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ROLE OF PERCUTANEOUS TRANSHEPATIC BILIARY DRAINAGE IN THE MANAGEMENT OF BILIARY OBSTRUCTION

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Abstract: Background: Percutaneous transhepatic biliary drainage (PTBD) is an effective and widely used procedure in the management of biliary obstructions. Biliary obstruction can be of benign or malignant causes leading to impaired biliary drainage, obstruction of bile flow, elevated level of bilirubin, and associated complication and morbidity. PTBD offers patients a minimally invasive alternative to surgery, with the potential for immediate symptom relief and improvement of liver function.

Objectives: To assess the effectiveness of percutaneous transhepatic biliary drainage in the management of biliary obstruction.

Method: A total of 30 patients included in this study (16 males and 14 females) with a mean age of 60.1±14.604, the biliary obstruction was due to malignant causes in 16 patients and benign in 14 patients, out of 30 patients biliary drainage with internal external catheter performed in 21, external biliary drainage in 6 patients and combined (rendezvous) techniques in 3 cases, 30 days post-procedure follow up done to evaluate improvement in liver function test (LFT) and total serum bilirubin (TSB) levels, clinical symptoms and addressing procedure-related complications.

Results: A high technical success rate of 100% and a high clinical success rate of 100% in terms of reduction of LFT and TSB, improvement of the obstruction-related morbidities observed (P value < 0.001), no statically significance difference in procedure-related factors observed in the between RT and LT duct entry access also between benign and malignant biliary strictures (P value >0.5).

Conclusion: PTBD is an effective procedure for management of the patients with biliary obstruction, providing both diagnostic information and therapeutic relief. Its minimally invasive nature with high success rates. With appropriate care and follow-up, PTBD can significantly improve patient's quality of life and aid in the management of various conditions affecting the biliary system.

Keywords: PTBD, biliary obstruction.

1.Introduction

Percutaneous transhepatic biliary drainage (PTBD) is a well-established and successful treatment for both benign and malignant bile duct obstruction, first reported in 1962 (1-2). The primary goal in managing biliary system obstruction is the relief of jaundice. While surgical bypass is one palliative option, non-operative techniques like Endoscopic Retrograde Cholangiopancreatography (ERCP) and PTBD are often

preferred for selected patients (3-4). ERCP stands as the most common non-operative method for accessing the biliary tree, boasting success rates over 90% in patients with normal anatomy (5). However, ERCP may fail due to surgically altered anatomy, gastric outlet obstruction, ampullary pathology, or periampullary diverticula, necessitating an alternative approach (6).

In circumstances where the biliary tree is endoscopically inaccessible or ERCP attempts have failed, PTBD is considered the gold standard minimally invasive procedure (7-8). Its fundamental role is to normalize plasma bilirubin levels and alleviate debilitating symptoms like cholangitis and pruritus. This drainage improves the patient's quality of life and, critically, optimizes their clinical state to allow for further management with surgical resection or palliative radio- and chemotherapy. Furthermore, the frequency of PTBD procedures has risen, partly due to an increased incidence of post-surgical bile leaks at sites of biliodigestive anastomosis (9-10).

The indications for PTBD are diverse, covering both malignant and benign etiologies (11). Malignant obstructions frequently result from cholangiocarcinoma, pancreatic carcinoma, or metastatic disease (12). Benign causes are equally varied, including iatrogenic strictures from procedures like liver transplantation and laparoscopic cholecystectomy, inflammatory conditions such as chronic pancreatitis, and biliary calculi (12-13). Beyond simple drainage, PTBD provides crucial access for subsequent interventions, including the dilatation of strictures, stent placement, stone extraction, and performing rendezvous procedures to facilitate difficult ERCPs (13-14). Technical success rates for PTBD are very high, approaching 100% in dilated systems, cementing its role as a vital tool in the management of complex biliary disease (9, 15).

So, this study aims to evaluate the effectiveness of percutaneous transhepatic biliary drainage in the management of biliary obstruction, assessing success rate, outcomes and procedure related complications.

