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Percutaneous Transhepatic Biliary Drainage as a Viable Alternative to Failed Endoscopic Retrograde Cholangiopancreatography in Hepatobiliary Disorders: A Retrospective Analysis

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ABSTRACT

The conventional second-line treatment for failed ERCP was Percutaneous Transhepatic Biliary Drainage (PTBD). Because of its high level of success and accessibility, PTBD has evolved into a well-established rescue therapy. **Objective:** To assess the procedural outcomes of PTBD following a failed ERCP in patients with hepatobiliary disorders. Additionally, it was focused on finding the significant factors that impact PTBD outcomes. **Methods:** A retrospective descriptive analysis was performed on 128 individuals at Dow Hospital Ojha Campus Karachi, who received PTBD following a failed ERCP. Between January 2023 and March 2024, we evaluated the clinical success rate, post-PTBD complications, and mortality. **Results:** The mean age of the patients was 65.9+/-11.7 years, and 76 (59.4%) patients were female. The clinical success rate was 77.3%, and complications after PTBD were 20(15.6%). A prolonged hospital stay was reported in 29 (22.7%) patients, and 13 (10.2%) patients died within 30 days. Younger age, etiology, and type of PTBD had a significant association with clinical success (P<0.05). Older age, female patients, and malignant etiology had a higher complication rate and mortality (P<0.05). **Conclusions:** PTBD provides a safe, effective, and viable alternative approach for patients with hepatobiliary disorders. It has a low rate of complications, a high rate of procedural success, and a low risk of mortality after a failed ERCP. Adverse events were more common in patients with a malignant etiology, older age, and female gender.

INTRODUCTION

Biliary obstruction is commonly defined as the blockage of the extrahepatic biliary obstruction. It might occur anywhere along this path and lead to serious complications [1]. Furthermore, the biliary obstruction may get colonized by germs, leading to infections. Pancreatic cancer, cholelithiasis, choledocholithiasis, cholangitis, and cholangiocarcinoma are only a few of the malignant and benign hepatobiliary illnesses that frequently result in biliary blockage [2]. These obstructions have an effect on a significant proportion of the global population, leading to low life expectancy and elevated rates of morbidity and mortality. For every 1,000 individuals, there are around five cases of biliary obstruction [3]. The fluoroscopic or combined fluoroscopic and ultrasound guidance can be used to perform image-guided PTBD functions. There are several signs and symptoms associated with it, ranging

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from obstructive to non-obstructive etiologies. The indications of PTBD for palliation in obstructive jaundice include cholangiocarcinoma, reduced serum bilirubin before beginning chemotherapy, cholangitis, pain relief, pruritus, and accessing the biliary system for additional palliative procedures like stent implantation [4]. Because of its high degree of technical success and accessibility, PTBD has evolved into the standard rescue therapy. However, there are a number of significant drawbacks to PTBD, such as a generally high incidence of adverse events (20-30%), a need for repeated reinterventions, and a decline in the quality of life for patients [5, 6]. In order to treat such hepatobiliary disorders, ERCP serves as the gold standard for obtaining biliary access. Over 90% of ERCP cases are successful [2]. Despite being the most often used treatment to palliate patients with biliary blockage, ERCP with biliary drainage is unsuccessful in 3–10% of cases. Inadequate drainage, anatomical variance, tumor expansion, previous surgery, and/or operator inexperience all contribute to failure [7]. There are typically three more approaches to accessing the biliary tree in the event that an ERCP fails. With a success rate of 63–78%, the initial procedure is a repeat ERCP. In 63–86% of cases, biliary access is obtained using the PTBD method for biliary tree drainage [2, 8]. According to guidelines, biliary cannulation of dilated ducts should be performed in 95% of cases, with serious complications in 10% of cases [9]. Because it requires immediate diagnosis and treatment, advanced malignant biliary obstruction continues to be a difficult clinical scenario [10]. In situations of malignant or benign blockage, PTBD is used to decompress the intra and extrahepatic biliary channels in order to relieve symptoms, lower bilirubin levels, and make biliary placement of stents easier [3, 11]. However, the in-hospital death rate estimated almost 20% for patients undergoing PTBD. Higher mortality is correlated with older age, male gender, and those with co-morbidities, for unresectable biliary tract blockage, and, specifically, to inexperienced clinicians [12]. Based on the location of the blockage and the cause of the disease, multidisciplinary teams should choose the appropriate kind of intervention. Though it is currently the standard of therapy and readily available, endoscopic ultrasound's ongoing advancements may eventually result in a declining indication of percutaneous drainage. A significant benefit of percutaneous intervention is its high technical success rate, which can reach 94–100% when compared to the less successful outcomes of ERCP [13, 14]. This study seeks to assess the therapeutic efficacy and safety profile of PTBD as a minimally invasive alternative to failed ERCP for the management of biliary symptoms, with the potential to inform evidence-based practice and optimize patient outcomes. Advancing patient care and outcomes through innovative research and evidence-based practice. This groundbreaking study on PTBD addresses a critical knowledge gap in hepatobiliary management, improving patient safety, reducing morbidity, and enhancing quality of life.

