

Ultrasound-Guided Percutaneous Transhepatic Biliary Drainage Outcome at Tertiary Care Centre of North India

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Abstract

Aims: The aim of this study is to know the feasibility and outcome of ultrasound-guided percutaneous transhepatic biliary drainage (PTBD) at tertiary care center of North India.

Materials and Methods: This is a prospective observational study conducted on patients affected by biliary tree obstruction with jaundice referred to department of radiodiagnosis for management of obstructive jaundice. Procedure (PTBD) has been performed by single step puncturing the biliary system under ultrasound guidance.

Results: 110 patients affected by biliary tree obstruction were included in this study. The biliary obstruction was malignant in 102 and benign in eight cases. Technical success considered as positioning of a drainage tube into the biliary tree by only ultrasound guidance and single step puncture was 100%.

Conclusions: Only ultrasound guidance to access the biliary tree and single step puncture of bile duct for PTBD was a safe, low cost, and effective technique for the management of obstructive biliary pathology.

Key words: Percutaneous transhepatic biliary drainage, Obstructive biliary pathology, Ultrasound, Jaundice, Complications

INTRODUCTION

Obstructive jaundice can be of benign and malignant etiologies. Of the malignant cause's carcinoma gall bladder, cholangiocarcinoma, pancreatic adenocarcinoma, metastasis, and lymph nodal compression of common bile duct (CBD) constitute the majority of cases. Most of the cases of malignant obstructive jaundice are already advanced and unresectable by the time they are diagnosed, hence carry dismal prognosis with palliation being the only option left. Obstruction needs to be drained even

in such cases for alleviation of pain, cholangitis, and pruritus or in certain cases to initiate chemo or intrabiliary brachytherapy. Over the years, palliative care has evolved with the introduction of newer methods and improvisation of existing techniques. Recent palliative measures not only prolong longevity but also improve the quality of life, hence increasing the acceptance to such procedures.

Methods of Biliary Drainage Include

- a. Surgical bypass
- b. Minimally invasive procedures
 - I. Endoscopic retrograde cholangiopancreatography (ERCP)
 - II. Percutaneous transhepatic biliary drainage (PTBD).

Both ERCP and PTBD are well-established and effective means of biliary drainage for palliation in unresectable cases. With increased technical success rate and expertise in these

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minimally invasive procedure, recent time has witnessed an exemplary surge in the demand for such procedure over surgical bypass. Selecting an option over other, however, is a multidisciplinary opinion, which not only involves expertise of operator and the site of obstruction but also takes into consideration other factors such as expected survival and the level of post-procedural care provided to the patients. ERCP is usually performed in cases of distal CBD block (beyond hilum), where primary and secondary confluence are patent and only one stent is required, which proximal end is placed in common hepatic duct or intrahepatic bile duct and distal end in the duodenum or beyond the stricture. ERCP is not preferred in patients with loss of primary or secondary hepatic confluences due to need of multiple stent and technical difficulty. PTBD is preferred in proximal biliary obstruction with loss of primary or secondary hepatic confluence because multiple segments can be drained with multiple external/internal bile drainage catheter. PTBD is also indicated in post roux-y anastomosis patients with biliary obstruction because endoscopic procedure is technically not feasible. In patients with severe cholangitis and other comorbidities where patient is not fit for pre procedure anesthesia PTBD can be done which may be lifesaving procedure. Only ultrasound-guided PTBD can be done at low infrastructure center where fluoroscopy X-ray machine is not available or endoscopic biliary stenting facility not available or failed endoscopic biliary stenting.

MATERIALS AND METHODS

The prospective study was conducted on 110 patients from October 2020 to April 2021 with obstructive jaundice and referred from department of Radiation Oncology, Medical Oncology, Gastro-medicine, Gastro-surgery, General Medicine, and General surgery for PTBD and palliative relief of jaundice.

