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# Feasibility and safety of endoscopic ultrasound-guided gallbladder drainage using a newly designed lumen-apposing metal stent

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## Abstract

**Background and aims** Endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) is increasingly accepted as an effective treatment option in patients who require drainage for acute cholecystitis. A newly designed lumen-apposing metal stent (LAMS) has been introduced recently in this procedure. In this study, we evaluated the feasibility and safety of the newly designed LAMS in patients with acute cholecystitis who were unsuitable for cholecystectomy.

**Methods** Between Mar 2017 and Oct 2017, 22 patients with acute cholecystitis who were unsuitable for cholecystectomy underwent EUS-GBD with the newly designed LAMS. We evaluated the technical and clinical success and the adverse event profiles.

**Results** EUS-GBD with newly designed LAMS was technically and clinically successful in 21 of the 22 patients. EUS-GB stenting was performed at urgent setting in 17 patients, while 5 patients, who had undergone initial PTGBD, underwent EUS-GB stenting to remove PTGBD tube. The median procedure time was 11.5 (range 8.8–17.0) min. A late adverse event of stent occlusion developed in one patient. Stent migration was not observed during follow-up (median 318.0 days, range 39.0–398.0 days) and cumulative stent patency rate at 1 year was 95%.

**Conclusion** EUS-GBD with newly designed LAMS is feasible and shows acceptable safety profiles for both the urgent drainage of acute cholecystitis and elective internalization following PTGBD in patients with high surgical risk.

**Keywords** Endoscopic ultrasound · Cholecystitis · Gallbladder · Drainage · Metal stent

## Abbreviations

| | |
|---|---|
| PTGBD | Percutaneous transhepatic gallbladder drainage |
| EUS-GBD | Endoscopic ultrasound-guided gallbladder drainage |
| LAMS | Lumen-apposing metal stent |
| ASA | American Society of Anesthesiologists |
| SD | Standard deviation |
| IQR | Interquartile range |
| CI | Confidence interval |

Acute cholecystitis is the most common emergency of the biliary system and cholecystectomy is the definitive treatment along with drainage when necessary [1, 2]. However, cholecystectomy is still associated with substantial perioperative morbidity in patients with high surgical risk [3]. Percutaneous transhepatic gallbladder drainage (PTGBD) has been considered as the standard of care for these patients, but may be unsuitable for patients with coagulopathy/ascites and there is a significant risk of adverse events such as pneumoperitoneum, bile leak, pain, and catheter malfunction/dislodgement [4, 5]. Endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) has been introduced as an alternative to PTGBD and has shown comparable effectiveness and safety profiles to PTGBD in several previous studies [6, 7].

Commercially available lumen-apposing metal stents (LAMS, Axios; Boston Scientific, Marlborough, Massachusetts, USA) have been used for EUS-GBD and show technical safety and effectiveness in patients who are poor surgical candidates [8, 9]. However, AXIOS stent is still not widely

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available in several countries and it has a relatively large stiff delivery system which can be technically demanding [10].

Recently, a newly designed LAMS was introduced. This newly designed LAMS was first investigated for EUS-guided drainage by Moon et al. in a preliminary study conducted with six animals and seven patients [11]. In their study, EUS-GBD was conducted with newly designed LAMS in only three patients. Although, all of them showed resolution of cholecystitis, there remains a limited data regarding feasibility, safety profiles, and long term outcomes of EUS-GBD with newly designed LAMS. Therefore, we evaluated the clinical outcomes of EUS-GBD with the newly designed LAMS in this study.

## Patients and methods

### Patients

Between Mar 2017 and Oct 2017, 22 consecutive patients with acute cholecystitis underwent EUS-GBD with newly designed LAMS. Acute cholecystitis was diagnosed according to the Tokyo guidelines [12]. The patients were regarded as having high risk of surgery if the American Society of Anesthesiologists (ASA) Physical Status Classification was three or higher, if there was advanced malignancy, and/or if they were deemed unsuitable for any other reason based on surgical consultation. All the patients were provided informed consent before the procedure. This study was approved by the institutional review board of Asan Medical Center, Korea (IRB number: 2018-0112).