By investigating the efficacy and safety of PTBD, we will generate crucial data to inform institutional guidelines, refine treatment protocols, and contribute meaningfully to the global scientific community.

METHODS

This retrospective descriptive study was conducted at the Department of Vascular Interventional Radiology, Dow Hospital Ojha Campus Karachi, after receiving ethical approval (Ref: IRB-3470/DUHS/EXEMPTION/2024/138) from the Institutional Review Board. The IRB waived the prerequisite for written informed consent because the study was retrospective in nature. Sample size was calculated 128 using PTBD success rate 77% (3) at margin of error 7.5% and confidence interval 95%. All 128 patients aged over 18 years with hepatobiliary obstruction who underwent PTBD after failed ERCP from January 2023 to March 2024 were included in the study following non-probability consecutive sampling technique. Patients with deranged LFTs (liver function tests) and optimal intrahepatic ductal dilatation were included. The exclusion criteria comprised missing clinical data but the data was well maintained and properly reported and all the required information's were extractable during data collection of data. Patient's demographic details, laboratory tests, imaging results, and outcomes of PTBD, such as hospital stay, mortality, complications (such as infection, fever, post-procedural bleeding, had drain dislocation, and sepsis etc.), and clinical success were obtained from electronic health records and the photo archiving and communication system. Technical success of PTBD was deemed as the procedural completion with the placement of biliary catheter and clinical success considered as the normal WBC count, with no fever or organ failure within one month. Procedural complications were reported as per society of interventional radiology guidelines [8]. The Experienced interventional radiologists utilizing conventional tools and standardized methods carried out the PTBD procedures. In the current study, all PTBD procedures were conducted with the placement of an around 8 Fr small pigtail drainage catheter and were performed by interventional radiologists with more than ten years of experience in biliary intervention. All statistical analyses were performed using IBM SPSS statistical software version 22 for Windows (IBM Corp., Armonk, New York, USA). Continuous variables were measured as the mean± SD, and categorical variables were presented as frequency and percentage. Study outcomes (clinical failure, complications, and mortality) were compared using the logistic regression analysis. A univariate and multivariate analyses were performed to identify risk factors associated with clinical outcomes for PTBD. A P-

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value<0.05 was considered statistically significant.

RESULTS

Demographic and procedural outcomes data of 128 patients with hepatobiliary disorder who underwent PTBD after failed ERCP were shown in Table 1. The mean age of the patients was 65.9+/-11.7 years, and 76 (59.4%) patients were female. Most of the 99 patients (77.3%) who underwent PTBD procedures had malignant conditions. Clinical failure was reported in 29 (22.7%) patients, and complications after PTBD were 20 (15.6%). A prolonged hospital stay was reported in 29 (22.7%) patients, while 99 (77.3%) patients were discharged the next day of the procedure, and 13 (10.2%) patients died within 30-days (Table 1).

Table 1: Demographic Characteristics and Procedural Outcomes of Patients

Study Variables		Mean ± SD / N (%)
Age (Years)		65.9 ± 11.7
Serum Bilirubin (umol/l)		364.6 ± 192.6
Age Groups	65 or Less	57 (44.5%)
	More Than 65	71 (55.5%)
Gender	Female	76 (59.4%)
	Male	52 (40.6%)
Etiology (BO)	Benign	29 (22.7%)
	Malignant	99 (77.3%)
Diagnosis	Benign Biliary Stricture	25 (19.5%)
	Carcinoma Gallbladder	22 (17.2%)
	Cholangiocarcinoma	59 (46.1%)
	Pancreatic Head Carcinoma	22 (17.2%)
Indication for PTBD	Contra Indicated ERCP	5 (3.9%)
	Failed ERCP	123(96.1%)
Clinical Failure	No	99 (77.3%)
	Yes	29 (22.7%)
Complications	Yes	20 (15.6%)
	No	108 (84.4%)
Prolonged Hospital Stay	Discharged Next Day	99 (77.3%)
	Prolonged	29 (22.7%)
Mortality	Yes	13 (10.2%)
	No	115 (89.8%)
Total		128 (100%)

