
Classification of ASA	
III	57.1 (8)
II	42.9 (5)
Disease	
Pancreatic cancer	64.3 (9)
Gastric cancer	21.4 (3)
Bile duct cancer	14.3 (2)
Reason for EUS-BD	
Duodenal obstruction	78.6 (11)
Surgically altered anatomy	21.4 (3)

IQR: Interquartile range; ASA: American Society of Anesthesiologists; BD: Biliary drainage

Table 2. Technical outcome of this study

Variable	% (*n*)
Technical success	
Yes	100 (14)
No	0
Clinical success	
Yes	100
No	0
Procedure time (min), median (IQR)	7 (5.00-10.00)
Procedure-related adverse event	0
Stent-related adverse event	7.1 (1)
Follow-up period (days), median (range)	111 (89-170)

IQR: Interquartile range

Among 64 patients who underwent EUS-HGS (n = 49) and EUS-guided pancreatic duct drainage (n = 15), 33 patients underwent fistula dilation using the ultra-tapered MD, and 31 patients underwent using an ED. As a result, initial dilation was successfully achieved in 95.3% (61/64); 97% (32/33) in the MD group, and 93.3% (29/31) in the ED group. AEs were observed in 14 patients (abdominal pain in eight and bleeding in six). All bleeding events occurred in the ED group, with no bleeding in the MD group (P = 0.04). They, therefore, recommended that ED should be avoided to prevent AEs, if possible. A similar result was reported in another study.[19] From the perspective of preventing bleeding, the use of non-EDs might be important. On the other hand, abdominal pain, bile leakage, and peritonitis are more commonly observed as procedure-related AEs. These AEs sometimes prove critical for patients with a poor general condition. In addition, if these AEs are observed, the time to resumption of oral intake is postponed, and quality of life might be decreased. These AEs should therefore be avoided along with bleeding. One of the scenarios regarding the occurrence of AEs might be bile leakage during an EUS-HGS procedure. The conventional EUS-HGS method is as follows: bile duct puncture, guidewire insertion, fistula dilation, and stent deployment. To prevent bile leakage, reducing the number of device changes and minimizing the procedure time are important.[21] Fistula dilation is therefore ideal to prevent bile leakage through the fistula and shortens the procedure time. Indeed, the procedure time in this study was extremely short, and no AEs (including abdominal pain and bile leakage) were seen in any patients. Park *et al.* also conducted a prospective randomized study of one-step EUS-HGS.[22] In their study, a dedicated stent with a 3-Fr-tip 4-Fr-tapered metal 7-Fr introducer was used as the EUS-HGS stent. The technical success rate of one-step EUS-HGS was 88% (14/16). In addition, compared with conventional metal stents, the procedure time was significantly shorter (10 *vs.* 15 min; P = 0.007). Among patients who underwent successful

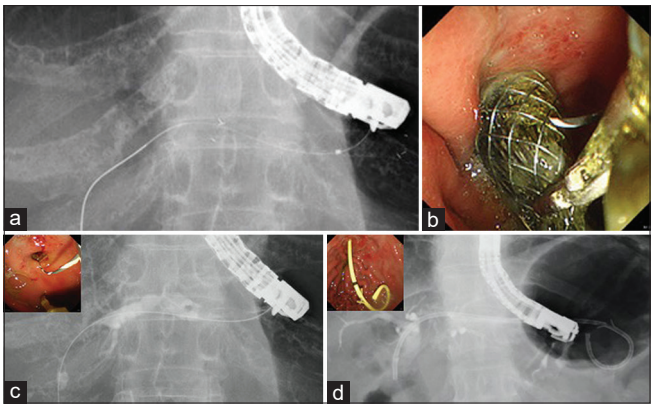

Figure 4. (a) A guidewire is inserted into the biliary tract through the endoscopic ultrasound-guided hepaticogastrostomy stent. (b) The metal stent is removed using a forceps biopsy device. (c) The guidewire is still placed in the biliary tract. (d) Plastic stent deployment is performed