2. Method

This prospective, descriptive study was conducted to evaluate the role of percutaneous transhepatic biliary drainage (PTBD) in managing various biliary disorders. A total of 30 patients were enrolled from the Radiology Department at Sulaymaniyah Teaching Hospital in the Kurdistan Region of Iraq between January 2023 and December 2023. The study protocol received approval from the scientific committee of the Iraqi Board of Diagnostic Radiology, and all participants provided written informed consent for the procedure and verbal consent for the use of their data in the research.

Inclusion criteria were specific to patients with biliary obstruction or stenosis who were not surgical candidates, had previously failed Endoscopic Retrograde Cholangiopancreatography (ERCP), required biliary decompression prior to surgery or chemotherapy, or needed a combined PTBD-ERCP (Rendezvous) technique for biliary access. Patients with marked ascites, advanced liver cirrhosis, uncorrectable coagulopathy, or those with incomplete follow-up data were excluded. Prior to the intervention, all patients, referred by gastroenterologists or surgeons, underwent a comprehensive evaluation that included a clinical assessment, laboratory tests (liver function, renal function, CBC, coagulation profile), and a review of radiological imaging, typically an MRI/MRCP or CT scan. An immediate pre-procedure ultrasound was also performed to plan the access route, and all patients were prepared with a 4-6 hour fast and an established intravenous line.

All interventional procedures were performed in a fluoroscopy suite under ultrasound and fluoroscopic guidance. Patients received local anesthesia and moderate sedation, with an anesthesiologist present for cases requiring deep sedation. The standard technique involved a US-guided puncture of a peripheral biliary duct with an 18 or 22-gauge Chiba needle, followed by a diagnostic cholangiogram to map the biliary tree. A guidewire was then used to cross the stenotic segment, the tract was dilated, and a drainage catheter (8Fr or 10Fr) was placed. Depending on the anatomy and pathology, one of three drainage methods was utilized: internal-external drainage (n=21), external-only drainage for uncrossable lesions (n=6), or a combined

Rendezvous technique with gastroenterology (n=3). Radiation safety was maintained by adhering to the As Low As Reasonably Achievable (ALARA) principle.

Following the procedure, patients were monitored for up to 24 hours before discharge. They received detailed instructions on long-term catheter care, including flushing and recognizing signs of complications. Data collected for the study included patient demographics, laboratory values, and characteristics of the biliary obstruction. The primary outcomes were technical success (defined as successful catheter placement with free bile flow) and clinical success (defined as a >30% reduction in serum bilirubin and symptomatic improvement). Any adverse events occurring within 30 days were recorded and classified as major or minor. All collected data were analyzed using SPSS version 26, employing descriptive statistics, Pearson Chi-square, and paired sample t-tests, with a P-value of ≤ 0.05 considered statistically significant.

3.Results

3.1. Demographic data

The present study was conducted on 30 patients. These patients were classified into two categories, benign and malignant causes of biliary obstructions, where 14 patients (46.7%) have benign causes of biliary obstruction, 16 patients (53.3%) have malignant biliary causes of biliary obstruction (**Figure 3.1**).