Mean+/-SD; n (%);BO :Biliary Obstruction ; PTBD: percutaneous transhepatic biliary drainage

Clinical failure was compared with the associated factors to identify the risk factors. Univariate analysis identified older age, female gender, diagnosis and type of PTBD as the significant factor for clinical failure (P<0.20). Multivariate analysis found older age of patients as a highly associated factors for clinical failure. (OR: 3.39, 95% CI: 1.22-9.40; P=0.019)(Table 2).

Table 2: : Association of PTBD Outcomes(Clinical Failure)with Associated Factors

Study Variables		Clinical Failure N (%)		Unadjusted OR (95% CI; Sig)	Adjusted OR (95% CI; Sig)
		Yes	No		
Age Groups	65 or Less	6 (10.5%)	51 (89.5%)	Ref	Ref
	More Than 65	23 (32.4%)	48 (67.6%)	4.07 (1.53-10.86; 0.005)	3.39 (1.22-9.40; 0.019)
Gender	Male	7 (13.5%)	45 (86.5%)	Ref	Ref
	Female	22 (28.9%)	54 (71.1%)	2.62 (1.02-6.69; 0.044)	1.95 (0.72-5.27; 0.190)
Etiology (BO)	Benign	4 (13.8%)	25 (86.2%)	Ref	-
	Malignant	25 (25.3%)	74 (74.7%)	2.11 (0.67-6.66; 0.202)	-
Diagnosis	Benign Biliary Stricture	3 (12%)	22 (88%)	Ref	Ref
	Carcinoma Gallbladder	4 (18.2%)	18 (81.8%)	1.63 (0.32-8.25; 0.555)	0.87 (0.14-5.43; 0.879)
	Cholangiocarcinoma	16 (27.1%)	43 (72.9%)	2.73 (0.72-10.38; 0.141)	1.18 (0.26-5.49; 0.141)
	Pancreatic Head Carcinoma	6 (27.3%)	16 (72.7%)	2.75 (0.59-12.68; 0.194)	1.08 (0.18-6.89; 0.936)
Indication for PTBD	Contra Indicated ERCP	1 (20%)	4 (80%)	Ref	-
	Failed ERCP	28 (22.8%)	95 (77.2%)	1.18 (0.13-10.98; 0.885)	-
Type of PTBD	Internal/External	10 (14.7%)	58 (85.3%)	Ref	Ref
	External	19 (31.7%)	41 (68.3%)	2.69 (1.13-6.38; 0.025)	2.10 (0.74-5.98; 0.164)

For Univariate logistic regression significance level set at 0.20.
For Multiivariate logistic regression significance level set at 0. 05.

Post PTBD complication status was compared with the factors. Univariate analysis identified older age, female gender, malignant etiology, diagnosis and type of PTBD as the significant factor for post-operative complications (P<0.20). Multivariate analysis found older age of patients as a highly associated factors of post PTBD complication similar to the clinical failure. (OR: 7.48, 95% CI: 1.58-35.5; P=0.011) while other factors remained insignificant (P>0.05)(Table 3).

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Table 3: : Association of PTBD Outcomes (Post-Operative Complications) with Associated Factors

Study Variables		Post-Operative Complications N (%)		Unadjusted OR (95% CI; Sig)	Adjusted OR (95% CI; Sig)
		No	Yes		
Age Groups	65 or Less	55 (96.5%)	2 (3.5%)	Ref	Ref
	More Than 65	53 (74.6%)	18 (25.4%)	9.34 (2.07-42.23; 0.004)	7.48 (1.58-35.49; 0.011)
Gender	Male	49 (94.2%)	3 (5.8%)	Ref	Ref
	Female	59 (77.69%)	17 (22.4%)	4.71 (1.30-17; 0.018)	3.86 (0.96-15.57; 0.058)
Etiology (BO)	Benign	27 (93.1%)	225 (6.9%)	Ref	Ref
	Malignant	81 (81.8%)	18 (18.2%)	3(0.65-13.78; 0.158)	0.41(0.03-5.75; 0.508)
Diagnosis	Benign Biliary Stricture	24 (96%)	1 (4%)	Ref	Ref
	Carcinoma Gallbladder	18 (81.8%)	4 (18.2%)	5.33 (0.55-51.9; 0.149)	8.44 (0.26-272.8; 0.229)
	Cholangiocarcinoma	48 (81.4%)	11 (18.6%)	5.50 (0.67-45.14; 0.112)	5.40 (0.23-128.8; 0.297)
	Pancreatic Head Carcinoma	18 (81.8%)	4 (18.2%)	5.33 (0.55-51.88; 0.49)	5.66 (0.17-182.9; 0.329)
Indication for PTBD	Contra Indicated ERCP	5 (100%)	0 (0%)	Ref	Ref
	Failed ERCP	103 (83.7%)	20 (16.3%)	-	-
Type of PTBD	Internal/External	61 (89.7%)	7 (10.3%)	Ref	Ref
	External	47 (78.3%)	13 (21.7%)	2.41 (0.89-6.52; 0.083)	1.32 (0.38-4.64; 0.662)