one-step EUS-HGS, no AEs were observed. However, technical success was not obtained in two patients because of transmural resistance to stent introduction; this might have been due to the 7-Fr introducer. On the other hand, the stent introducer in our study was only 5.9 Fr, which was smaller than the ERCP catheter. Therefore, although our study had several limitations, such as the single arm, retrospective design, and the small patient cohort, our stent appears to be suitable for one-step EUS-HGS. Another strength of our study is the stent diameter. Compared with stents with a 6-mm diameter, 8-mm diameter of the FCSEMS has high radial force; therefore, the risk of stent dislocation is low. Indeed, according to clinical study on EUS-HGS using a 6-mm diameter FCSEMS,[23] the stent dislocation rate was 20% (4/20). In a similar study on one-step EUS-HGS study using a 6-mm diameter FCSEMS,[24] stent migration was seen in 20% (1/6). On the other hand, in the present study, no stent dislocation or migration was seen in any patient. Therefore, if a 6-mm diameter FCSEMS is used as the EUS-HGS stent, stent dislocation or migration may occur. However, the selection of the metal stent diameter should be decided according to the intrahepatic bile duct dilatation. If a large diameter metal stent is placed in a small diameter bile duct, tissue hyperplasia and side brunch occlusion may occur. However, a 6-mm diameter metal stent is associated with an increased risk of stent dislocation because of its small radial force, as described above. If a metal stent can be placed across a sufficient amount of hepatic parenchyma, several AEs, such as stent dislocation or bile leakage, might be prevented.[21] Therefore, when a small diameter metal stent is placed, a sufficient amount of hepatic parenchyma may be needed to prevent stent dislocation.

In the present study, because of the FCSEMS design, focal cholangitis arose as a complication in one patient because of obstruction in the B2 segment. If stent deployment is performed at an inappropriate site, focal cholangitis can occur as a result of side brunch obstruction, although the risk of tissue hyperplasia might be lower compared with using a partially covered self-expandable metal stent (PCSEMS). On the other hand, focal cholangitis could be prevented if our stent design is partially covered, although tissue hyperplasia can be complicated at this uncovered site. A comparison study between PCSEMS and FCSEMS is therefore needed to determinate which stent should be used. To prevent stent migration into the abdominal cavity, further improvements in stent design, such as a lumen-apposing shape, are needed. However, in this design, the delivery system is large; therefore, because fistula dilation is needed, the procedure time may be prolonged and the risk of bile leakage may be increased. To prevent stent migration or dislocation, we usually pay attention to the diameter of the hepatic parenchyma and tips for the stent release technique. If intrahepatic bile duct puncturing is performed across a sufficient amount of hepatic parenchyma, the risk of stent migration or dislocation may be reduced. In addition, if the intra-scope channel release technique[14] is used, adhesion between hepatic parenchyma and stomach wall may be obtained, and stent migration into the abdominal cavity may be prevented. Further evaluation in a prospective study should be conducted to confirm this theory. Furthermore, in this study, because of the short follow-up period, stent dysfunction was observed in one patient (focal cholangitis). Therefore, the feasibility of reintervention should be evaluated in a long-term follow-up study.

CONCLUSIONS

In conclusion, one-step EUS-HGS using a novel 8-mm diameter covered metal stent with a fine-gauge stent delivery system is technically feasible and shortens the procedure time with no requirement for additional fistula dilation, resulting in a potential reduction in procedure-related AEs. A prospective randomized study on conventional self-expandable metal stents is needed to verify our results.

Financial support and sponsorship
Nil.

Conflicts of interest
Takeshi Ogura is an Editorial Board Member of the journal *Endoscopic Ultrasound*. The article was subject to the journal's standard procedures, with peer review handled independently of him and his research groups.

REFERENCES

1. McLean GK, Burke DR. Role of endoprostheses in the management of malignant biliary obstruction. *Radiology* 1989;170:961-7.
2. Shapiro MJ. Management of malignant biliary obstruction: Nonoperative and palliative techniques. *Oncology (Williston Park)* 1995;9:493-6, 499.
3. Stern N, Sturgess R. Endoscopic therapy in the management of malignant biliary obstruction. *Eur J Surg Oncol* 2008;34:313-7.
4. Dhindsa BS, Mashiana HS, Dhaliwal A, *et al.* EUS-guided biliary drainage: A systematic review and meta-analysis. *Endosc Ultrasound* 2020;9:101-9.
5. Giovannini M. EUS-guided hepaticogastrostomy. *Endosc Ultrasound* 2019;28:S44-9.