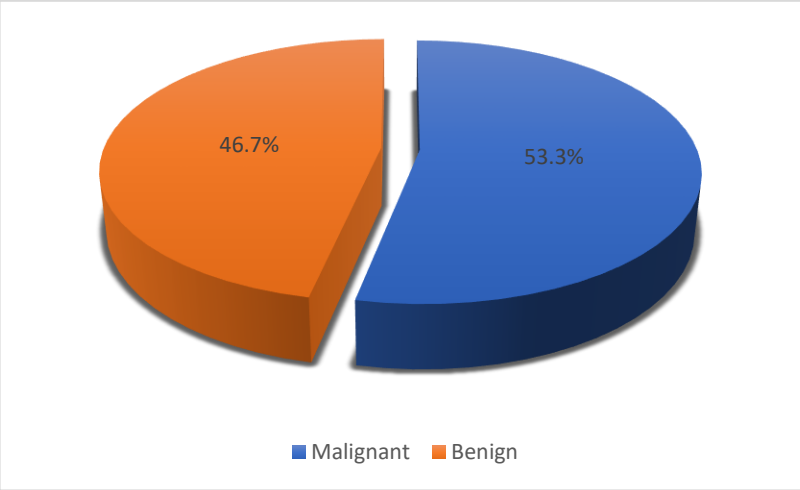

Figure 3.1 Classification of biliary obstruction among studied patients

The age of the patients is in the range of 37 to 87 years. As shown in **Table 3.1**, most of the patients were in the age range of 67 to 76 years, which corresponds to the malignant group, but in the benign group, most of the patients were in the age range of 37 to 46 years. The average age of all patients is 60.1, and the average age of patients in benign and malignant biliary groups is 53.36 and 66 years, respectively.

A statistically significant relationship between the type of biliary obstruction and the age of patients has not been observed, because the p-value is equal to 0.065, which is higher than the level of statistical significance. 16 patients were male and 14 patients were female, while majority of patient with malignant biliary obstruction were male (62.5%), but most of the patients with benign biliary obstruction were female (57.14%). Since the p-value is greater than 0.05, no significant statistical relationship between the cause of biliary obstruction and gender has been observed (p-value = 0.282)

Table (3.1): Information of Patient's demographics

Parameters		Biliary Condition			P value
		Malignant [N (%)] N = 16	Benign [N (%)] N = 14	Total [N (%)] N = 30	
Age (years)	37-46	1 (6.25)	6 (42.85)	7 (23.33)	
	47-56	2 (12.5)	3 (21.42)	5 (16.66)	

	57-66	4 (25)	2 (14.28)	6 (20)	
	67-76	7 (43.75)	1 (7.14)	8 (26.66)	
	>77	2 (12.5)	2 (14.28)	4 (13.33)	
Mean ± SD		66 ±10.912	53.36 ± 15.702	60.10 ±14.604	
Gender	Male	10 (62.50)	6 (42.85)	16 (53.3)	0.282
	Female	6 (37.50)	8 (57.14)	14 (46.7)	

The degree of biliary dilatation is divided into four categories, 2 patients showed minimal biliary dilatation (6.66%), 6 patients showed mild degree (20%), 9 patients showed moderate degree (30%) and the last 13 patients showed a marked degree of biliary dilatation (43.3%) (**Table 3.2**). The patients with benign causes of biliary obstruction mostly presented with a moderate degree of biliary dilatation (50%), while most of the patients with malignant causes presented with a marked degree of biliary dilatation (68.75%). the p-value is equal to 0.03, which means that there is a statistically significant relationship between the cause of biliary obstruction and the degree of biliary dilatation.

Table (3.2): Degree of biliary dilatation among malignant and benign groups

Parameter	Biliary Condition			P value
Degree of biliary dilatation	Malignant [N (%)] N = 16	Benign [N (%)] N = 14	Total [N (%)] N = 30	
Minimal	2 (12.5)	0 (0)	2 (6.66)	0.03
Mild	1 (6.25)	5 (35.71)	6 (20)	
Moderate	2 (12.5)	7 (50)	9 (30)	
Marked	11 (68.75)	2 (14.28)	13 (43.33)	

According to location of biliary stricture **(Figure 3.2),** 5 of studied patients had intrahepatic stricture (16.6%), in 12 patients the obstruction were at hilar level (40%), 3 patients were at proximal CBD level (10%), 10 patients were at the level of distal CBD (33%).

