Technical issues stemming from endoscopic-ultrasound-guided gallbladder drainage: A single center experience

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ABSTRACT

Background/Aims: *This study was conducted to evaluate the outcomes of endoscopic-ultrasound-guided gallbladder drainage (EUS-GBD) using traditional biliary stents without lumen-apposing stents and to determine technical issues.*

Materials and Methods: *All 18 patients who underwent EUS-GBD at our center between 2012 and 2018 were evaluated. After the clinical outcomes (including technical success, clinical effectiveness, adverse events, and recurrence) were analyzed, technical countermeasures for problems extracted from the analysis were developed.*

Results: *The rates of technical success, clinical effectiveness, severe adverse event occurrence, and recurrence of acute cholecystitis were 94% (17/18), 88% (15/17), 6% (1/18, massive bile leakage), and 27% (4/15), respectively. Distal gastrectomy causing scope instability, the non-swollen gallbladder, and double pigtail stent use caused technical difficulties. A fully covered metal stent (fcMS) should be placed in a shallow position so that it does not wedge into the opposite site. When the puncture route involves the gastric wall, the proximal portion of an fcMS located in the stomach can migrate toward the abdominal cavity.*

Conclusion: *Although the clinical outcomes of EUS-GBD were relatively favorable, several technical issues related specifically to EUS-GBD were observed. Technical countermeasures would improve the outcomes.*

Keywords: *EUS-guided biliary drainage, endosonography, lumen-apposing stent, cholecystoduodenostomy, endoscopic retrograde cholangiopancreatography*

INTRODUCTION

Although acute cholecystitis is normally resolved using surgical cholecystectomy, there are various factors that make the surgery difficult (1,2). Invasive interventions with general anesthesia should be avoided in patients with highly advanced malignancy. Moreover, surgery cannot be performed on patients with extreme risk for general anesthesia, such as advanced age or severe comorbidity.

When surgical cholecystectomy is not indicated for acute cholecystitis that cannot be treated with conservative methods, alternative drainage techniques, including percutaneous drainage, transpapillary drainage via the cystic duct, and endoscopic ultrasound (EUS)-guided drainage, are feasible options. Percutaneous drainage has been established as a relatively safe technique in terms of not only technical adverse events but also sedation-related adverse events (3-5). Transpapillary drainage has been challenging but safe because it is not necessary to puncture any organs to create new access routes (5). In contrast, EUS-guided gallbladder drainage (EUS-GBD) has not been fully established, although it is theoretically feasible. The efficacy of EUS-GBD has been reported in several publications, whereas the outcomes have not been evaluated with a large sample size (6-13). Moreover, most reports on EUS-GBD have focused on the feasibility using a lumen-apposing metal stent (LAMS), which has not been officially approved in most countries (11,14-18). Data on EUS-GBD using traditional devices available for common practitioners are extremely scarce.

We often encounter technical issues characteristic for EUS-GBD. Such issues should be marshaled and carefully examined. This study was conducted to evaluate initial outcomes and to extract technical issues concerning EUS-GBD without LAMSs at a single center with sufficient experience in performing EUS-guided interventions, including EUS-guided biliary drainage (EUS-BD).

MATERIALS AND METHODS

Patients

All patients who underwent EUS-GBD at our center between January 2012 and August 2018 were included

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in this study. Patients were extracted using a prospectively maintained database for EUS-guided interventions.

EUS-GBD has not been prioritized over other drainage techniques, including surgery, percutaneous drainage, and transpapillary drainage (Figure 1). For patients who could not undergo surgical cholecystectomy, percutaneous intervention was the first option. However, when acute cholecystitis did not disappear, or when it recurred soon after percutaneous transhepatic gallbladder aspiration without tube placement (PTGBA), endoscopic drainage was the option if the patient desired to avoid percutaneous transhepatic gallbladder drainage with external tubes (PTGBD). For endoscopic drainage, endoscopic transpapillary gallbladder drainage via the cystic duct (ETGBD) was prioritized over EUS-GBD. In cases where there was a cystic duct obstruction due to a metal stent deployed for malignant biliary obstruction, EUS-GBD was performed without attempting ETGBD. In addition, EUS-GBD was an option for patients with distal bile duct obstruction that could not be treated using other traditional techniques, such as transpapillary biliary drainage, PTGBD, and EUS-GBD.