For Univariate logistic regression significance level set at 0.20.
For Multivariate logistic regression significance level set at 0.05.

Older age was indicated as the significant factor for mortality (P=0.024), and as compared to male patients, mortality was found to be higher in female patients (P = 0.032). The type of PTBD also had a significant association with mortality. Mortality status was compared with the associated. Univariate analysis identified older age, female gender, malignant etiology, diagnosis and type of PTBD as the significant factor for mortality (P<0.20) (Table 4).

Table 4 : Association of PTBD Outcomes (Mortality) with Associated Factors

Study Variables		Mortality N (%)		Unadjusted OR (95% CI; Sig)	Adjusted OR (95% CI; Sig)
		No	Yes		
Age Groups	65 or Less	57 (100%)	0 (0%)	Ref	-
	More Than 65	58 (81.7%)	13 (18.3%)	26.5 (1.54-457; 0.024)	N/A
Gender	Male	51 (98.1%)	1 (1.9%)	Ref	Ref
	Female	64 (84.2%)	12 (15.8%)	9.56 (1.20-76; 0.032)	3.57 (0.91-14.02; 0.068)
Etiology (BO)	Benign	29 (100%)	0 (0%)	Ref	-
	Malignant	86 (86.9%)	13 (13.1%)	9.21 (0.53-159.7; 0.127)	N/A
Diagnosis	Benign Biliary Stricture	25 (100%)	0 (0%)	Ref	-
	Carcinoma Gallbladder	18 (81.8%)	4 (18.2%)	12.4 (0.63-244.8; 0.098)	N/A
	Cholangiocarcinoma	52 (88.1%)	7 (11.9%)	7.28 (0.40-132; 0.179)	N/A
	Pancreatic Head Carcinoma	20 (90.9%)	2 (79.1%)	6.22 (0.28-136.9; 0.25	N/A
Indication for PTBD	Contra Indicated ERCP	5 (100%)	0 (0%)	Ref	-
	Failed ERCP	110 (89.4%)	13 (10.6%)	1.34 (0.07-25.7; 0.844)	N/A
Type of PTBD	Internal/External	65 (95.6%)	3 (4.4%)	Ref	Ref
	External	50 (83.3%)	10 (16.7%)	4.33 (1.13-16.58; 0.032)	8.09 (1.0-65.3; 0.05)

For Univariate logistic regression significance level set at 0.20.
For Multiivariate logistic regression significance level set at 0.05.
N/A: Not Applicable (0 frequency)

DISCUSSION

ERCP and PTBD have been the mainstays of treatment choices for many years. As with biliary drainage, initial ERCP was the gold standard of treatment; PTBD was often done following an unsuccessful ERCP surgery. If the biliary tree was endoscopically inaccessible, PTBD was the recommended course of action for treating either benign or malignant hepatobiliary disorders. Anatomical landmarks have been used to guide biliary punctures under fluoroscopic guidance in the past; however, the current procedural approach differs depending on operator expertise and preference [15]. Recent advanced procedural approaches have resulted in a notable decline in overall morbidity and mortality rates for malignant hepatobiliary diseases. In the current situation, patient-centered death with improved quality of life and clear immediate survival advantages makes palliative care with