### Characteristics of newly designed LAMS

Figure 1 shows the newly designed LAMS (Spaxus®; Taewoong Medical Co, Ltd, Goyang-si, Korea) used in this study. It is a fully covered metal stent with a bi-flange shape. The diameter of the flange at both ends is 25 mm and folding back the luminal surface causes lumen apposition (Fig. 1A). Moreover, the flexible design of the newly designed LAMS helps accommodative apposition regardless of wall thickness (Fig. 1B). The diameter of the stent is 10 mm and the length is 20 mm. The delivery system is a 9F conventional delivery system allowing minimal tract dilatation and easy insertion during EUS-GBD. This is a modified version of LAMS which have decreased the diameter of delivery system than that described in previous preliminary report [11].

### EUS-GBD procedure

All the EUS procedures were performed by one interventional endosonographer (S.S.L) who performed more than 150 cases of EUS-GBD and 200 cases of EUS-guided

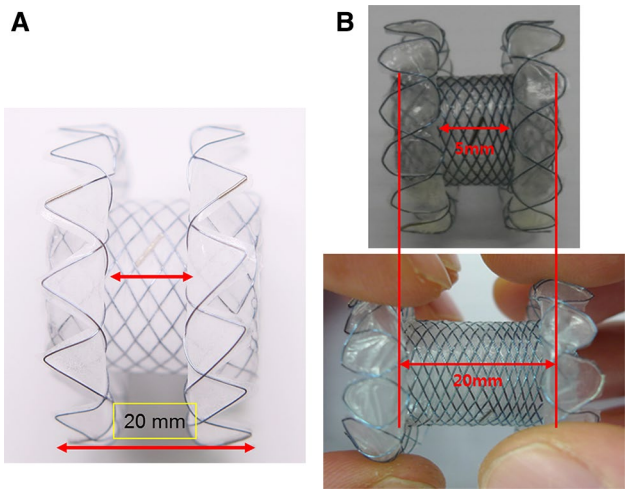


**Fig. 1** The newly designed lumen-apposing metal stent (Spaxus; Taewoong Medical Co, Ltd, Goyang-si, Korea). **A** This is a fully covered metal stent with a bi-flange shape. The diameter of the flange at both ends is 25 mm and folding back the luminal surface causes lumen apposition. **B** The flexible design of LAMS helps accommodative apposition regardless of wall thickness. The diameter of the lumen does not change until 20 mm thickness

pseudocyst or walled-off necrosis drainage using tubular metal stents. The patients were sedated using intravenous administration of midazolam and meperidine or (occasionally) propofol. All the patients received antibiotic treatment prior to the procedure. EUS-GBD with newly designed LAMS was performed using a linear-array echoendoscope (GF-UCT 240 or 260-AL 10; Olympus Optical Co., LTD., Tokyo, Japan) with fluoroscopic guidance. Either the prepyloric antrum of the stomach or the bulb of the duodenum was chosen as the puncture point for accessing the gallbladder body or neck and avoiding any intervening blood vessels. A 19-gauge needle (EUSN-19-T; Cook Endoscopy, Winston-Salem, North Carolina, USA) was used to puncture the gallbladder through the gastric or duodenal wall. After the stylet was removed, bile fluid was aspirated for microbacterial culture and contrast was injected into the gallbladder under fluoroscopic guidance to confirm access. A 0.035 inch guidewire (Jagwire; Boston Scientific, Natick, Massachusetts, USA) or a 0.025-inch guidewire (VisiGlide; Olymphus, Tokyo, Japan) was passed through the EUS needle and then coiled in the gallbladder. Next, the needle was withdrawn and a triple-lumen needle-knife (Microtome; Boston Scientific) with a 7-Fr shaft diameter was used to dilate the tract using a brief burst of pure cutting current. After tract dilatation, the delivery catheter of the newly designed LAMS was placed over the guidewire and inserted. During stent placement, additional balloon dilatation was not needed for tract dilatation. After placing the stent between the gallbladder and stomach or duodenum, the newly designed LAMS was

deployed under fluoroscopic and endoscopic monitoring (Fig. 2A–C).

