EUS-guided gallbladder drainage for rescue treatment of malignant
distal biliary obstruction after unsuccessful ERCP

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**Background and Aims:** EUS-guided bile duct drainage (EUS-BD) is a well-recognized rescue biliary drainage method after unsuccessful ERCP. EUS-guided gallbladder drainage (EUS-GBD) was recently used to treat acute cholecystitis. The aim of this study was to assess the efficacy and safety of EUS-GBD for malignant biliary stricture–induced obstructive jaundice after unsuccessful ERCP as well as unsuccessful or impractical EUS-BD.

**Methods:** Between January 2006 and October 2014, 12 patients with obstructive jaundice due to unresectable malignant distal biliary stricture underwent EUS-GBD after ERCP failed. EUS-GBD was performed under the guidance of EUS and fluoroscopy by puncturing the gallbladder with a needle, inserting a guidewire, dilating the puncture hole, and placing a stent. The technical and functional success rates, adverse events rate, overall patient survival time, and stent dysfunction rate during patient survival were measured.

**Results:** The rates of technical success, functional success, adverse events, and stent dysfunction were 100%, 91.7%, 16.7%, and 8.3%, respectively. The median survival time after EUS-GBD was 105 days (range 15 - 236 days).

**Conclusions:** EUS-GBD is a possible alternative route for decompression of the biliary system when ERCP is unsuccessful.

ERCP is the criterion standard for treating malignant obstructive jaundice. However, it is sometimes difficult to perform because of the presence of duodenal stenosis and/or previous surgical reconstruction. EUS-guided bile duct drainage (EUS-BD) techniques such as EUS-guided choledochoduodenostomy (EUS-CDS), EUS-guided hepaticogastrostomy (EUS-HGS), EUS-guided antegrade stenting, and EUS-guided rendezvous stenting (EUS-RVS) are alternative biliary drainage methods after unsuccessful ERCP.1-10 Recently, EUS-guided gallbladder drainage (EUS-GBD) was reported to be useful for acute cholecystitis.11-22 Moreover, Jang et al20 showed that EUS-GBD was comparable to percutaneous transhepatic gallbladder drainage in terms of its technical feasibility, efficacy, and safety of the procedures. Thus, when it is difficult to treat malignant distal biliary obstruction by both ERCP and EUS-BD, EUS-GBD may be a suitable alternative. This is because the gallbladder is a large organ on EUS; this makes EUS-GBD access easier than EUS-CDS or EUS-HGS. EUS-GBD is thus used at our institution to treat malignant obstructive jaundice when other methods are unsuccessful or not feasible. The aim of this study was to evaluate the outcomes of EUS-GBD for obstructive jaundice in terms of technical success, functional success, overall patient survival, adverse events, stent patency, and stent dysfunction.

**PATIENTS AND METHODS**

**Patients**

Between January 2006 and October 2014, 511 consecutive patients were admitted to our hospital because of obstructive jaundice caused by unresectable malignant distal biliary stricture. These patients were identified by retrospective review of the medical database of our hospital. This study was approved by the institutional review board of the Kinki University Faculty of Medicine.

Obstructive jaundice was diagnosed in all cases on the basis of the characteristic clinical features (jaundice and...
Assessment of outcomes

The outcomes that were assessed were the technical success rate, functional success rate, adverse events rate, overall patient survival time, and rate of stent dysfunction during patient survival. Technical success was defined as successful stent deployment between the gallbladder lumen and the stomach or duodenum. Functional success was defined as a decrease in bilirubin levels to <50% of the pretreatment value within 2 weeks. The incidence of the following adverse events was assessed: peritonitis, bile leakage, bleeding, stent migration, and stent occlusion. Early and late adverse events were defined as those that presented within and after 30 days of stent placement, respectively. Stent dysfunction was defined as the need for endoscopic, surgical, or percutaneous procedures to improve symptoms after placement of the stent.

RESULTS

In 101 of these 511 patients, ERCP could not be performed due to duodenal involvement of the tumor or postsurgical reconstruction. ERCP was attempted in the remaining 410 patients, which was successful in 376 patients and unsuccessful in 34 patients. ERCP was unsuccessful or not feasible in a total of 135 patients. Seven of these patients elected best supportive care. The remaining 128 patients were advised that they could undergo either PTBD or EUS-BD. PTBD was performed in 11 of the 101 patients unable to undergo ERCP and in 4 of the 34 patients in whom ERCP failed. The remaining 113 did not want to undergo PTBD because they wanted to avoid the external drainage tube. EUS-BD, including EUS-RVS, EUS-CDS, and EUS-HGS, was then attempted in these 113 patients. In 12 of these patients, EUS-BD was not possible or failed because of the presence of duodenal stenosis, thickened bile duct walls, intervening vessels, and/or nondilation of the intrahepatic bile ducts. These 12 patients then underwent EUS-GBD (the first case in February 2009), as described in Figure 2. The remaining 101 patients underwent successful EUS-BD. The demographic and clinical characteristics of the 12 patients who underwent EUS-GBD are shown in Table 1. The patients were, on average, 67.3 ± 13.9 years old, and 8 were male. The main primary disease was pancreatic cancer, followed by lymph node metastasis, bile duct cancer, and malignant lymphoma. The EUS-GBD procedure was performed via the stomach in 7 patients and the duodenum in 5 patients. In 7 patients, a plastic double pigtail stent was inserted in the SEMS to prevent stent migration. The technical success and functional success rates were 100% (12/12) and 91.7% (11/12), respectively. The 1 patient who did not exhibit functional success had sustained hyperbilirubinemia for 2 weeks because of rapid tumor progression. Two early adverse events were observed in this study. One was peritonitis that improved with conservative treatment. The other was stent dysfunction that was due to entrapment of the cystic duct by the growing...
tumor. PTBD was performed as a reintervention in this case. There were no late adverse events. No bleeding or stent migration occurred throughout the observation period. Thus, the adverse event rate was 16.7% (2/12), and the stent dysfunction rate was 8.3% (1/12). At the time that the records were subjected to retrospective evaluation (December 31, 2014), all 12 patients had died. The median survival time after EUS-GBD for these patients was 105 days.