The computed tomography (CT) and/or magnetic resonance (MR) examinations in details, evaluation of stenosis/occlusion level and interposing anatomical limiting factors (bowels and ascites) were evaluated for the best access to biliary system in terms of lesions and anatomy. Patients consuming clopidogrel and aspirin were strictly recommended to withhold for 5 days before procedure. Wide-spectrum antibiotics were administered prophylactically in accordance with specific-site protocols.

Inclusion Criteria

All patients of obstructive jaundice referred for biliary drainage.

(Patients of obstructive jaundice in which either endoscopic biliary drainage procedure is failed or not done due to time

constrain, cost constrain or any other hindrance which precludes endoscopic drainage and patients were not fit for surgical drainage procedures).

Exclusion Criteria

Un-correctable bleeding diathesis, INR >1.5, Thrombocytes count <50,000 were excluded from the study.

Equipments

Samsung HD 60 color Doppler machine was used as USG guidance for biliary duct puncture and liver tissue visualization. Vygone/Chiba 18 gauze puncture needle, Ultra stiff guidewire (0–035" × 80/145 cm), 10 f fascial dilator and malecot drainage catheter along with connector, urine bag, and suture material.

Pre-procedural patient's Preparation

1. Adequate antibiotic coverage (preferably intravenous) was instituted before and after the procedure, as manipulations in obstructed system carry the risk of cholangitis and sepsis.
2. Patient was preferably fasting or on clear liquid diets for at least 4 h before the procedure.
3. Written informed consent was obtained from all patients before the procedure.

Technique

Routinely PTBD procedure is performed under ultrasound and fluoroscopic combined method but in our study, it was done by only ultrasound guidance. Before the initiation of procedure, three-dimensional cross-sectional imaging, that is, CT or MR imaging of the patient needs to be reviewed to determine the following:

Site of obstruction

High or low: In proximal obstruction, primary biliary confluence may be blocked with variable involvement of secondary confluence. Low obstruction occurs beyond the level of primary biliary confluence (i.e., distal to cystic duct insertion). PTBD and ERCP are the preferred drainage procedures in high and low biliary obstructions, respectively.

Selection of appropriate target duct in PTBD

Right versus left PTBD: In case of involvement of biliary confluence, selected duct should drain at least one-sixth of the liver parenchyma. However, in distal obstruction, since primary biliary confluence is patent, a single puncture with placement of single drainage catheter usually suffices. There should be no atrophy or portal vein involvement of the targeted lobe, as even after biliary drainage liver function would not improve due to the lack of functioning hepatic parenchyma. The procedure can be performed either through right

(subcostal or intercostal) or left ductal (subxiphoid) approach. Selection of appropriate side duct (right or left) is a personal preference, although there are certain advantages and disadvantages of both. Reviewing ultrasound before biliary puncture is invaluable for assessing the suitability of puncture as well as any contraindication to the procedure. In case of suitably dilated biliary radicle dilatation, with an 18G puncture needle, under ultrasound guidance, appropriate segmental duct is punctured. In portal triad, biliary radicle is flanked by the branch of hepatic artery and portal vein, caliber of which increases toward the hepatic hilum. Due to this, site of puncture should be as peripheral as possible as more central puncture incurs more risk of major vascular injury. When the outflow of bile starts, a 0.035-inch ultra-stiff guide wire is passed through the puncture needle, punctured needle is withdrawn over the guidewire, tract is dilated under the vision of ultrasound to avoid vascular injury and hepatic parenchymal injury, position of dilator is assessed by ultrasound, after adequate dilation 10F malecot was placed over the stiff guidewire. Position of malecot catheter is again assessed by ultrasound. If catheter tip was suitable in position and adequate drainage of bile noted, after confirmation of satisfactory position of catheter tip the catheter is fixed with suture. In our study, terumo guide wire was not used because it is not visible under ultrasound. Sometime free flow of bile not seen through puncturing needle although needle tip is inside the biliary system due to thick pus content in the biliary system, in that cases pus is aspirated with help of 20 ml syringe. More flexible or PTFE guidewire were used in some cases but more incidence of wire displacement during dilatation or catheter displacement over the guidewire noted with more softer the guidewire. Merits of left-sided PTBD are relatively easy to perform, better patient's compliance with less catheter pulled out rate, preferred in ascites due to less peri catheter leakage of ascitic fluid. Merits of right sided PTBD-more segment of liver cover. Right lobe catheter placement is more difficult than left lobe and in right lobe segment vii and viii are more difficult than segment v and vi. Right lobe difficulty is due to intercostal approach, angulated tract of biliary access, pleural and lung base interference in complete visualization of needle tract and dilatation of diaphragm in the tract. Segment iii puncture is straight and more superficial access of biliary system, subcostal location and easier tract dilatation make it relatively easier as compared with other segments or right lobe.