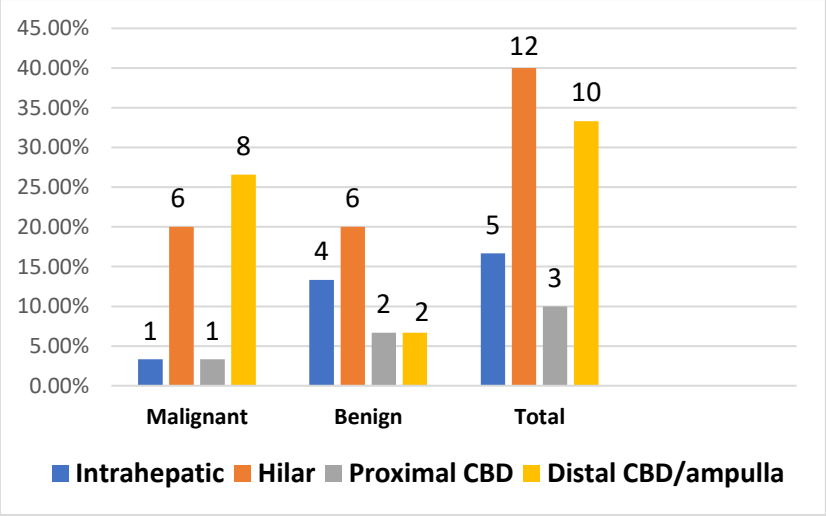

Figure 3.2 Location of biliary stricture among studied group

Biliary obstruction has various causes, some of which are mentioned in **Table 3.3** As it is clear from **Table 3.3**, biliary-enteric anastomosis was the most common cause of benign biliary stricture in 50% of patients. Followed by post-operative (iatrogenic) bile injury with 21.42% of patients, while the most common cause of malignant biliary stricture was Cholangiocarcinoma in 43.75% of patients. Followed by metastasis from variable primary tumors in 37.5% of patients.

Table (3.3) Causes of biliary obstruction among the studied patients.

Parameters	Malignant [N (%)] N = 16 (53.3)	Parameters	Benign [N (%)] N = 14 (46.6)
Cholangiocarcinoma	7 (43.75)	Biliary-enteric anastomosis	7 (50)
Periampullary tumor	2 (12.5)	Post-operative (iatrogenic) bile injury	3 (21.42)
CA head of pancreas	1 (6.25)	Sclerosing cholangitis	2 (14.28)
Metastasis from variable primary tumors	6 (37.5)	Post liver transplantation	1 (7.14)
		Choledocolithiasis	1 (7.14)

3.2. Procedure evaluation

The technical success rate, defined as the positioning of a drainage tube into the biliary tree was 100%. While majority of the cases underwent single procedure (90%), three patients needed repeated procedure.

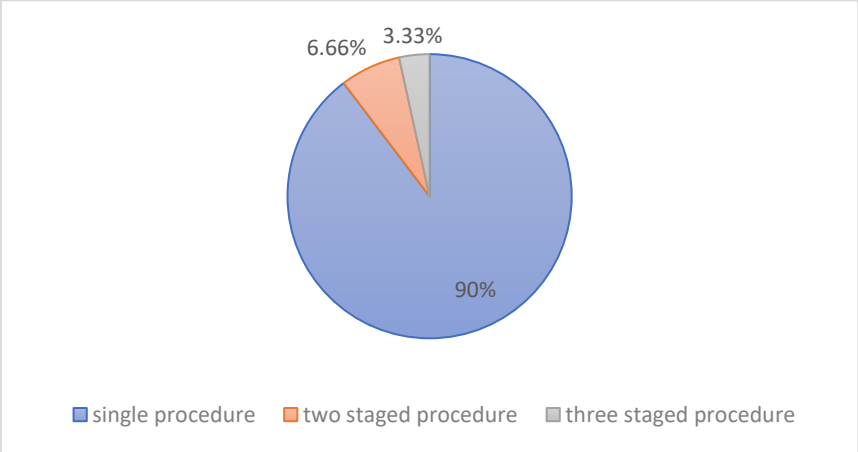

Figure 3.3 Number of procedures needed to treat the patients

RT-sided approach was used in 22 patients, while in 4 patients subcostal epigastric LT-sided approach was done, similarly 4 patients required both RT and LT-sided approach, the site access depended on the involved lobe in intrahepatic obstruction, in patients with hilar disease the lobe with larger degree of biliary dilatation preferred by the operator for puncture, in case of CBD obstruction, the access site depend on operator preference.