The patients fasted until the next morning after the procedure. All the patients underwent a daily physical examination and laboratory tests until the symptoms and laboratory abnormalities were eliminated. Follow-up endoscopic examination was performed in all the patients one or two days after EUS-GBD to secure the appropriate position of the newly designed LAMS. During endoscopic examination, direct cholecystoscopy was performed if technically feasible using slim endoscope (GIF-XP 260N; Olympus. Optical, Tokyo, Japan) to evaluate appropriate location of the stent as well as residual gallbladder stones or intracholecystic abnormalities (Fig. 2D).

### Follow-up

Patient follow-up was based on outpatient examinations every 6 months or whenever adverse events developed. Blood tests and simple abdominal X-rays were performed every visit, and endoscope and abdominal CT was additionally performed in patients with adverse events. The newly designed LAMS was left in place in all patients unless a LAMS-related adverse event occurred.

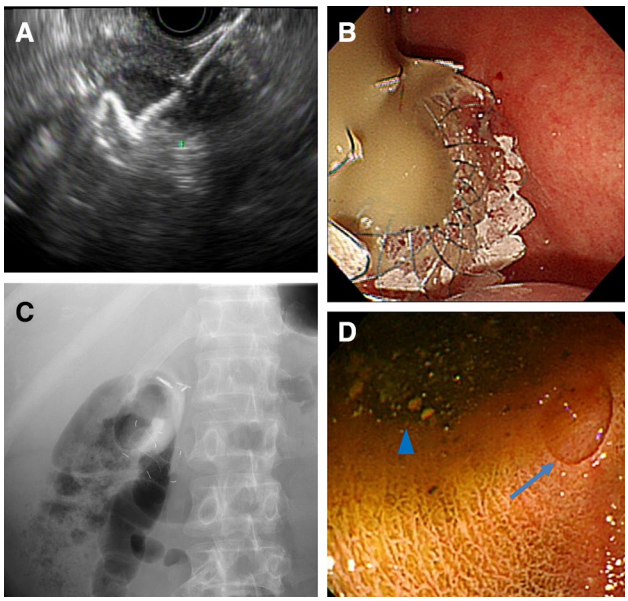


**Fig. 2** EUS-guided gallbladder drainage with the newly designed LAMS (Spaxus stent) and cholecystoscopy. **A** Deployment of the proximal flange is well visualized on EUS. **B** Endoscopic view reveals the intragastric flange in the antrum with drainage of pus. **C** The LAMS (Spaxus stent) is identified on the fluoroscopic view. **D** Direct cholecystoscopy through the stent shows small gallbladder stones (arrow head) and the opening of the cystic duct (arrow)

### Definition of events

The main outcomes measures were as follows: (1) technical success, (2) clinical success, (3) procedural and stent-related late adverse events, and (4) recurrence of cholecystitis. Technical success was defined as successful placement of the stent across the stomach or duodenum into the gallbladder for EUS-GBD, along with adequate flow of radio contrast and bile through the stent. Clinical success was defined as complete resolution of clinical symptoms with normalization of laboratory tests. Procedural adverse events were defined as any procedure-related adverse events that occurred within 2 weeks, including bleeding, bile peritonitis, pneumoperitoneum, and perforation. Stent-related late adverse events were defined as any stent-related adverse events occurring later than 2 weeks after stent placement, including stent migration, occlusion. Recurrence of cholecystitis was defined as the recurrence of typical symptoms with characteristic imaging findings. Reintervention was defined as any type of endoscopic, percutaneous, or surgical procedure that was required to improve GBD after placement of the LAMS for EUS-GBD. The procedure time was measured from the echoendoscope insertion to successful transmural stenting.