Complications of PTBD

With increased expertise and better instrumentation, observed technical success rate of PTBD is approx. 95–100% with fewer complications observed nowadays. These complications can be further reduced by keeping

the biliary manipulation to minimum and good antibiotic coverage.

Minor complications - pain, peri catheter leak, catheter dislodgment, or blockage.

Major complications - Cholangitis, sepsis, Biliary peritonitis, Hemorrhage, Pancreatitis, Pleural effusion, and pneumothorax (inadvertent pleural puncture).

Catheter dislodgement is more common in external than internal drainage catheters due to better anchorage in the latter. It can be managed by repositioning or probing by a guide wire through previous catheter's tract or fresh tract. Peri catheter leak (bile leak along catheter) is a frequently observed complication. It can be due to side holes catheter lying outside the biliary system, catheter kink/block, or ascites. Management in such cases consists of repositioning or upgradation depending on the findings of check cholangiogram or by percutaneous peritoneal drain catheter placement. Catheter blockage is either due to kinking of tip/shaft of catheter or due to luminal narrowing with debris/biliary sludge. Cholangitis and biliary sepsis are inevitable complications which can occur despite adequate antibiotic coverage. Risk of cholangitis is very less as compared with fluoroscopy-guided PTBD in which if positive contrast media is injected into biliary system and drainage of bile is not adequate or incomplete drainage, in that condition severe cholangitis may develop which may be fatal. Although exact etiology is unknown, it can occur due to multitude of factors such as retrograde reflux of intestinal flora during the procedure, *ex vitro* infection tracking along the drainage catheter, or may be of hematogenous origin. Prophylactically, broad spectrum intravenous antibiotics covering Gram-negative bacteria were given to prevent any risk of cholangitis. In addition, during the procedure, manipulations should be kept to minimum coupled with no use of iodinated contrast during ultrasound-guided PTBD procedures. No any case of hemorrhage or pancreatitis developed in our study.

PTBD performed from October 2020 to April 2021 have been included in this analysis. Data have been collected prospectively in Microsoft excel data sheet. Data analysis is done with Microsoft excel software. Collected demographic data included: Age, gender, bilirubin value, dilation of the biliary tree, anatomical level of the biliary stenosis/occlusion, and etiology of the lesions. Procedural evaluated factors were as follows: Technical and clinical successes, right-/left-sided access, and number of liver punctures (intended as passage of the needle through the hepatic capsule) to gain the biliary tree and complication rates.