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PTBD the recommended norm for instances of hepatobiliary illnesses. It was now abundantly clear that the operator's expertise plays a major role in both technological success and unfavorable incidents [10]. In current study, PTBD's documented technical success rate was 100%, which was a reflection of previous studies as well, where the clinical success rate was reported to be over 90% with a smaller number of complications observed. By using adequate antibiotic coverage and limiting biliary manipulation, these problems can be further decreased [4, 16]. In this cohort results suggested that younger age, benign etiology, and the type of PTBD optimize success rate and minimize complications. Out of 128 patients enrolled in the current study, 59.4% were female. The patients' mean age was 65.9 ± 11.7 years. The most common cause of hepatobiliary disorder was cholangiocarcinoma 46.1%. For patients with malignant hepatobiliary disorders, PTBD, or minimally invasive surgery, was a crucial part of their management. It was most frequently performed as a palliative procedure with the goal of reducing morbidity related to the disease and improving quality of life while relieving symptoms (such as cholangitis, pruritus, etc.). However, it will not change the underlying prognosis of the disease. It was an affordable and safe way to clear obstructions in the biliary obstruction [17]. This study investigated the PTBD clinical success rate of 77.3% (benign 86.2% and malignant 74.7%) in patients with hepatobiliary disorders. Similar to this study finding, Hsu YC *et al.*, demonstrated the clinical success rate of PTBD at 77% in malignant biliary obstruction patients, which was comparable to this study clinical success rate, and also other studies reported similar rates of 76% and 76% and 76% [3, 18, 19]. Furthermore, we found that the type of PTBD affected its clinical success. According to this study findings, internal/external PTBD clinical success rates were substantially higher than external ($P<0.05$). Koutlas NJ *et al.*, reported in a review of PTBD following an unsuccessful ERCP [5]. High technical success rates of 98% for PTBD were demonstrated by the analysis's findings. In this investigation, PTBD achieved 100% technical success. Lesmana CR et al., did another trial that revealed 75% clinical success and 58% reported adverse effects for PTBD[10]. A total of 90 patients with failed ERCP subsequently PTBD. Although technical success was higher in the PTBD group 78%, clinical success was 63%. PTBD was associated with adverse event rate 28% [20]. In a recent local study 100% technical success and over 9% clinical success was achieved with 5% procedural complications [21]. In this study post-procedural complications rate was 15.6%, which was relatively low as compared to previous studies. In another retrospective study complications were reported in 5.9% and 20% in 3-months. Infection was the most common complication, with 2.4% of patients experiencing this within a week and 9% within a month. In addition, this study showed that morbidity and death were related to provider PTBD expertise, age, gender, co-morbidities, deprivation, type of malignancy and pre-existing renal failure [12]. In the current study, 20(15.6%)patients suffered from post-PTBD complications (19/20; 95% of patients had post-PTBD infection and fever, 5/20; 50% had post-procedural bleeding, 2/20; 10% had abdominal bleeding, 2/20; 10% had drain dislocation, 2/10; 10% had sepsis), prolonged hospital stays were reported in 22.7% of cases, and 10.2% died within 30-days. Associated factors such as older age, female gender, malignant etiology, cholangiocarcinoma, carcinoma gallbladder, and pancreatic head carcinoma were identified as significant contributors to post-PTBD complications and mortality. We recognized the limitations of the study; the sample size might not be large enough. The retrospective design because participants in the current research were not randomized and data collection relied on the availability and quality of registration and follow-up information, the design of the study was more prone to bias. The study's retrospective design restricts the amount of data that can be analyzed, including data on long-term outcomes and quality of life post-PTBD. Moreover, the study's strength was its focus of patients underwent PTBD after failed ERCP, regardless of the cause. The expert clinicians have utilized the strict standard protocols, potentially improvising outcomes.

CONCLUSIONS

In Patients with Hepatobiliary Disorders, PTBD offers a safe, efficient, and viable alternative approach with a high rate of clinical and technical success, a low rate of complications, and a low risk of death following failed ERCP. The findings further showed that PTBD was associated with complications, in particular infection, bleeding, prolonged hospital stay, and mortality. Moreover, mortality within 30 days in patients undergoing PTBD for relief of biliary obstruction was high at 10.2%. Older age, female gender, and malignant etiology have a poorer prognosis. It was determined that PTBD, which relieves hepatobiliary disorders and provides symptomatic relief, should only be carried out at experienced facilities in order to attain low rates of death and morbidity and high success rates. Additionally, palliative care for these terminally ill patients should also be provided. Aside from being economical, the process doesn't require plenty of expensive equipment to be installed.

Authors Contribution

Conceptualization: MA
Methodology: AS
Formal analysis: NAQ
Writing, review and editing: MA, NN, PA, ZA

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Conflicts of Interest

All the authors declare no conflict of interest.

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