### Statistical analysis

Statistical analysis was performed using SPSS software, version 24 (SPSS Inc., Chicago, IL). Descriptive statistics were used to describe patient characteristics such as demographics, indications, and treatment outcomes. The results are reported as the mean [standard deviation (SD)] or median (interquartile range) for quantitative variables, and percentages for categorical variables. The Kaplan–Meier method was used to estimate the survival and stent patency rate.

## Results

### Patient characteristics

The baseline characteristics of patients are summarized in Table 1. A total of 22 consecutive patients with acute cholecystitis underwent EUS-GBD with the newly designed LAMS. The median age of enrolled patients was 74.5 (68.0–81.7) years and 15 of 22 patients were male. All of the patients were considered unfit for cholecystectomy because of advanced malignances or scores of 3 to 4 on the ASA physical status classification. The median Charlson's comorbidity index of the patients was 6 (5–9). Among them, three patients had coagulopathy of platelet count less than 100,000/mm$^3$ and an international normalized ratio $\geq 2$ at the time of EUS-GBD (two patients were under anticoagulation due to cardiovascular disease and one patient had

**Table 1** Baseline characteristics of patients

| | EUS-GBD with newly designed LAMS ($n=22$) |
|---|---|
| Age, median (IQR), year | 74.5 (68.0–81.7) |
| Male:female | 15:7 |
| Causes of cholecystitis | |
| Calculous cholecystitis | 14 (63.6%) |
| Acalculous cholecystitis | 2 (9.1%) |
| Malignant obstruction of cystic duct | 6 (27.3%) |
| Charlson's comorbidity index, median (IQR) | 6 (5–9) |
| ASA classification | |
| III | 12 (54.5%) |
| IV | 3 (13.6%) |
| Advanced malignancy | 7 (31.8%) |
| Purpose of EUS-GBD | |
| Urgent drainage for acute cholecystitis | 17 (77.3%) |
| Elective drainage after PTGBD | 5 (22.7%) |

*IQR* interquartile range, *ASA* American society of anesthesiologist, *EUS-GBD* endoscopic ultrasound-guided gallbladder drainage, *PTGBD* percutaneous transhepatic gallbladder drainage

**Table 2** Clinical outcomes of EUS-GBD with newly designed LAMS

| | EUS-GBD with newly designed LAMS ($n=22$) |
|---|---|
| Puncture site | |
| Trans-duodenal approach | 15 (68.2%) |
| Trans-gastric approach | 6 (27.3%) |
| Trans-jejunal approach | 1 (4.5%) |
| Procedure time median (IQR), min | 11.5 (8.8–17.0) |
| Technical success | 21/22 (95.5%) |
| Clinical success | 21/21 (100%) |
| Direct cholecystoscopy | 10 (45.0%) |
| Hospital stay, median (IQR), day | 7 (5.0–8.0) |
| Follow up duration, median (IQR), day | 318.0 (39.0–398.0) |
| Late adverse event | |
| Stent occlusion | 1 (4.5%) |
| Cumulative survival at 1 year[a] | 82% |
| Cumulative patency rate at 1 year[a] | 95% |

*IQR* interquartile range, *CI* confidence interval

[a]Cumulative survival and patency rate were estimated using Kaplan–Meier method

hepatic dysfunction due to extensive cholangiocarcinoma) and one patient had ascites due to peritoneal metastasis of cholangiocarcinoma. The purpose of EUS-GBD was urgent drainage in 17 patients and establishing internal drainage before PTGBD tube removal in 5 patients.

## Technical and clinical outcomes

Table 2 shows the clinical outcomes of EUS-GBD with newly designed LAMS. EUS-GBD was performed trans-duodenal approach in 15 patients, trans-gastric approach in 6 patients, and trans-jejunal approach in 1 patient. Median procedure time was 11.5 (8.8–17.0) min. EUS-GBD with the newly designed LAMS was technically successful in 21 of 22 patients (technical success rate, 95.5%). Technical failure occurred in a 70-year-old male patient with acute calculous cholecystitis who had advanced small bowel cancer. The LAMS was inwardly migrated during deployment and the proximal flange was not identified on the endoscopic view. The tubular shaped fully covered metal stent was inserted through the LAMS lumen as a rescue, and further adverse events were avoided. All the patients (21/21) who achieved technical success experienced a complete resolution of clinical symptoms with normalization of laboratory tests and were discharged without symptoms even after eating (clinical success rate, 100%).

