ORIGINAL ARTICLE

Is Ultrasound-guided Bedside Percutaneous Transhepatic Biliary Drainage Safe and Feasible in Critically Ill Patients with Severe Cholangitis? A Preliminary Single-center Experience

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Abstract

Background and aim: Severe cholangitis secondary to biliary obstruction carries high mortality unless biliary drainage is performed urgently. Owing to various patient-related and logistical issues, bedside biliary drainage is considered a salvage therapeutic option. This study aims to evaluate the safety and efficacy of ultrasonography (USG)-guided biliary drainage at the bedside in patients with severe cholangitis admitted to the intensive care unit (ICU).

Materials and methods: A total of 20 patients with severe cholangitis admitted to ICU who underwent bedside percutaneous transhepatic biliary drainage (PTBD) under USG guidance were retrospectively evaluated. Clinical outcomes, details about the PTBD procedure, and complications were recorded and analyzed.

Results: Among 20 patients, 13 were male and 7 were female with a mean age of 50.5 years. The most common cause of biliary obstruction was gall bladder malignancy (45%, $n = 9$) followed by cholangiocarcinoma (25%, $n = 5$). Left- and right-sided PTBD was performed in 40% ($n = 8$) and 35% ($n = 7$) patients, respectively, while 25% ($n = 5$) of patients underwent bilateral PTBD. The technical success rate was 100%. A total of 65% ($n = 13$) of patients were discharged from ICU upon improvement while the remaining 35% ($n = 7$) died despite bedside PTBD. None of the patients had any major procedure-related complications.

Conclusions: Ultrsound-guided bedside PTBD seems to be a safe and effective option in critically ill patients with severe cholangitis when shifting of patients is not feasible.

Keywords: Bedside percutaneous transhepatic biliary drainage, Cholangitis, Critically ill.

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Highlights

This study highlights the utility of bedside ultrasound or USG-guided PTBD as a technically feasible and safe procedure with an acceptable clinical outcome in patients who are critically ill with biliary obstruction and severe cholangitis where biliary drainage is imperative.

Introduction

Presently, the majority of the biliary drainage is performed through the endoscopic approach. Despite technical advancements and improved therapeutic expertise, the endoscopic approach may not be feasible, necessitating PTBD. Common indications of PTBD include failed endoscopic retrograde cholangiopancreatography (ERCP), hilar obstruction, or altered anatomy due to prior entero-biliary surgery.[1] Acute severe cholangitis secondary to obstructive biliopathy needs special mention. Such patients are critically ill and often require admission to the ICU.[2] Unless managed expeditiously, severe cholangitis poses high mortality.[3,4] In addition to systemic antibiotic therapy and other ICU management, severe cholangitis due to biliary obstruction requires urgent biliary drainage. Percutaneous transhepatic biliary drainage plays a crucial role in such a situation.[5] Many of the patients with acute severe cholangitis are on mechanical ventilation which makes their shifting difficult and risky. Endoscopic biliary drainage may not be feasible in these critically ill patients. Furthermore, most of the centers, particularly in developing countries lack ERCP facilities and expertise as well as the facility of the fluoroscopic suite. These logistic and patient-related issues may cause a delay in biliary drainage that results in the worsening of the sepsis. Bedside USG has become an essential component of intensive