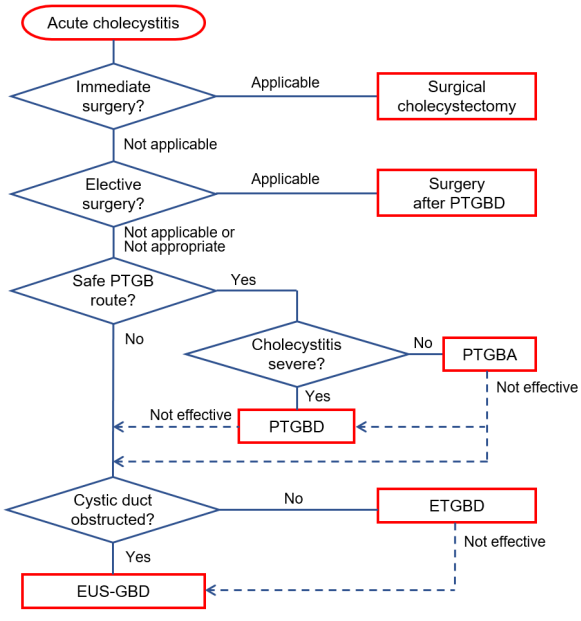

Figure 1. Flowchart for the treatment of acute cholecystitis at the Sendai City Medical Center.
PTGBD: percutaneous transhepatic gallbladder drainage with an external tube; PTGBD, percutaneous transhepatic gallbladder; PTGBA: percutaneous transhepatic gallbladder aspiration without tube placement; ETGBD: endoscopic transpapillary gallbladder drainage; EUS-GBD: endoscopic ultrasound-guided gallbladder drainage.

EUS-GBD procedures

Using an echoendoscope (GF-UCT260, Olympus Co., Tokyo, Japan) that was inserted into the gastric antrum or the duodenal bulb via the mouth, the gallbladder was visualized using the EUS imaging. The gallbladder was punctured using a 19-gauge needle for EUS-guided fine needle aspiration (EZ Shot 3 Plus, Olympus; or Expect, slim line, flex type, Boston Scientific Japan K.K., Tokyo, Japan) via the shortest route without intervening vessels. After injection of contrast material, a 0.025-inch guidewire was inserted into the gallbladder through the needle. The punctured tract was dilated if required using a bougie dilator (ES Dilator, Zeon Medical, Tokyo, Japan) or cautery dilator (6-Fr Cysto-Gastro Set, Cook Japan, Tokyo, Japan). A 7-Fr double pigtail plastic stent and/or a metal stent was finally deployed at the puncture site bridging the gallbladder and the intestinal tract. The type of the deployed stent(s) was decided at endosonographer's discretion.

In the early period of this study, plastic stents were used because of a lack of data on the safety of covered metal stents. As covered metal stents became common for gallbladder drainage, fully covered metal stents started to be used. LAMSs were not used because they were not approved for EUS-GBD in Japan in the study period.

The procedures were all performed by one of four expert endoscopists with the experience of >1000 ERCP sessions, >1000 EUS examinations, and >100 EUS-FNA procedures as a main operator. Some of the experts or well-experienced trainees assisted during the procedures.

Outcome measurements and definitions

This study was conducted to evaluate technical issues that could occur during EUS-GBD. Technical success, clinical effectiveness, procedure-related adverse events, and recurrence of acute cholecystitis were evaluated to extract technical issues. Possible countermeasures are discussed in the Discussion section.