Table (3.4): Distribution of patients according to approach and success rate of the procedure

Approach	No.	%
RT	22/30	73.3%
LT	4/30	13.3%
RT and LT	4/30	13.33%
Technique Success rate	30/30	100%

The procedural data was evaluated according to the RT sided VS LT sided biliary duct entry approach (**Table 3.5**) and according to the type of biliary obstruction (malignant VS benign stricture), the mean total procedure time was 10 min (Range 7-18 mints), the mean total fluoroscopy time was 210s (Range: 50-520s), concerning the X-ray dose assessment dose are product (DAP) reported by fluoroscopy machine was used, the mean total DAP was 8.82+/-3.1 Gy cm^2 , no statically significance differences observed in term of No. of liver puncture, total mean duration of the procedure, fluoroscopy time, dose area product.

Table (3.5) procedural data for RT sided and LT sided biliary entry approach

Parameter	RT sided approach (N 26)	LT sided approach (N8)	(P value)
No. of liver puncture	1.11±0.51	1.19±0.58	0.550
Mean total procedural time (m)	8.8 ±5.2	9.5±6.1	0.668
FT (s)	201±152.8	208±161	0.624
DAP (Gy cm^2)	8.4±4.1	9.2±2.1	0.775

FT, fluoroscopy time; DAP, dose area product.

Table (3.6) Procedural data for benign and malignant biliary obstruction.

Parameter	Benign (N14)	Malignant (N16)	(P value)
No. of liver puncture	1.1± 0.42	1.22±0.51	0.423
Mean total procedural time(m)	9.8 ±6.2	8.5 ±5.8	0.223
FT (s)	210±156	182±108	0.265
DAP (Gy cm^2)	9.1±3.3	5.9±2.7	0.331

FT, fluoroscopy time; DAP, dose area product.

As shown in **Figure 3.4**, in 70% an internal-external biliary drainage was positioned while in 20% the occlusion was uncrossable so an external drainage was left in place, rendezvous technique was done in 10% of the patients. According to the preference of the operator and availability caliper of the drainage tubes was 8 Fr in 75% and 10 Fr in 25% of the cases.

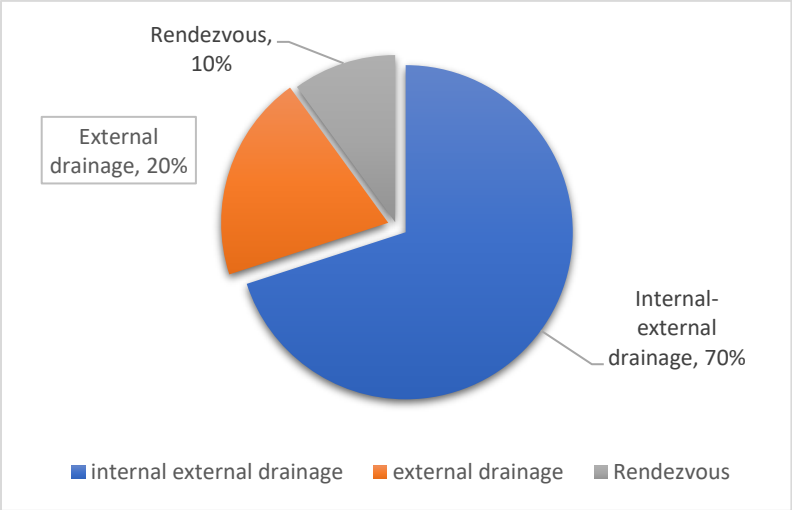

Figure 3.4 type of interventional procedures performed among studied patients

3.3. Patient outcome

Laboratory tests were conducted before (last result immediately before the drainage) and after the procedure (within 2 wks.) to assess their general condition and effectiveness of the treatment. Laboratory tests include TSB, ALT, AST and ALP. The clinical success rate as defined as decreased level of the total serum bilirubin after the procedure was 100%, the total bilirubin level decreased significantly post procedure as shown in **Table 3.7**, the mean time for follow up of the TSB level was 4.3 +/- 2 days (ranging from 1-8 days), the mean value of TSB before biliary drainage was 17.4 (Range of 1.5 to 27 mg/dl), which after biliary drainage was 6.3 mg/dl (Range 1 to 12 mg/dl) (p value < 0.01).