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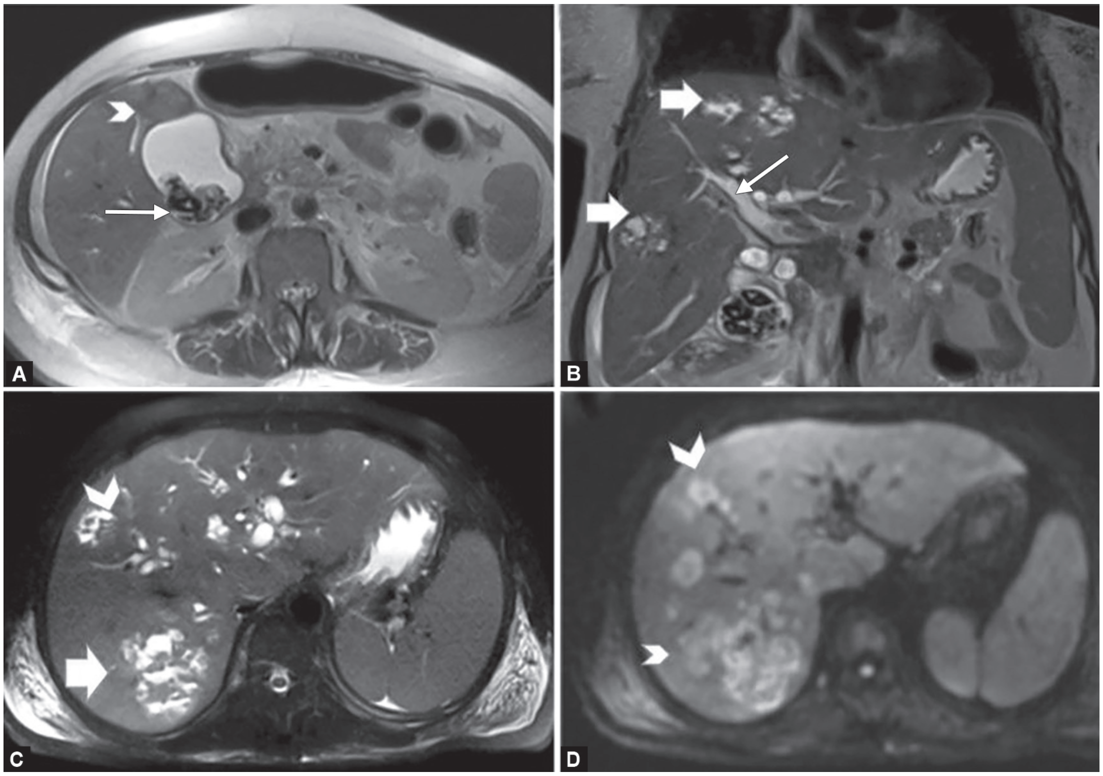


Figs 1A to D: Magnetic resonance imaging abdomen of the patient presented with obstructive jaundice and pain abdomen. (A) Axial T2-weighted section shows gall bladder calculi (arrow) and iso-hyperintense fundal thickening infiltrating the liver parenchyma (arrowhead); (B) Coronal half-fourier acquisition single-shot turbo-spin-echo (HASTE) sequence section shows dilated common bile duct (CBD) (arrow) and multiple irregular cholangiolar abscesses in right lobe of liver (open arrow); (C) Axial section of short tau inversion recovery (STIR) sequence shows multiple abscesses (arrow head and open arrow); (D) Same finding which are previously described is noted on diffusion weighted imaging (DWI) sequence section as areas of restriction diffusion (arrow head) in the previously mentioned abscesses

care management for diagnostic and interventional procedures, thus bedside percutaneous drainage seems to be a more feasible option in such critically ill patients.[6]

Ultrsound-guided bedside biliary drainage is a minimally invasive procedure in the setting of cholangitis and may act as a salvage procedure that will allow rapid biliary decompression.[7–9] This study aims to evaluate the practical feasibility of bedside USG-guided PTBD (USG-PTBD) and to establish its initial safety and efficacy in patients with severe acute cholangitis due to obstructive biliopathy.

Materials and Methods

A single-arm observational retrospective study was performed after approval from the institutional scientific and ethical committee. Patients with acute severe cholangitis who underwent bedside USG-PTBD in the ICU between September 2020 and September 2021 were consecutively included. Patients with incomplete data were excluded. Finally, a total of 20 patients comprised the study cohort.

Tokyo's guidelines 2018 were followed to diagnose and assess the severity of acute cholangitis in patients with obstructive biliopathy.[10] All patients received intravenous antibiotics and other supportive measures on a case-to-case basis. Bedside PTBD was planned only when a patient could not be shifted to a fluoroscopic suite. The failure to mobilize the patients outside the ICU was due to unstable conditions, ongoing mechanical ventilation/impending need for mechanical ventilation, or continuous requirement of ionotropic support, as assessed by the attending intensivist.