OBSERVATION AND DISCUSSION

A total of 110 cases of PTBD were done between October 2020 and March 2021. All patients were drained with external biliary drainage with 10 f malecot catheter and catheter is sutured with mersilk 1-0 or 2-0 suture. No fluoroscopy or iodine contrast media is used in all the procedures. No any pancreatitis, hemorrhage or procedure related mortality noted during procedure or after post-procedure follow-up. Etiology of obstructive biliary pathology in our study was carcinoma gall bladder in 90 cases, seven cases of cholangiocarcinoma, nine cases periampullary carcinoma and two cases of benign biliary stricture (post cholecystectomy), and two cases of CBD calculus with cholangitis and septicemia. Gall bladder carcinoma cases were mostly in the fourth and fifth decades but case as young as 20-year-old male and as older as 78 years female were also noted. Cholangiocarcinoma cases show age incidence in 4 and 5 decades. Periampullary carcinomas age incidence is in 5 and 6 decades. Majority of gall bladder carcinoma show hilar infiltration with lack of formation of primary confluence and endoscopic drainage procedure was failed, out of 90 gall bladder carcinoma 18 have patent primary confluence, 60 have lost primary confluence, and 22 have lost primary as well as secondary confluence. Out of total 110 cases 104 cases are approached through left lobe (segment iii) and 60 cases by both left and right lobe and 6 cases are through only right lobe. In right lobe segment v approach is more common. Left lobe approach is easier approach because subcostal location, shorter distance of puncturing segment iii ducts, no intervening pleura for obscuration of segment iii duct visualization and easier tract dilatation. In 22 of the cases show loss of primary as well as secondary confluence, in these cases 2 or 3 ductal system with good liver volume were drained because draining all obstructed segments (4–8 no.) is cumbersome and increased morbidity. Most of the periampullary carcinoma cases are drained by single left lobar drainage. Four cases of periampullary carcinoma with mild dilated biliary system were drained by transhepatic cholecystostomy when patients were irritable and incomparable. Transhepatic cholecystostomy was an alternative and rapid procedure to drain the obstructed biliary system with patent common hepatic duct and primary hepatic confluence. Cholecystostomy may be also done in distal CBD stricture or mass in morbid and irritable patients. Cholecystostomy in empyema gall bladder decrease morbidity associated with primary cholecystectomy. In our study, most of the cases show moderate or grossly dilated biliary system. Biliary duct punctured with 18 gauge vygon needle is not too difficult. Introduction of guidewire in the biliary duct punctured needle were also not difficult but guidewire advancement

in the ductal system up to obstruction site is difficult in ten cases due to tortuous course of ducts. Tract dilatation were easy with ultra-stiff guide wire with little chances of guidewires displacement; however, it was more difficult with flexible or PTFE guidewire with more incidence of guidewire dislocation especially in stiff liver. In two cases, there was puncture of left hepatic artery branch however bleeding is stopped within few minutes and no e/o pseudoaneurysm or fistula formation. Six cases show puncture of portal vein branches but no e/o excessive blood loss or persistent hemobilia. None of the cases show procedure induced septicemia. Peri catheter leak or bilioma formation noted in eight cases and mostly due to partial pulled out of catheter, these cases were managed with reinsertion of PTBD catheter along with drainage of peritoneal collection with 12 f pigtail catheter drainage.

From the first description of fluoro-guided PTBD in 1962,^[1] several techniques have been proposed without clear standardization. According to the literature data, procedural related complications rates are substantial even if heterogeneous.^[2] Especially for biliary ducts puncture, multiple fluoroscopic and US-guided approaches have been reported. Even if US-guided PTBD has been described as an effective and safe method since time,^[3] only limited data are available in literature.^[2,4-7] Actually, both fluoro-guided and US-guided techniques are adopted in the clinical practice and the choice depends mainly on operator preference; some interventionalists prefer US guidance only for technically challenging cases and left-sided puncture, to avoid gastrointestinal structures.^[8,9] In moderate to grossly dilated IHBR USG guided biliary puncture and cannulation are not difficult [Figure 1], and after catheterization position of catheter can be demonstrable in USG as parallel echogenic lines [Figure 2]. Moreover, US guidance may allow to avoid the accidental puncture of liver lesions in case of bilobar intrahepatic metastatic disease. The SIR guidelines for PTBD recommended a procedural threshold for major complications of 10% and a biliary tree cannulation success rates of 95% and 70% in case of dilated and non-dilated ducts, respectively.^[10] In this series, the complication rate was 5% with low grades (all between Grade I and Grade III of CIRSE classification complications system), while the cannulation of the biliary tree was feasible in 100%; these data, compared to literature-reported outcomes of fluoro-guided PTBD,^[1,5,8,10-14,25] seems to encourage US guidance. This is in accordance with two previous published studies in 1995^[6] and 2004^[15] and a recent study of 2017^[14] which described an advantageous overall interventional complications rate for US-guided PTBD over fluoro-guidance.