Table (3.7): Comparison of total bilirubin level before and after procedure among different studied patients.

	Total Bilirubin before Mean (SD) (mg/dl)	Total Bilirubin after Mean (SD) (mg/dl)	test p-value
External drainage N=6	24.5 (5.3)	6.2(3.1)	<0.05*
Internal-external drainage N=21	16.4 (3.2)	10(4.3)	<0.01**
Rendezvous N=3	9.2 (2.2)	1.4 (0.4)	<0.01**

The mean values of ALT, AST, and ALP were calculated in all patients before and after biliary drainage. Mean calculations are shown in **figure 3.5**. As it is clear, a significant decrease was observed in the post-procedure values (the p-value <0.05). ALT, Alanine transaminase AST, Aspartate aminotransferase ALP, alkaline phosphatase

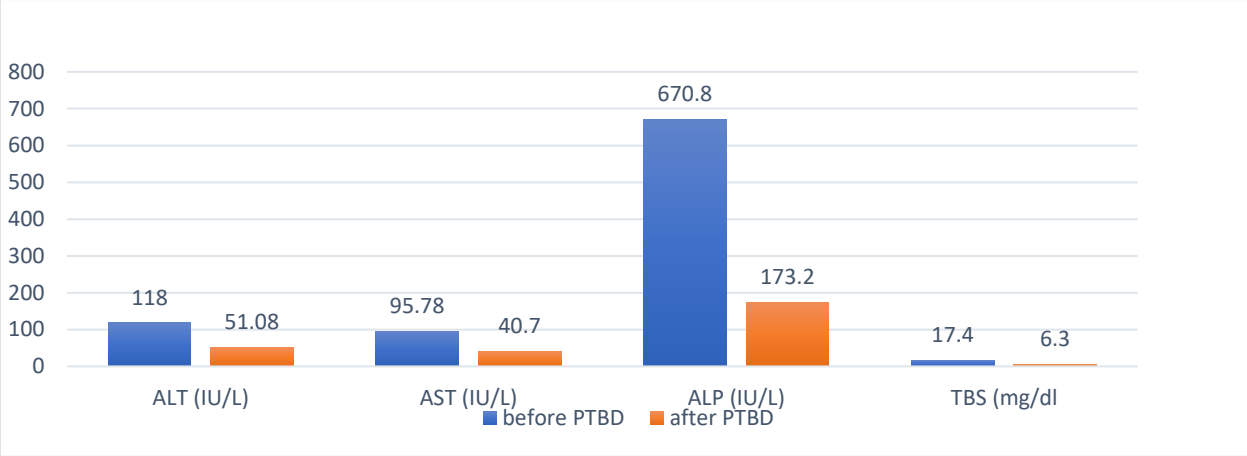

Figure 3.5 Mean value of laboratory tests before and after drainage

The clinical symptoms of the patients were examined before the intervention and one week after the intervention. The findings are summarized in **Table 3.8**, before the intervention, the most common clinical symptom was jaundice in 28 patients and itching in 20 patients. One week after the intervention, the clinical symptoms were reevaluated and categorized as disappeared, decreased, not changed, or increased. None of the patients reported increased clinical symptoms one week after the intervention, and most of the clinical symptoms decreased or disappeared after the intervention.

Table (3.8): Clinical symptoms before and after intervention

Initial symptoms	Before intervention	One week after intervention			
	Patients with symptoms	Patients with disappeared symptoms	Patients with decreased symptoms	Patients with no change in symptoms	Patients with increased symptoms
Itching	20	20			0
Malaise	16	10	4	2	0
Nausea	8	5	2	1	0
Jaundice	28	9	19		0
Anorexia	17	9	6	2	0

3.4. Complications

Complications rate was evaluated up to 30 days post procedure, minor complication such as pain and discomfort was reported by 5 patients, In 2 patients immediately after the procedure hemobilia reported, tubal blockage in 1 patient and tubal dislodgment in 2 cases that needed tube replacement, no major complications or death recorded among the studied group during follow up period.