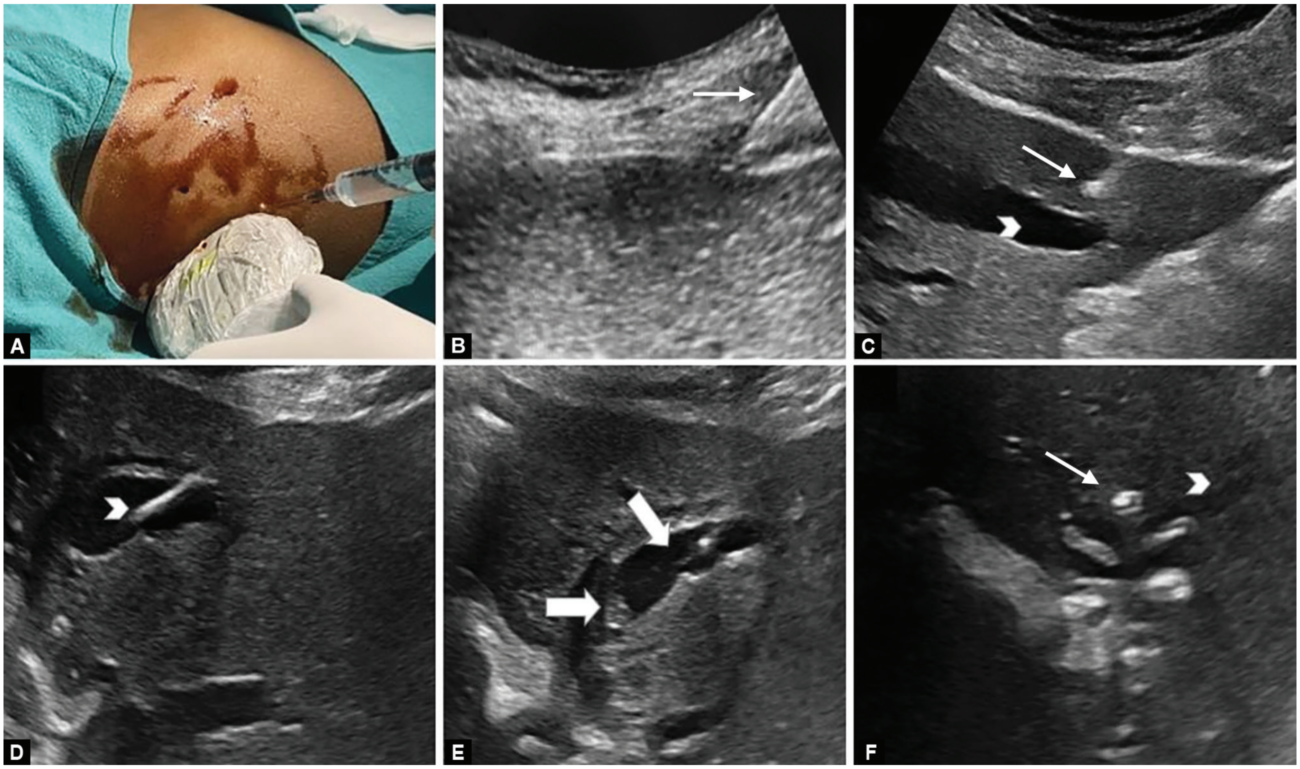
Preprocedural Consideration

The preprocedural assessment included the review of the latest imaging (Fig. 1) and routine investigations. On imaging, proximal obstruction was defined as those above the level of cystic duct–extrahepatic bile duct junction, and biliary obstruction distal to it was defined as distal obstruction.[11]

Being a high bleeding-risk procedure as per the Society of Interventional radiology (SIR) guideline, coagulation profiles were routinely documented.[12,13] Coagulopathy was corrected using platelet concentrate and fresh frozen plasma in case of low platelet count (<50000/mm^3), and elevated international normalized ratio (INR) (>1.5), respectively. No additional pre-procedural antibiotic was given since all patients were already on systemic antibiotic therapy for cholangitis.

