

# 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.<sup>1-10</sup> Recently, EUS-guided gallbladder drainage (EUS-GBD) was reported to be useful for acute cholecys-

titis.<sup>11-22</sup> Moreover, Jang et al<sup>20</sup> 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.

*Abbreviations:* EUS-BD, EUS-guided bile duct drainage; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-GBD, EUS-guided gallbladder drainage; EUS-HGS, EUS-guided hepaticogastrostomy; EUS-RVS, EUS-guided rendezvous stenting; PTBD, percutaneous transhepatic biliary drainage; SEMS, self-expandable metal stent.

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## 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

fever), laboratory data (elevated bilirubin levels and alkaline phosphatase levels), and imaging studies. The malignant distal biliary obstruction cases that were difficult to treat with ERCP were managed with the following strategy. In all cases in which ERCP failed, we suggested to the patient that percutaneous transhepatic biliary drainage (PTBD) or EUS-BD could be performed. Those who gave written informed consent to undergo EUS-BD then underwent EUS-BD, including EUS-RVS, EUS-CDS, and EUS-HGS. If EUS-BD was difficult because of the presence of duodenal stenosis, thickened bile-duct wall, intervening vessels, and/or nondilation of the intrahepatic bile ducts, we performed EUS-GBD. The case series reported in this article consisted of all patients who underwent EUS-GBD as a rescue treatment because neither ERCP nor EUS-BD could be performed.

### EUS-GBD technique

An echoendoscope (GF-UCT240-AL5; Olympus, Tokyo, Japan) was introduced into the stomach or duodenum. The echoendoscopic images were used to ensure that the cystic duct was intact and dilated before EUS-GBD was performed (if the cystic duct was entrapped by tumor, EUS-GBD was not performed). After visualization of the swollen gallbladder adjacent to the antrum or the duodenal bulb, the echoendoscope was manipulated until an appropriate puncture route without interposing vessels was identified. The neck or body of the gallbladder was generally chosen as the ideal target and was then punctured with a 19-gauge needle (EchoTip Ultra; Cook Medical, Bloomington, Ind) under echoendoscopic guidance (Fig. 1A). The gallbladder was irrigated with saline solution to prevent peritonitis caused by bile leaking out of the 19-gauge needle immediately after the gallbladder was punctured. The gallbladder was irrigated more than 10 times with a saline solution-filled 20-mL syringe. Thus, the total irrigation volume was at least 200 mL. Irrigation was continued until the color of the bile became faint. Thereafter, a sufficient length of 0.035-inch guidewire (Revowave; PIOLAX, Yokohama, Japan) was inserted into the gallbladder lumen until there were more than 2 coils in the lumen (Fig. 1B). The puncture tract was then serially dilated with biliary dilation catheters (6F→7F→9F) (Soehendra Biliary Dilation Catheter; Cook Medical) or a balloon dilator (Max Pass, 4 mm; Olympus) over the guidewire. A self-expandable metal stent (SEMS) (Wallflex partially covered stent, 8 mm in diameter, 6 cm in length; Boston Scientific, Marlborough, Mass) was deployed between the gallbladder and the stomach or the duodenum (Figs. 1C and 1D). This new technique was approved by the institutional review board of the Kinki University Faculty of Medicine.

### 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.<sup>5</sup> 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,  $67.3 \pm 13.9$  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

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