Table (3.9) Complications During and After the Procedure

Complication	Timing	Percentage (%)
Hemobilia	During procedure	2 (6.66%)
Perforation of bile duct	During procedure	0
Pneumothorax	During procedure	0
Pain and discomfort	After procedure	5 (16.66%)
Tube blockage	After procedure	1 (3.33%)
Tube dislodgment	After procedure	2 (6.66%)

4. Discussion

Percutaneous transhepatic biliary drainage (PTBD) is an essential diagnostic and therapeutic procedure for managing obstructive jaundice from both benign and malignant causes (2, 4-6, 8,). This study evaluated the outcomes of PTBD in 30 patients, reaffirming its role as a highly effective method for biliary decompression. Our cohort was nearly evenly split between malignant (53.3%) and benign (46.7%) etiologies. The demographic finding that malignant cases were more common in older males (mean age 66) while benign cases were more prevalent in younger females (mean age 53.36) aligns with previous reports (12, 16).

In our series, the most common benign causes were biliary-enteric anastomosis strictures and post-surgical injuries, consistent with findings that iatrogenic injury is a leading cause of benign strictures (17). For malignant obstructions, cholangiocarcinoma and metastases were most frequent. This contrasts with some studies where pancreatic head carcinoma is the primary cause (17, 18). This difference may be explained by local referral patterns, where many pancreatic cancer cases are managed primarily by surgery or ERCP without referral for PTBD. As expected, and in line with other studies, malignant obstructions were associated with a more marked degree of biliary dilatation compared to benign cases (9, 10).

The technical success rate in our study was 100%, and the stricture was successfully bypassed in 80% of attempts. These results are excellent and consistent with success rates reported in other studies on dilated biliary systems, which often exceed 97% (7, 19, 20). A right-sided approach was predominantly used (73.3%), though our data showed no significant difference in procedural time, radiation dose, or the number of punctures between right- and left-sided access, which is consistent with other reports (7). This supports the consensus that the choice of approach should be guided by operator preference, patient anatomy, and the specific clinical scenario (12).

A significant finding of this study was the exceptionally low mean fluoroscopy time (210 sec) and radiation dose (DAP 8.82 Gy·cm²). These values are considerably lower than those reported in many multicenter and national studies from Europe, the US, and Asia (7, 9, 20, 21). Our favorable results, which align closely with those of Park et al. (2), are likely attributable to extensive operator experience, the routine use of ultrasound for initial biliary puncture, and strict adherence to the ALARA (As Low As Reasonably Achievable) principle. We also found that the primary determinant of procedural difficulty and time was the degree of intrahepatic ductal dilatation, not the etiology (benign vs. malignant) or access side. This suggests that procedures in non-dilated or mildly dilated systems are inherently more challenging (2, 8).

Clinically, the procedure was highly successful, with a 100% clinical success rate demonstrated by a statistically significant decline in post-procedure TSB and LFT levels and resolution of clinical symptoms. This outcome is superior to some published rates (22) and aligns with others demonstrating significant biochemical and clinical improvement post-PTBD (23). The complication rate was low, with no major complications or procedure-related mortality. Pain was the most common minor complaint, while hemobilia and tube dislodgement were the most frequent procedure-related issues, a profile consistent with other studies (18, 23).

5.Conclusion

PTBD is an effective method for the management of biliary obstruction caused by benign or malignant biliary strictures when endoscopic and surgical techniques fail, the procedure allows for relieving of the biliary obstruction, draining of the bile, and alleviating the symptoms related to it, used as temporary method allowed for biliary diversion till more definite method of treatment can be employed, or as a palliative method in non-operable cases to facilitated for further management by chemotherapy, improving quality of life. In experienced hand the procedure allowed a success rate reaching 100% with relatively low complication rates, the guidance of the US for biliary puncture much lower radiation dose expected than previously reported.

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