Procedure

Written informed consent was obtained from the patient or the patient's attendant before the procedure. The PTBD procedures were performed by an interventional radiologist having 3 years of experience in hepatobiliary intervention. Analgesia was provided with an intravenous infusion of 1000 mg paracetamol, or a slow intravenous injection of tramadol 100 mg depending upon the availability. All procedures were performed under the guidance of USG only. Detailed USG assessment of the entire biliary system



Figs 2A to F: Bedside PTBD in patient had acute cholangitis and sepsis (for the same patient described in Fig. 1). (A) Sterile in-plane ultrasound probe with 25G needle was used to give local anesthesia; (B) Ultrasound image of the 25G needle (arrow) reaching up to the capsule to anesthetize the capsule and skin to minimize the pan related discomfort; (C) Ultrasound-guided transhepatic puncture through hepatic capsule was done with puncture (Chiba) needle (arrow). The needle (arrow) is in plane with intrahepatic biliary duct (arrowhead) in the left liver lobe. Identification of a dilated intrahepatic bile duct was done with color Doppler ultrasound to reduce the vessel related complications; (D) Selection of an appropriate cannulation path avoiding vascular structures with puncture needle was noted in the dilated bile duct and needle position was confirm by free flow of the bile after removal of stylet; (E) The external drainage catheter (open arrow) was placed after track dilation with dilator over the stiff wire; (F) After aspiration through the catheter, there was reduce dilatation of the bile duct (arrowhead) and minimal pneumobilia was also noted (arrow)

using a 5 MHz frequency curvilinear transducer was done before the procedure and a suitable bile duct was chosen for puncture (Fig. 2). Color Doppler was used to differentiate the bile duct from the adjacent vessels. In the presence of perihepatic fluid along the right lobe, the left-sided biliary puncture was preferred. When the right PTBD was required, perihepatic fluid was drained before proceeding for PTBD.

The patient's upper abdomen was prepared (10% betadine) and draped. Using a 25G needle, 2% lignocaine solution (maximum dose of 10–15 mL) was infiltrated at the intended skin puncture site till the liver capsule was under the USG guidance. The bile duct was punctured under the real-time USG guidance using an 18G Chiba needle. A single wall puncture technique was used, avoiding puncture of the posterior wall of the dilated biliary radicle. The needle tip position within the bile duct was visualized on the greyscale tissue harmonic imaging. Correct positioning within the bile duct was further confirmed by free backflow of bile through the needle after the removal of the stylet. Following this, a J-tip hydrophilic guidewire was manipulated into the biliary system through the needle under real-time sonographic control. The distance between the needle tip and the skin entry site was measured to decide an appropriate catheter length. Then, slowly, the needle was pulled out while securing the guidewire inside the biliary tree. A stiff guidewire (Amplatz, Boston Scientific) was exchanged for the hydrophilic guidewire over a 5 F (Kumpe access catheter, Cook Medical) catheter. The parenchymal tract was serially dilated using stiff fascial dilators (ranging from 6 to 10 Fr) and an external biliary drainage catheter (8 F or 10 Fr) was advanced over the stiff guidewire into the biliary system. Finally, the catheter was fixed to the skin with sutures and adhesive patches to prevent migration. The nature of drain output was documented and bile was sent for culture and sensitivity. Drain output was charted daily.

Owing to the increased risk of bleeding and catheter dislodgement in case of moderate to gross ascites, an 8-Fr pigtail catheter was placed in the perihepatic space to drain the ascitic fluid.

Imaging Follow-up

The patients were assessed using USG at 1 hour following the procedure, and thereafter every 2 hours for 6 hours to assess puncture-related complications and decompression of the bile ducts. Thereafter, follow-up USG was done everyday or on an alternate day.

Clinical Follow-up

Patient's clinical and laboratory parameters were assessed regularly by the treating team of intensivists. Upon improvement, they were transferred out of ICU at the discretion of the treating team. Patients were followed up till their discharge from the hospital or death whichever was earlier.

Table 1: Demographic and baseline characteristics of the study cohort ($n = 20$)*