Portal branches run ventrally to the biliary tree and may be intercepted along the PTBD track. Compared to literature

data,^[16] the low rate of cholangitis-related fever may be due to the high percentage of internal drainage positioned. An alternative to PTBD may be endoscopic ultrasound-guided biliary drainage: This novel procedure involves accessing the biliary tree from within the lumen of the gastrointestinal system using echo endoscopy and fluoroscopy, creating a fistulous tract and deploying a stent in a single-step procedure, obviating the need for external drain.^[17] Compared to PTBD, main advantages of this procedure are a better nutrition absorption avoiding electrolyte loss and preventing the stress of external drain;^[18] however, the procedure is technically complex requiring specialized training and a steep learning curve to avoid complications.

A meta-analysis study in 2017 show that PTBD has a lower rate of complications than EBD as the initial procedure to perform preoperative biliary drainage in resectable pancreatic head carcinoma and it is associated with less conversion and lower rates of pancreatitis and cholangitis.^[19]

Gupta study in 2020 show that PTBD can be effectively and safely performed even in situations deemed to predispose patients to increased risk for adverse events.^[20]

A systematic review and network meta-analysis in 2018 show that no pre-operative biliary drainage may be the best management of pre-operative jaundice in patients with resectable pancreatic head carcinoma before pancreaticoduodenectomy.^[21]

PTBD was associated with similar overall complication rates in patients with dilated versus non-dilated bile ducts in a study in 2021.^[22]

Major drawback of external PTBD catheter drainage is accidental/inadvertently pull out of the catheter which time duration is extends from 1 days to 90 days with mean duration is of 34 days. However, the advantage of external biliary drainage is replacement of external drainage catheter with minimal effort and very much cost effective Few of the failed endoscopic drainage cases show concurrent and large cholangiolar abscesses in which concurrent percutaneous drain was placed. Two cases of endoscopically placed metallic stent with non-decreasing trend of serum bilirubin were also placed external ptbd catheter after which downtrends of serum bilirubin noted. Four cases of gall bladder mass where retrospective stenting not possible by endoscopically were antegrade metallic stenting done after external biliary drainage. Accidental/inadvertently catheter pulled out was common with prolonged percutaneous biliary drainage, though it was observed that when catheter pulled out occur after 2 weeks of its placement then repeat introduction of the catheter over the guidewire through the previous tract is more

feasible. Another advantage of percutaneous drainage is that whenever catheter get blocked it is much easier to flush the catheter or exchange the catheter over the guidewire as contrast with endoscopic catheter exchange which is more costly, require anesthesia and time taking. Cost effectiveness is another advantage of PTBD and external drainage, consumables cost is hardly 60 dollars. Further cost cutting were done by using the guidewire and dilater sterilized by glutaraldehyde (cidex) solution. Almost all cases with obstructive jaundice subsided completely or decreased markedly with PTBD procedures. In cases with blockage of primary as well as secondary hepatic duct confluence reduction in serum bilirubin was gradual or even complete reduction was not possible. All the septicemia cases with all segmental drainage recovered with PTBD procedures. All patients with intact primary confluence relief from obstructive jaundice and patient with intact secondary confluence get definite improvement in their bilirubin level by doing bilobar PTBD. Patients with lost primary as well as secondary confluence have poor reduction in bilirubin level even after bilobar PTBD. Five cases undergo for antegrade metallic stenting after PTBD procedure. ERCP with placement of plastic stent (polyethylene endoprosthesis) is another effective method of biliary drainage. It is the preferred procedure in cases of obstruction beyond the level of hilum, that is, if the primary biliary confluence is patent as adequate biliary drainage can be accomplished by the placement of single stent. Furthermore, in such cases of low biliary obstruction, ERCP is preferred, as it is a safer procedure in comparison to PTBD.

Endoscopic (ERCP) Versus Percutaneous Drainage (PTBD) - In inoperable malignancies causing biliary obstruction, ERCP with placement of plastic endoprosthesis or PTBD with metallic stenting remains the minimally invasive options. However, choosing a procedure over other depends on the level of obstruction, operator's expertise, and the level of post-procedural care provided to the patient.