Technical success was defined as a successful deployment of a stent at the puncture site bridging the gallbladder and the intestinal tract. EUS-GBD was considered to be effective (1) when acute cholecystitis completely recovered without additional intervention; (2) when cholecystitis that had improved with previous PTGBD did not recur after clamping external tubes; or (3) when biliary drainage was achieved with the normalization of the serum bilirubin level if EUS-GBD was applied as a salvage for distal bile duct ob-

struction. Status without acute cholecystitis was defined as a non-infectious condition without gallbladder swelling derived from obstruction in imaging examinations. Procedure-related adverse events were defined as unfavorable events that occurred within 7 days after the procedure. Bile peritonitis was defined as abdominal tenderness with peritoneal signs that newly emerged or deteriorated after the procedure. Recurrence of acute cholecystitis was diagnosed only when primary acute cholecystitis improved and disappeared >7 days after the initial EUS-GBD. Recurrence was defined as gallbladder swelling accompanied by infection that required intervention. When the disappearance of acute cholecystitis lasted <7 days, the primary acute cholecystitis was considered not to improve (EUS-GBD was defined as being ineffective). When acute cholecystitis did not recur, stent migration was not defined as recurrence or stent malfunctioning.

Table 1. Characteristics of the patients.

Sex, M:F	12:6
Age, years, mean±SD	75±15
Reason for selecting EUS-GBD	
Acute cholecystitis after MS placement in the bile duct	11
Acute calculous cholecystitis when the conditions of the patient excluded surgery	5
Distal bile duct obstruction that could not be resolved using other techniques	2
Performance status [18]	
0	10
1	5
2	2
3	1
Antithrombotic therapy	1*
Charlson Comorbidity Index,[19] mean (range)	3.5 (2–6)

SD: standard deviation; EUS-GBD: EUS-guided gallbladder drainage; MS: metal stent. *medicated with low-dose aspirin.

Table 2. Clinical outcomes of EUS-guided Gallbladder drainage using a traditional metal stent and/or a plastic stent.

Technical success rate	94% (17/18)
Stent placed	
MS	11
PS	4
MS + anchoring PS	2
Punctured intestine	
Gastric antrum	7
Duodenal bulb	10
Procedure-related adverse events	30% (6/18)
Bile peritonitis, mild	5
Massive bile leakage	1
Clinical effectiveness rate	88% (15/17)
Recurrence rate	27% (4/15)

MS: metal stent; PS: plastic stent.

Ethics

Both the EUS-GBD procedure and this study were approved by the Institutional Review Board of the Sendai City Medical Center. Written informed consent for EUS-GBD was obtained with explanations of risks and benefits in comparison with other possible options from all patients before the procedure.

All authors had access to the study data and approved the final manuscript.

RESULTS

Technical success

EUS-GBD was attempted in 18 patients during the study period. Patients' characteristics are summarized in Table 1 (19,20). The reason for selecting EUS-GBD was acute cholecystitis after metal stent placement in malignant biliary strictures in 11 patients, acute calculous cholecystitis with poor tolerance for surgical cholecystectomy in 5, and distal bile duct obstruction that could not be resolved using other techniques in 2. The PTGBA and PTGBD were performed in 4 and 2 patients, respectively, before EUS-GBD.

EUS-GBD was technically successful in 17 patients (94%) (Table 2). In one unsuccessful case (Case #1, Figure 2), an attempt to deploy a 7-Fr double pigtail stent fixed to the delivery catheter at the puncture site was made. The patient who had previously undergone distal gastrectomy with Billroth-I reconstruction suffered from repetitive cholangitis due to a kink of the distal bile duct. Double pigtail plastic stents through the ampulla induced intolerable abdominal pain, which clearly disappeared after removal, and multiple straight plastic stents and a covered metal stent spontaneously migrated shortly after deployment. Percutaneous drainage might have resolved the problem but was not performed because it required permanent external tubes. EUS-guided hepaticogastrostomy could not be applied because intrahepatic bile ducts were not dilated. EUS-guided choledochoduodenostomy failed because of a thin extrahepatic bile duct