Regarding the 101 patients who successfully underwent EUS-BD, the technical success, functional success, and adverse events rates were 92.1%, 84.2%, and 19.8%, respectively.

**DISCUSSION**

EUS-GBD was recently reported to be useful for acute cholecystitis.\(^{11-22}\) The current study is the first case series on the feasibility of EUS-GBD for malignant obstructive jaundice. In this study, EUS-GBD was performed when ERCP was unsuccessful or not feasible and EUS-BD was difficult to perform. Several studies have reported on the usefulness of EUS-BD in malignant obstructive jaundice when ERCP is unsuccessful: the functional success and adverse event rates of this procedure were 67% to 100% and 0% to 46%, respectively.\(^{1-10}\) Our study showed that the functional success and adverse event rates in the 101 patients who were successfully managed with EUS-BD were similar (84.2% and 19.8%, respectively). With regard to the 12 patients who could not be managed with either ERCP or EUS-BD and had to be managed with EUS-GBD, the functional success and adverse event rates appear to be similar to those for EUS-BD (91.7% and 16.7%, respectively). Thus, this study shows that EUS-GBD may be useful as an alternative treatment option for malignant stricture of the distal bile duct after transpapillary drainage has failed.

The main risk of EUS-BD is bile leakage into the peritoneal space, which can cause bile peritonitis. The bile...

**Figure 2.** Flow chart representing progress of rescue treatment of malignant distal biliary obstruction after the ERCP was unsuccessful or not feasible. *EUS-BD includes EUS-guided choledochoduodenostomy, hepaticogastrostomy, and rendezvous stenting. BSC, best supportive care; EUS-BD, EUS-guided bile duct drainage; EUS-GBD, EUS-guided gallbladder drainage; PTBD, percutaneous transhepatic biliary drainage.

**TABLE 1.** Demographic, clinical characteristics, and outcomes of patients who underwent EUS-guided gallbladder drainage for malignant distal biliary obstruction

<table>
<thead>
<tr>
<th>Age, y, mean ± SD</th>
<th>67.3 ± 13.9</th>
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<tbody>
<tr>
<td>Sex, male/female, n</td>
<td>8/4</td>
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<tr>
<td>Primary disease, % (n/N)</td>
<td></td>
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<tr>
<td>Pancreatic cancer</td>
<td>50.0 (6/12)</td>
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<tr>
<td>Bile duct cancer</td>
<td>16.7 (2/12)</td>
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<tr>
<td>Lymph node metastasis</td>
<td>25.0 (3/12)</td>
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<tr>
<td>Malignant lymphoma</td>
<td>8.3 (1/12)</td>
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<tr>
<td>Technical success rate, % (n/N)</td>
<td>100 (12/12)</td>
</tr>
<tr>
<td>Functional success rate, % (n/N)</td>
<td>91.7 (11/12)</td>
</tr>
<tr>
<td>Adverse events, % (n/N)</td>
<td>16.7 (2/12)</td>
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<tr>
<td>Overall survival, days median (range)</td>
<td>105 (15–236)</td>
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<tr>
<td>Stent dysfunction during patient survival, % (n/N)</td>
<td>8.3 (1/12)</td>
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leakage is caused by migration of the stent and the gap between the fistula and the stent. In this case series, several techniques were used to avoid such bile leakage. First, the guidewire was inserted until at least 2 coils were in the lumen. The gallbladder lumen has more space for coiling than the bile duct. Such coiling yields better stability compared with that with the EUS-CDS or HGS technique. Second, we irrigated the gallbladder lumen with saline solution after puncturing the gallbladder and before proceeding to the next step. This irrigation procedure may reduce the chance of peritonitis due to bile leakage during dilation. We also used SEMSs in our study. Compared with plastic stents, SEMSs are better at sealing the gap between the stent and the needle tracts of the gallbladder wall, thus preventing bile leakage. Notably, 2 separate groups have reported that using novel lumen-apposing metal stents with anchor flanges and flares for EUS-GBD results in excellent outcomes. Thus, such EUS-GBD-specific stents may yield even better and safer outcomes than SEMSs.

In this study, balloon dilation was chosen as the first-line dilation method rather than cautery dilation because we were afraid of the risk of bleeding due to burning gastroduodenal and gallbladder walls. However, cautery dilation may lead to a rapid procedure. Lumen-apposing metal stents equipped with a cautery tip in the delivery system were recently developed. This allows single-step EUS-GBD from puncture to deployment of the stent with a single maneuver.

This study has a few limitations. First, the number of EUS-GBD patients was small, and all patients were from a single institution. Second, the indications for EUS-GBD were limited because this procedure was only performed in patients in whom EUS-BD was unsuccessful or not feasible. A larger study that compares the efficacy and safety of EUS-GBD and EUS-BD is warranted.

In conclusion, EUS-GBD is a possible alternative route for decompression of the biliary system when conventional ERCP is unsuccessful.

**REFERENCES**