PTGBD removal was possible in all the five patients who underwent initial PTGBD. Direct cholecystoscopy using an ultra-slim endoscope was possible in ten patients during the follow-up endoscopic examination. Most of the gallstones rolled out spontaneously through the stent lumen, and the remaining small gallstones were removed with a basket. We did not perform lithotripsy to remove large gallstones because most of the patients were unable to tolerate time consuming procedure.

## Adverse events

The procedural adverse event such as pneumoperitoneum, bleeding, or bile leakage was not observed except above mentioned technical failure case.

The stent-related late adverse event of stent occlusion developed in one patient (late adverse event rate, 4.5%) 36 days after the procedure. The patient was 74-year old male who had undergone total gastrectomy with esophago-jejunostomy for advanced gastric cancer 3 years ago. We, therefore, performed EUS-GB stenting as a trans-jejunal approach; cholecystojejunostomy. We inserted a second tubular self-expandable metal stent coaxially through the LAMS lumen during a follow-up endoscopy to prevent dislodgement in this case of doubt about the proper anchoring of the distal flanges. At the time of stent occlusion, endoscopic examination revealed that the stent was clogged with food materials. We removed the food material endoscopically and inserted four double pigtail plastic stents through the newly designed LAMS lumen to prevent food reflux. Since then, the patient has been doing well without any further problems. Except for this patient, stent migration or other LAMS-related adverse events such as delayed

bleeding or a buried LAMS syndrome were not observed during the follow-up period even though all stents were left in place permanently.

During follow up (median 318.0 days, range 39.0–398.0 days), 4 of 22 patients (18%) died in the setting of their underlying disease (advanced malignancy in 2 and cardiopulmonary disease in 2 patients). Cumulative survival rate at 1 year was 82% (Fig. 3). No procedure- or cholecystitis-related death has been observed. A total of 18 patients remained alive during follow up period and cumulative stent patency rate at 1 year was 95% (Fig. 4).

## Discussion

In this study, EUS-GBD with newly designed LAMS showed high technical and clinical success rates and a low adverse event rate comparable to those reported in the previous studies on EUS-GBD with LAMS.

Since it was first described in 2007 [13, 14], EUS-GBD has become recognized as an effective alternative for patients with acute cholecystitis who are unfit for surgery. In a landmark study published in 2012 [7], EUS-GBD showed similar results in terms of technical feasibility, effectiveness, and safety, compared with PTGBD in two groups of 30 and 29 patients without any severe adverse events. EUS-GBD has evolved as a definitive treatment for acute cholecystitis