with a low inner pressure, which caused a loss of dilation after puncture. The echoendoscope was extremely unstable because of the previous gastrectomy. Moreover, the puncture was performed on an EUS face where the gallbladder area was small, that is, the gallbladder was visualized at its edge, because several vessels interfered on the other faces with a larger gallbladder area, which meant that the gallbladder was visualized near the center. During the procedure, the gallbladder spontaneously decompressed, and the inner pressure was low. Although the puncture and dilation using a cautery device were successful and although the tip of the delivery catheter was unimpededly inserted, the tip of the stent did not advance through the gallbladder wall because of the diametrical difference between the delivery and the stent. The distal pigtail curve of the stent was finally shaped in the free abdominal cavity between the gallbladder and the duodenal wall without the stent passing across the gallbladder wall. The direction of the distal stent tip became turned back toward the intestinal wall. The fixed shape of the curved stent could not be recovered, and finally, the delivery and the guidewire slipped from the gallbladder to the abdominal cavity. Although mild peritonitis developed, it conservatively improved.

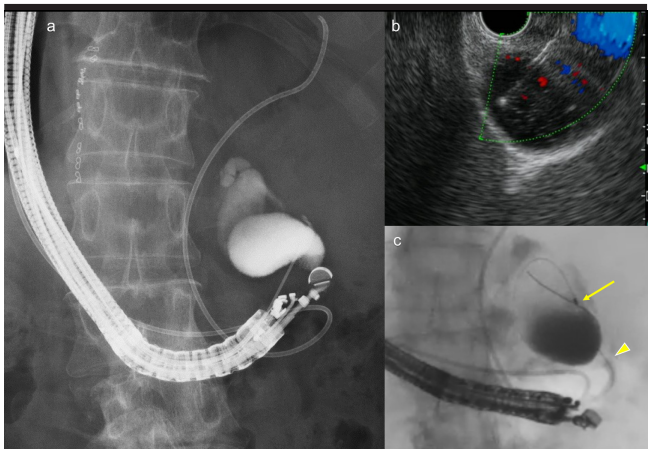

Figure 2. Case #1: technically unsuccessful case. (a) EUS-GBD was attempted in the patient with previous distal gastrectomy who was suffering from repetitive cholangitis due to a kink of the distal bile duct. (b) Puncture was performed on the EUS face where the gallbladder area was small. In addition, the gallbladder had spontaneously decompressed, and the inner pressure was low. (c) Although puncture and dilation using a cautery device was successful, and although the tip of the delivery catheter (arrow) was unimpededly inserted, the tip of the stent (arrowhead) did not advance through the gallbladder wall because of the diametrical difference between the delivery and the stent. Finally, the delivery and the guidewire slipped out from the gallbladder to the abdominal cavity.
EUS-GBD, endoscopic ultrasound-guided gallbladder drainage.

Clinical efficacy

Of the 11 cases who received technically successful EUS-GBD for active acute cholecystitis, EUS-GBD was clinically effective in 9 cases. For the remaining patients (5 with cholecystitis treated using PTGBD and 1 with biliary obstruction), EUS-GBD was clinically effective. For 1 of the 2 ineffective cases, surgical cholecystectomy was performed 2 days after the EUS-GBD procedure because of a massive bile leakage (described in the next section in detail).[21] For the other ineffective case (Case #2, Figure 3) with acute calculous cholecystitis, unimpeded EUS-GBD with a 15-minute procedure time using a fully covered metal stent (X-Suit NIR, 10 mm wide, 80 mm long; Olympus) was performed. However, tubography via the previously deployed percutaneous tube revealed that the stent did not function because it was wedged into the opposite gallbladder wall. A double pigtail plastic stent was endoscopically added through the metal stent to make a space between the edge of the metal stent and the gallbladder wall, resulting in the EUS-GBD functioning.

There were no patients in who the EUS-GBD stent was intentionally removed.