Variables	*Frequency*
Age (years), mean (range)	50.5 (34–70)
Male/female	13/7
Etiology of biliary obstruction, *n* (%)	
Gall bladder malignancy	9 (45%)
Cholangiocarcinoma	5 (25%)
Pancreatic head mass	3 (15%)
Periampullary mass	2 (10%)
CBD calculus	1 (5%)
Patency of primary biliary confluence, *n* (%)	
Patent	13 (65%)
Occluded	7 (35%)
Level of obstruction, *n* (%)	
Proximal obstruction	11 (55%)
Distal obstruction	9 (45%)
Laboratory parameters	
Total leucocyte counts ($\times 10^9$/L), median (IQR)	22.92 (7.5–23.5)
Total platelet counts ($\times 10^9$/L), median (IQR)	188.4 (98–215)
INR (mean ± SD)	1.43 ± 0.13
Total serum bilirubin (mg/dL), mean ± SD	18.21 ± 6.12
Direct serum bilirubin (mg/dL), mean ± SD	11.4 ± 3.92
Serum alkaline phosphatase (IU/mL), median (IQR)	750.4 (334.5–967)
γ-Glutamyl transferase (IU/mL), mean (IQR)	435.4 (266.85–538.25)

*Data are expressed as *n* (%), mean ± SD, or median (IQR). CBD, common bile duct; INR, international normalized ratio; IQR, interquartile range; SD, standard deviation

Procedural details were noted including the approach (left vs right), site of ductal puncture (segment-based), the number of punctures required to achieve successful biliary access, and unilateral or bilateral drainage. In addition, the patient's demographic, clinical, and laboratory parameters, etiology of biliary obstruction, and anatomical level of the biliary obstruction. Technical (defined as the ability to achieve successful biliary drainage) and clinical success (defined as the discharge from the ICU), as well as short-term complications (defined as complications that occurred during the period of hospital stay), were also recorded and analyzed further. A complication of grade above or equal to 3 according to the SIR classification system was considered "clinically significant."[12]

Results

The demographic and baseline characteristics of the patients are summarized in Table 1. A total of 20 patients underwent bedside PTBD, including 13 male and 7 female patients. The mean age of the cohort was 50.5 years, ranging from 34 to 70 years.

Table 2: Procedure-related events and clinical outcomes*

Variables	*Frequency*
Access to biliary duct, *n* (%)	
Left duct	8 (40%)
Right duct	7 (35%)
Both left and right duct	5 (25%)
Segment 3 duct	13 (52%)
Segment 5 duct	5 (20%)
Segment 6 duct	7 (28%)
Number of puncture attempted, *n* (%)	
Left/right duct	17/19
Total mean puncture	1.75
Mean left puncture	1.21
Mean right puncture	1.58
Complications, *n* (%)	
Pericatheter leak	5 (20%)
Transient hemobilia	3 (12%)
Catheter displacement	2 (8%)
Outcome, *n* (%)	
Discharge from ICU	13 (65%)
Death	7 (35%)

*Data are expressed as *n* (%), mean ± SD, or median (IQR). CBD, common bile duct; ICU, intensive care unit; INR, international normalized ratio; IQR, interquartile range; SD, standard deviation

Gall bladder malignancy (45%, $n = 9$) was the most common etiology of biliary obstruction, followed by cholangiocarcinoma (25%, $n = 5$). Among 20 patients, proximal obstruction was found in 55% ($n = 11$) of patients and primary biliary confluence was occluded in 65% ($n = 13$) of patients. All the patients had features of severe sepsis at the time of PTBD with median total leucocyte counts of 22.92×10^9/L. Six of the patients were on mechanical ventilation during the procedure. The mean total and direct bilirubin of the cohort were 18.21 ± 6.12 and 11.4 ± 3.92 mg/dL, respectively.

Technical success was achieved in all the patients. Left-sided PTBD was done in 40% ($n = 8$) of patients while 35% ($n = 7$) of patients underwent right-sided PTBD. The remaining 25% ($n = 5$) had bilateral PTBDs. The overall mean number of liver punctures attempted to access the biliary tree was 1.75 (1.21 for the left and 1.58 for the right lobe). All of the left-sided PTBDs were done through the segment 3 duct while most of the right-sided PTBDs were performed through the segment 6 duct. A total of 25 PTBD catheters were used, including ten 8 F and fifteen 10 F catheters. Initially, all the patients were kept on external drainage catheters. A total of 13 patients were discharged from the ICU; among them, 8 were still on external drainage at the time of the last follow-up while 5 underwent internalization. None of the patients had any major procedure-related complication although three patients developed transient hemobilia (minor complication) and one developed a small subcapsular hematoma. However, none of them required any further intervention. The catheter was displaced from the original position (noted on serial bedside abdominal radiograph) in five patients (three left and two right PTBDs). All of them required catheter repositioning without any need for additional biliary puncture (Table 2).