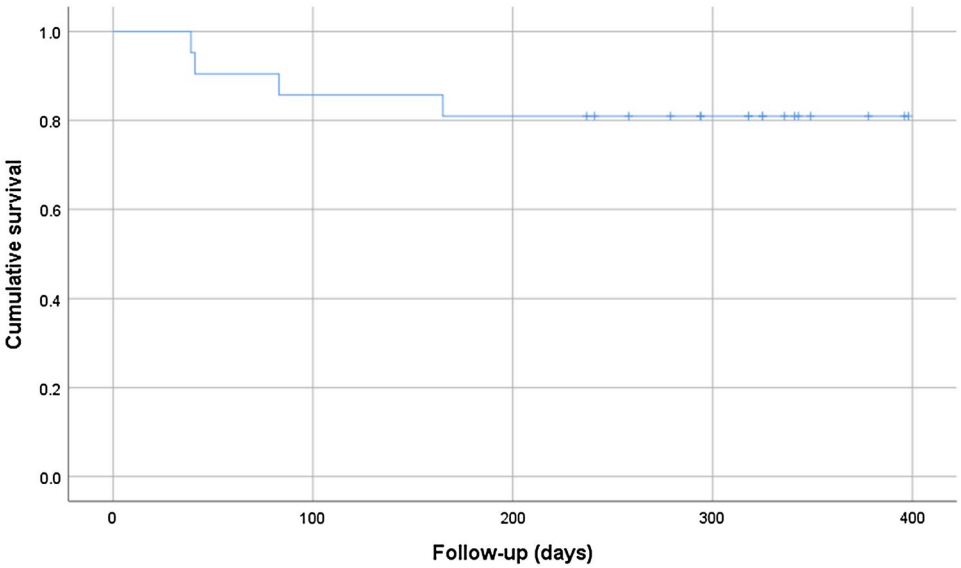


**Fig. 3** Kaplan–Meier curve showing the cumulative survival of patients after endoscopic ultrasonography-guided gallbladder drainage with newly designed lumen apposing metal stent

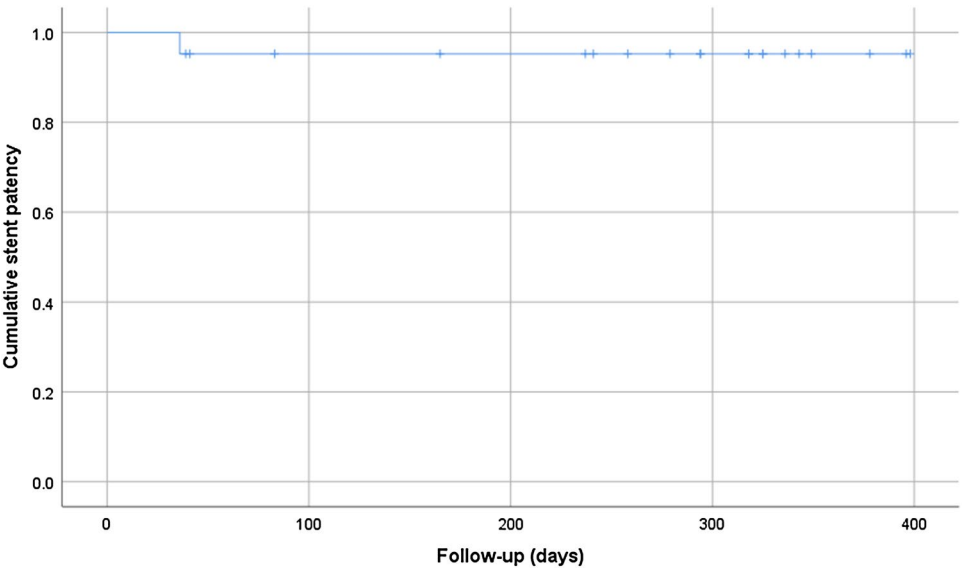


**Fig. 4** Kaplan–Meier cumulative curves for overall stent patency

in patients with high surgical risk, although the materials and method have yet to be standardized.

The tubular shaped (biliary type) metal stent used in EUS-GBD and has shown high technical/clinical success rates (84.6–100%) and low adverse event rates (4.8–28.5%) in previous studies [6, 15–17]. However, bile leakage and stent migration were observed in some patients with conventional biliary-type metal stents without anti-migrating design [15, 18]. Recently, EUS-GBD with LAMS is being increasingly investigated. Theoretically, LAMS should have an advantage of the ability to approximate the gallbladder wall to the intestinal lumen, reduce potential bile leaks, and prevent migration. Several studies of EUS-GBD with LAMS reported a 84.6–93.0% technical success rate and a 5.8–13% adverse event rate [8, 19, 20]. A systematic review reported similar efficacy between LAMS and tubular shape metal stent for EUS-GBD, but a lower adverse event rate in LAMS (9.9% vs. 12.3%) [21].