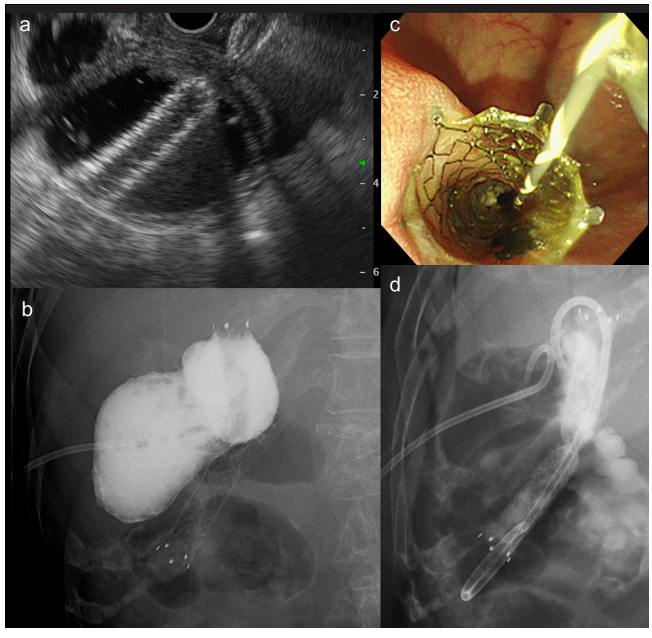

Figure 3. Case #2: clinically ineffective case. (a) EUS-GBD was unimpededly performed for acute calculous cholecystitis using a fully covered metal stent. (b) However, tubography via the previously deployed percutaneous tube revealed that the stent did not function because it was wedged into the opposite gallbladder wall. (c, d) A double pigtail plastic stent was endoscopically added through the metal stent, resulting in the EUS-GBD functioning.
EUS-GBD: endoscopic ultrasound-guided gallbladder drainage.

Adverse events related to the procedure

Procedure-related adverse events were observed in 6 patients (30%). One of them had the aforementioned massive bile leakage that required surgery (Case #3, Figure 4) (6% of severe adverse events rate), whereas the other 5 had mild bile peritonitis, which conservatively recovered in a few days. The surgery case (#3) had suffered from severe gangrenous cholecystitis indicated by "intramural membrane" findings from computed tomography (CT).[21] EUS-GBD procedures were unimpededly performed with a 12-minute procedure time using a fully covered metal stent (WallFlex, 10 mm wide, 60 mm long; Boston Scientific Japan) plus an anchoring double pigtail stent (Through & Pass, Gadelius Medical, Tokyo, Japan) through the metal stent. However, the body temperature was elevated, and the patient complained of abdominal pain the next day. CT revealed massive ascites and air in the abdominal cavity, although the stent remained in the appropriate position without slipping in either direction. Emergency surgery was performed to remove the gallbladder, clean the abdominal cavity, and close the duodenal hole created by using EUS-GBD.

Recurrence of acute cholecystitis was observed in 4 out of 15 patients in who EUS-GBD was clinically effective (27%) during the mean follow-up period of 271±323 days. For 1 patient, a fully covered metal stent completely slipped out. For the other 3 patients, a metal stent moved and dislocated toward the gallbladder side, and the stent edge embedded in the intestinal side (Figure 5). In all dislocation cases, the puncture site was the gastric pylorus.

DISCUSSION

Given the indications of EUS-GBD for which other intervention was not effective, appropriate, nor applicable in this study, the outcomes of EUS-GBD were found to be favorable with a technical success of 94%, a clinical efficacy of 88%, a severe adverse event occurrence of 6%, and a recurrence of 27%. These results appear similar to previous reports on EUS-GBD, including studies in which a LAMS has been used. However, several technical issues occurred during EUS-GBD.