Distal biliary obstruction ERCP is unambiguously the preferred procedure worldwide as it is a comparably safer procedure with relatively fewer contraindications. Unlike PTBD, burden of percutaneous drainage catheter and bag is obviated which further compounds the psychological burden of terminally ill patients. In the current scenario, in cases of distal CBD obstruction, ERCP is the preferred technique unless contraindicated, for which PTBD is done. Proximal biliary obstruction opinion is divided regarding the choice of technique with nearly comparable results regarding overall patient's survival and procedure related complication. However, at many institutions, PTBD is preferred in hilar isolation as ultrasound-guided puncture of appropriate segmental biliary radicle can be done, thus maximizing the drainage of functioning liver parenchyma. Further, malignant

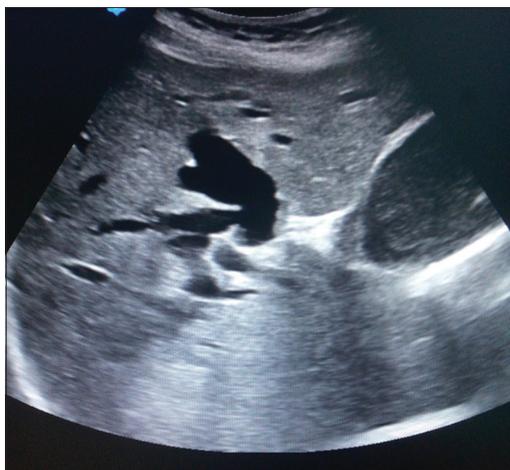


Figure 1: Grossly dilated biliary system made biliary puncture not difficult

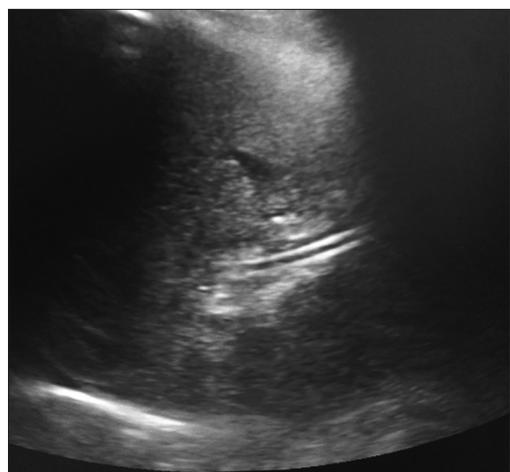


Figure 2: External biliary catheter visualization by ultrasound as parallel echogenic line

stricture is better negotiated in PTBD and the risk of inadvertent contrast instillation into isolated biliary segment is lesser as compared to ERCP. Various studies comparing PTBD and ERCP in distal CBD block have reported that both these procedures have nearly equivalent technical success rate with comparable incidences of procedure-related complications and mortality. The American College of Radiology (ACR) has recently proposed an evidence-based algorithmic approach for radiological management of malignant biliary obstruction. In the proposed criteria, various management options are rated based on their appropriateness for particular site of obstruction.

In general, as per the ACR recommendations of the various management options, PTBD is preferred for hilar block whereas ERCP with stenting in distal block. Endoscopic verses percutaneous biliary drainage.

- Proximal biliary obstruction (hilar involvement) - PTBD or ERCP.
- Distal (beyond hilum) obstruction: ERCP preferred.

- Inoperable cases with short life expectancy (6–12 months) - Metallic biliary stenting.

CONCLUSION

Single step and ultrasound-guided percutaneous biliary drainage (PTBD) is feasible, rapid, and effective method for relief of obstructive jaundice as well as associated septicemia. Fluoroscopy machine as well as contrast is not required for this procedure so it is cost effective and feasible at low infrastructure set up where ultrasound machine and trained radiologist are available. PTBD is very effective in decreasing the morbidity and mortality of not only neoplastic lesion but also benign lesions such as benign biliary stricture, choledocholithiasis with septicemia, and cholangitis due to other benign lesions.

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