In the current study, we left the newly designed LAMS in place permanently in all the patients, and buried LAMS syndrome was not encountered during follow-up. Buried LAMS syndrome was supposed to be caused by the excessive pressure that has been applied to the luminal surface while lumen apposition. Regarding EUS-GBD with LAMS, Walter et al. [20] also was encountered buried LAMS syndrome at the time of Axios removal in 3 out of 15 patients. The plausible explanation (of no developing buried LAMS syndrome by using newly designed LAMS) is that the newly designed LAMS has folding-back of wide anchoring flanges that result in accommodative apposition regardless of wall thickening which might provide less compressive pressure to both lumens. It means that this design may reduce the risk of buried LAMS syndrome. However, further follow-up data might be required.

In the current study, EUS-GBD was performed either trans-gastric or trans-duodenal approach. The most appropriate puncture site is different for each patient. It was chosen to be the shortest distance and the most stable location where gallbladder is well visualized without intervening vessel on the EUS. In our experience, there were no differences in the technical and clinical outcomes between two approaches. However, we though trans-duodenal approach seems to be more appropriate for EUS-GBD with LAMS because there is a risk of buried LAMS in trans-gastric approach due to the nature of LAMS.

There was a case of technical failure of inward migration of LAMS during deployment. Migration of metal stent could occur while EUS guided transluminal stenting because it is not easy to maintain position of endoscope and to obtain endoscopic view during deployment. First of all, it is important to recognize immediately if stent migration occurs. If it occurs, guidewire must be left in place and immediate insertion of second long tubular stent through the lumen of the previous stent could prevent further adverse event such as bile peritonitis or perforation. We were also able to avoid such adverse event through insertion of coaxial tubular stent through LAMS. The patient started to eat after fasting for 2 days, and was discharged on the fourth day of hospitalization without symptoms of cholecystitis or bile peritonitis.

Another possible adverse event was food reflux into the gallbladder. Recently, Kim et al. reported two cases of retrograde reflux of gastric contents into the gallbladder following EUS-GBD with LAMS [22]. However, reflux cholecystitis in EUS-GBD was not common in our experience. In the current study, stent occlusion by food reflux occurred in one patient who underwent EUS-GBD through the trans-jejunal approach because he had received total gastrectomy for stomach cancer. We suppose that food reflux in this patient occurred because the axial lumen of the LAMS was placed parallel to the passage of food material. No stent occlusion due to food reflux occurred in patients who underwent EUS-GB stenting in normal anatomical structures.

Direct cholecystoscopy through the LAMS was conducted 1 or 2 days after EUS-GBD in the current study. Of the total patients, introduction of the scope into the gallbladder lumen through the LAMS was possible in ten patients, but full cholecystoscopic evaluation of the gallbladder lumen was possible in only seven patients. Endoscopic manipulation was not easy during direct cholecystoscopy because the length of the tubular portion of the newly designed LAMS is 20 mm, which is longer than the Axios stent which is disadvantage for the therapeutic interventions within the gallbladder.

This study has several limitations. First, it was performed at a highly specialized center by a single operator with a relatively small number of patients. In addition, it is a non-control study and so direct comparison with other stents or procedures may be difficult.

To date, only one kind of LAMS has been available for use in EUS-GBD, offering no choice for clinicians. The current study supports the feasibility and effectiveness of the newly designed LAMS for EUS-GBD.

In conclusion, EUS-GBD with the newly designed LAMS shows acceptable safety profiles both for urgent drainage of acute cholecystitis and elective internalization following PTGBD in patients with high surgical risk.

**Author contributions** DHC were responsible for the conception and design of the study; generation, collection, assembly, analysis, and interpretation of data; and drafting of the manuscript. SSL was responsible for the conception and design of the study; generation, collection, assembly, analysis, and interpretation of data; revision of the manuscript; and approval of the final version of the manuscript. SJJ, JHL, TJS, DHP, SKL, M-HK were responsible for the collection and analysis of data and revision of the manuscript.

## Compliance with ethical standards

**Disclosures** Drs. Dong Hui Cho, Seok Jung Jo, Jae Hoon Lee, Tae Jun Song, Do Hyun Park, Sung Koo Lee, Myung-Hwan Kim, and Sang Soo Lee have no conflicts of interest or financial ties to disclose.

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