6. Itoi T, Isayama H, Sofuni A, *et al.* Stent selection and tips on placement technique of EUS-guided biliary drainage: Transduodenal and transgastric stenting. *J Hepatobiliary Pancreat Sci* 2011;18:664-72.
7. Katanuma A, Hayashi T, Kin T, *et al.* Interventional endoscopic ultrasonography in patients with surgically altered anatomy: Techniques and literature review. *Dig Endosc* 2020;32:263-74.
8. Mukai S, Tsuchiya T, Itoi T. Interventional endoscopic ultrasonography for benign biliary diseases in patients with surgically altered anatomy. *Curr Opin Gastroenterol* 2019;35:408-15.
9. Sun B, Moon JH, Cai Q, *et al.* Review article: Asia-Pacific consensus recommendations on endoscopic tissue acquisition for biliary strictures. *Aliment Pharmacol Ther* 2018;48:138-51.
10. Ogura T, Higuchi K. Endoscopic ultrasound-guided gallbladder drainage: Current status and future prospects. *Dig Endosc* 2019;31 Suppl 1:55-64.
11. Logiudice FP, Bernardo WM, Galetti F, *et al.* Endoscopic ultrasound-guided vs endoscopic retrograde cholangiopancreatography biliary drainage for obstructed distal malignant biliary strictures: A systematic review and meta-analysis. *World J Gastrointest Endosc* 2019;11:281-91.
12. Miller CS, Barkun AN, Martel M, *et al.* Endoscopic ultrasound-guided biliary drainage for distal malignant obstruction: A systematic review and meta-analysis of randomized trials. *Endosc Int Open* 2019;7:E1563-73.
13. Ogura T, Higuchi K. Technical tips for endoscopic ultrasound-guided hepaticogastrostomy. *World J Gastroenterol* 2016;22:3945-51.
14. Miyano A, Ogura T, Yamamoto K, *et al.* Clinical impact of the intra-scope channel stent release technique in preventing stent migration during EUS-guided hepaticogastrostomy. *J Gastrointest Surg* 2018;22:1312-8.
15. American Society of Anesthesiologists. Standards for Basic Anesthetic Monitoring American Society of Anesthesiologists; 2011. Available from: https://www.asahq.org/~/media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/standards-for-basic-anesthetic-monitoring.pdf. [Last accessed on 2020 Jan 10].
16. Cotton PB, Eisen GM, Aabakken L, *et al.* A lexicon for endoscopic adverse events: Report of an ASGE workshop. *Gastrointest Endosc* 2010;71:446-54.
17. Ogura T, Nishioka N, Yamada M, *et al.* Novel transluminal treatment protocol for hepaticojejunostomy stricture using covered self-expandable metal stent. *Surg Endosc* 2021;35:209-15.
18. Honjo M, Itoi T, Tsuchiya T, *et al.* Saftey and efficacy of ultra-tapered mechanical dilator for EUS-guided hepaticogastrostomy and pancreatic duct drainage compared with electrocautery dilator (with video). *Endosc Ultrasound* 2018;7:376-82.
19. Park DH, Jang JW, Lee SS, *et al.* EUS-guided biliary drainage with transluminal stenting after failed ERCP: Predictors of adverse events and long-term results. *Gastrointest Endosc* 2011;74:1276-84.
20. Yamamoto Y, Ogura T, Nishioka N, *et al.* Risk factors for adverse events associated with bile leak during EUS-guided hepaticogastrostomy. *Endosc Ultrasound* 2020;9:110-5.
21. Paik WH, Park DH. Outcomes and limitations: EUS-guided hepaticogastrostomy. *Endosc Ultrasound* 2019;8:S44-9.
22. Park DH, Lee TH, Paik WH, *et al.* Feasibility and safety of a novel dedicated device for one-step EUS-guided biliary drainage: A randomized trial. *J Gastroenterol Hepatol* 2015;30:1461-6.
23. Okuno N, Hara K, Mizuno N, *et al.* Efficacy of the 6-mm fully covered self-expandable metal stent during endoscopic ultrasound-guided hepaticogastrostomy as a primary biliary drainage for the cases estimated difficult endoscopic retrograde cholangiopancreatography: A prospective clinical study. *J Gastroenterol Hepatol* 2018;33:1413-21.
24. Maehara K, Hijioka S, Nagashio Y, *et al.* Endoscopic ultrasound-guided hepaticogastrostomy or hepaticojejunostomy without dilation using a stent with a thinner delivery system. *Endosc Int Open* 2020;8:E1034-8.