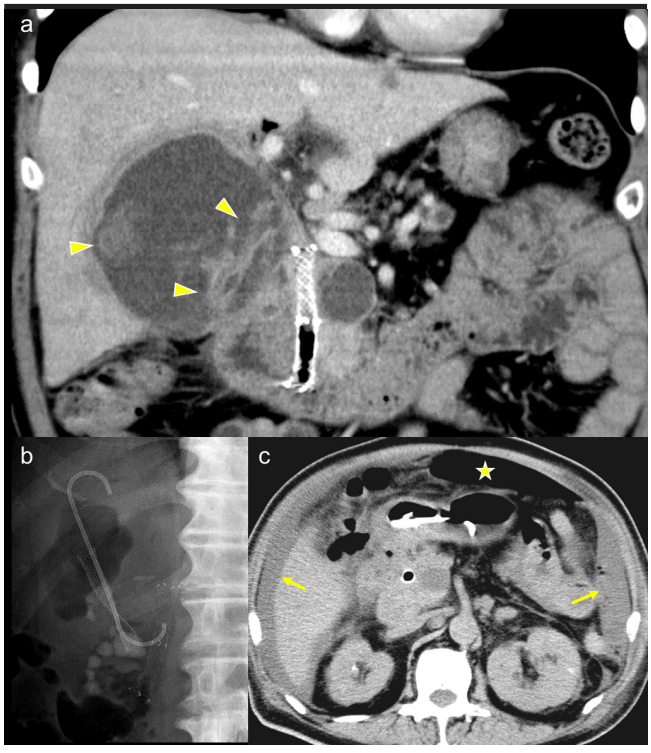

Figure 4. Case #3: case requiring emergency surgery. (a) EUS-GBD was performed for severe gangrenous cholecystitis indicated by "intramural membrane" findings (arrowheads) in CT. (b) Despite the unimpeded procedure using a fully covered metal stent plus an anchoring double pigtail plastic stent, massive ascites (arrows) and air (star) leakage were observed after the procedure, (c) requiring surgical treatment. CT and operative findings showed that the stents did not migrate from the appropriate position until surgery.
EUS-GBD: endoscopic ultrasound-guided gallbladder drainage; computed tomography (CT).

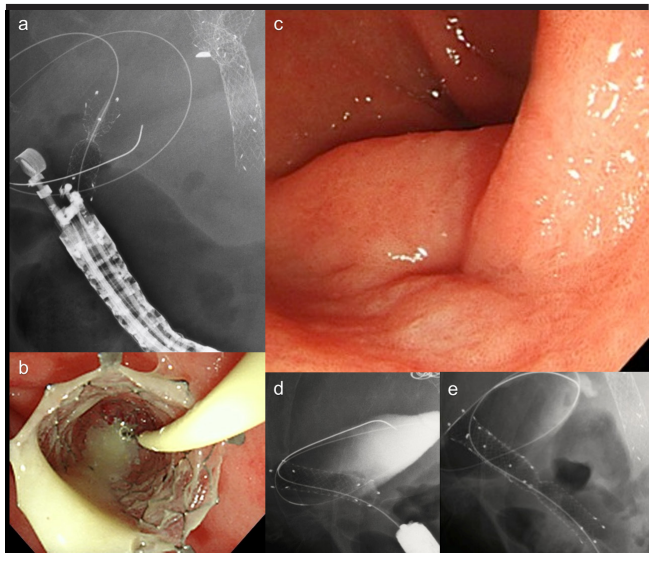

Figure 5. Case of recurrent acute cholecystitis. (a, b) EUS-GBD was performed bridging the gallbladder and the gastric antrum using a metal stent. (c) Although cholecystitis improved, it recurred 22 days after the procedure. CT and endoscopic observation revealed that the stent dislocated toward the gallbladder side, resulting in the stent edge embedding in the intestinal side. (d, e) A guidewire could be advanced into the gallbladder via the fistula and the stent so that a metal stent could be placed.
EUS-GBD: endoscopic ultrasound-guided gallbladder drainage; computed tomography (CT).

In most cases, EUS-GBD is relatively simple due to a large target and short puncture tract. However, the procedure failed for Case #1 in this study. Possible factors causing the procedural difficulties were (1) previous distal gastrectomy that made scope position extremely unstable; (2) a shrunken gallbladder with the low internal pressure that enables the wall to easily move far from the intestinal wall when devices were pushed; (3) a puncture point that was near the edge of the gallbladder, resulting in further easiness of the walls to separate without a device passing across the wall; and (4) use of a double pigtail plastic stent that has a diametrical difference and a directional change between the delivery catheter and the curved tip of the stent. Although the procedure might not be impossible when there is only one factor among them, each factor increases the difficulty.