Discussion

Biliary obstruction can occur due to various malignant and benign pathologies. Common one includes gall bladder carcinoma, cholangiocarcinoma, pancreatic adenocarcinoma, and metastatic disease, all of which have a poor prognosis. Biliary obstruction from any cause poses a risk of acute cholangitis due to biliary stasis. Unless expeditiously managed, acute severe cholangitis leads to septic shock and multiorgan failure, leading to death. It warrants prompt biliary decompression along with systemic antibiotics therapy and other supportive measures.[1–3,14] Currently, endoscopic biliary drainage is the standard treatment for biliary obstruction; however, the proximal obstruction may not be amenable for drainage through the endoscopic approach. Additionally, in the setting of severe cholangitis patients need continuous organ support and monitoring that requires different types of supportive equipment, connected with multiple lines/tubes. Thus, it is practically not a simple task to shift the patient into the fluoroscopic or ERCP suite. Furthermore, there is generally a shortage of round-the-clock trained manpower, particularly gastroenterologists and digital subtraction angiography (DSA) lab staff. All these factors often delay biliary decompression in critically ill patients. In such a situation, USG-PTBD may be a more suitable option and may improve the clinical outcome. Data regarding the feasibility and effectiveness of bedside PTBD using USG alone are limited. This study included twenty patients with acute severe cholangitis admitted to ICU who underwent USG-PTBD at the bedside. The technical success rate was 100%. 65% of patients improved clinically and got discharged from the ICU. Despite urgent bedside PTBD, 35% of patients died in ICU. All of them had a multiorgan failure and refractory shock at the time of PTBD. This emphasizes the need for early biliary decompression in patients with severe cholangitis before refractory shock and multiorgan failure supervene. Of note, none of the patients had major procedure-related complications. Although three patients had transient haemobilia and one had a small subcapsular hematoma, none of them required any further intervention.

A USG-guided bedside drainage is a well-established approach in critically ill patients. Ultrsound-guided biliary puncture has also been described in the literature.[15–20] In patients with minimally dilated USG helps to access the target duct. Even in a non-dilated system, USG offers the advantage of a peripheral portal vein-oriented puncture with an increased success rate, reducing the procedure and fluoroscopic time.[21] Further, the additional use of Doppler imaging helps in differentiating a vessel from the biliary tree and increases the chances of safe entry into the bile ducts.[16,18] A study by Nennstiel et al. demonstrated a comparable technical success between fluoroscopic-guided PTBD and USG-PTBD.[20] Interestingly, major complications were observed only in the case of fluoroscopic-guided PTBD; however, all USG-PTBDs were left-sided while all fluoroscopic-guided PTBDs were right-sided.[20] We had two patients with minimally dilated ducts (4 mm) in whom PTBD was successfully placed under USG guidance. Besides the advantage of no radiation exposure, USG-PTBD does not utilize iodinated contrast. Contrast material per se causes chemical cholangitis, and contrast administration increases the intraductal pressure, leading to bacteremia. Thus, USG-PTBD also reduces the risk of flaring up cholangitis.[22] Giurazza et al. demonstrated a high technical and clinical success rate of USG-PTBD with a low radiation dose.[17] The overall mean number of liver punctures to access the biliary tree was 1.57 by Giurazza et al. However, our study had a slightly higher mean number of punctures (1.75). The latest small series (n = 10) by Gupta et al. also illustrated that bedside PTBD using USG alone is a safe and technically feasible procedure in critically ill patients.[19]

Our study had a few limitations. There could be operator bias as all the procedures were performed by a single interventional radiologist. The associated comorbidities, organ failure, and timing of PTBD in relation to the onset of organ failure were not recorded which could have influenced the clinical outcomes. Additionally, the follow-up period was short, including only the ICU course. Therefore, multicentric prospective cohort studies with larger sample sizes are required to further validate our findings.

In conclusion, USG-PTBD at the bedside is a technically feasible procedure with an acceptable clinical outcome in patients with biliary obstruction and severe cholangitis. In a critically ill situation where biliary drainage is imperative, bedside USG-PTBD seems to be a salvage option.

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