For Case #2, the deployed fully covered metal stent wedged into the opposite gallbladder wall, resulting in complete occlusion of the bile outflow. A metal stent should be placed in the shallow position to avoid wedging into the opposite wall when a fully covered stent is utilized. Partially covered stents are an option to avoid occlusion due to the same mechanism. A double pigtail plastic stent placed through the metal stent in the same session would prevent such occlusions (22). When a plastic stent is to be placed through a metal stent, a braided type stent should be selected because devices, including plastic stents and dilation catheters, cannot advance through laser cut-type stents in the same session.

A massive leakage of bile and air developed in a patient with gangrenous cholecystitis (Case #3) (21). Since the procedure was unimpededly completed, and the stent did not migrate until surgery, the leakage would have occurred through the space between the stent and the necrotized fragile gallbladder wall that could not tighten the stent. It would be inappropriate to treat extremely severe cholecystitis using EUS-GBD. Moreover, severe cholecystitis cannot be treated using percutaneous techniques. It should be noted that gangrenous cholecystitis with CT findings of intracystic exfoliated tissues might not improve with drainage using tubes or stents.

Acute cholecystitis recurred because the proximal edge of the fully covered metal stent buried into the stomach wall of 3 patients. The stomach is not fixed in the retroperitoneal cavity, unlike the duodenum, resulting in a dynamic movement by food-filling and peristatic actions. This movement induces separation between the two puncture points on the gallbladder and the stomach walls. When the puncture is performed via the stomach, one of the following countermeasures to avoid stent burying should be considered: (1) the proximal portion of the metal stent located inside the stomach should be sufficiently long; (2) a plastic stent (perhaps a double pigtail stent is better) should be used instead of a metal stent; (3) a metal stent with an anti-migration structure, such as flanges, should be selected. LAMSs might be the best choice, as previously reported, although the use of a LAMS for EUS-GBD, to the best of our knowledge, has not been established and is an off-label application in most countries.

Such technical countermeasures could improve outcomes. However, these are not all the possible technical issues concerning EUS-GBD. The critical limitations of this study due to the small sample size will be overcome with further accumulation of cases. To establish such a developing technique, real-world data obtained from retrospective analyses including all cases should be used because prospective studies require patient enrollment with written informed consent and with qualification for strict inclusion criteria, accompanied by elimination of patients in a poor condition, those unable to express the will, those without sufficient time to obtain full informed consent, and those without a trusted relationship with their doctor.

In summary, EUS-GBD using a plastic stent or a traditional metal stent, excluding LAMSs, was found to be reasonable for acute cholecystitis when other interventions failed. Distal gastrectomy causing scope instability, a non-swollen gallbladder, and double pigtail stent use appear to cause technical difficulties. A fcMS should be placed in a shallow position so that it does not wedge into the opposite site. When the punctured route involves the gastric wall, the proximal portion of an fcMS located in the stomach might migrate toward the abdominal cavity. Further technical advances, such as the development of new devices, are necessary.

Ethics Committee Approval: Ethics committee approval was received for this study from the the Institutional Review Board of the Sendai City Medical Center.

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – Y.K., F.K., S.K., T.O., H.K., K.M., T.S., T.M., K.I.; Design - Y.K., F.K., S.K., T.O., H.K., K.M., T.S., T.M.,

K.I.; Supervision - Y.K., F.K., S.K., T.O., H.K., K.M., T.S., T.M., K.I.; Data Collection and/or Processing - Y.K., F.K., S.K., T.O., H.K., K.M., T.S., T.M., K.I.; Analysis and/or Interpretation - Y.K., F.K., S.K., T.O., H.K., K.M., T.S., T.M., K.I.; Literature Search - Y.K., F.K., S.K., T.O., H.K., K.M., T.S., T.M., K.I.; Writing Manuscript - Y.K., F.K., S.K., T.O., H.K., K.M., T.S., T.M., K.I.; Critical Review - Y.K., F.K., S.K., T.O., H.K., K.M., T.S., T.M., K.I.

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