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ORIGINAL ARTICLE | Pancreas and Biliary Tract

Percutaneous Transhepatic Biliary Intervention for The Management of Malignant Hilar Biliary Obstruction

Quoc Huy Vo[1], Minh Tuan Le[1], Dac Hong An Ngo[1], Ba Khanh Minh Le[2], Huu Thien Ho[3], Trong Khoan Le[1], Thanh Thao Nguyen[1], Quang Hung Dang[4], Hoang Huy Le[4], and Trong Binh Le[1]

Department of Radiology, University of Medicine and Pharmacy, Hue University[1], Hue city, Vietnam; Department of Radiology, Hue Central Hospital[2], Hue city, Vietnam; Department of Pediatric and Abdominal Emergency Surgery, Hue Central Hospital[3], Hue city, Vietnam; Department of Radiology, Hue University of Medicine and Pharmacy Hospital[4], Hue city, Vietnam

Background/Aims: This study evaluated the short-term safety and effectiveness of percutaneous transhepatic biliary drainage (PTBD) for a malignant hilar biliary obstruction (MHBO).
Methods: The data from 112 patients with MHBO who underwent PTBD between January 2019 and June 2024 were analyzed retrospectively. All MHBO was confirmed pathologically. Technical success was defined as the placement of a drainage tube within the biliary tract. Clinical success was defined as a decrease in the total bilirubin level of ≥20% within seven days post-procedure. The 30-day morbidity, mortality, and re-intervention were documented. One interventional radiologist with 15 years of experience performed all procedures.
Results: The average age was 62.6±12.3 years (range, 28–91 years), and the female-to-male ratio was 2:3. The most common etiology of MHBO was cholangiocarcinoma (68.8%). The Bismuth–Corlette classification scores were as follows: type 1 (17.9%), type 2 (23.2%), type 3A (25.9%), type 3B (16.0%), and type 4 (17.0%). The technical success rate was 99.1%; 41.4% of PTBD were bilateral, and 82% were internal–external drainage. Preoperative drainage and palliative drainage were indicated in 28.6% and 71.4% of cases, respectively. Biliary stents were implanted in 39 patients (35.1%), including 51.3% unilateral stents, 23.1% Y-stents, 20.5% kissing stents, and 5.1% T-stents. The clinical success rate was 69.6%. The minor complication rate was 18.8%. The 30-day re-intervention and mortality rates were 24.1% and 1.8%, respectively.
Conclusions: PTBD was safe and effective in managing MHBO. Further study of this specific subgroup and long-term follow-up is warranted. (Korean J Gastroenterol 2025;85:517-526)

Key Words: Bile; Drainage; Jaundice; Neoplams; Stents

INTRODUCTION

Malignant hilar biliary obstruction (MHBO) is a severe clinical condition leading to various, even life-threatening, local and systemic complications. The common causes of MHBO include hilar cholangiocarcinoma (65%), gallbladder carcinoma (12.5%), hepatocellular carcinoma HCC (10%), and metastasis (12.5%).[1,2] This condition requires complex and multidisciplinary interventions, but the outcome is usually suboptimal. A decompression and restoration of bile flow are crucial for symptom alleviation, life quality improvement, and further treatment.[2]

The curative treatment of MHBO remains challenging because of its limited resectability and anatomical complexity.

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Correspondence to: Trong Binh Le, Department of Radiology, Hue University of Medicine and Pharmacy, Hue University, 06 Ngo Quyen, Hue, Vietnam. Tel: +84-905215096, Fax: +84-234-3826269, E-mail: letrongbinh@hueuni.edu.vn, ORCID: https://orcid.org/0000-0001-5444-5708

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Palliative biliary-enteric anastomosis has been shown to reduce the complication rates and increase overall survival.[3,4] On the other hand, most MHBO patients are usually diagnosed at an advanced stage, presenting with extensive invasion, multiple complications, co-morbidities, and poor general condition, making them ineligible for surgery.[5]

Considering its minimally invasive nature, endoscopic retrograde cholangiopancreatography (ERCP) has traditionally been the first-line approach for biliary obstruction endorsed by various practice guidelines.[6] Consistent disadvantages of ERCP include the following: (i) high-level obstruction such as Bismuth–Corlette type 3 and 4 MHBO; (ii) prior gastroduodenal operation; (iii) severe biliary strictures; and (iv) cholangitis, septic shock, or poor general condition, which is contraindicated for general anesthesia.

The recent guidelines of the European Society of Gastrointestinal Endoscopy (ESGE) recommend percutaneous transhepatic biliary drainage (PTBD) as the first-line indication or in combination with ERCP for Bismuth–Corlette type 3 and 4 classifications.[4,7] ERCP and PTBD have comparable efficacy in managing Bismuth–Corlette type 1 or type 2 MHBO.[7-9] In contrast, PTBD has advantages over ERCP in terms of higher success rates and fewer complications, particularly in settings with complex perihilar obstructions, multiple-site obstructions, and extensive invasions. In addition, PTBD is considered a "life-saving procedure" for critically ill patients owing to complications, shock state, or poor general condition.[10] This study evaluated the short-term safety and efficacy of PTBD in managing MHBO.

SUBJECTS AND METHODS

1. Patient demographics

This study received institutional review board approval (approval number H2019/100), and informed consent was obtained from all patients. A retrospective study was conducted on 112 patients diagnosed with MHBO who underwent PTBD at two referral institutions from January 2019 to October 2024. All MHBO cases were confirmed pathologically. The PTBD indications were based on the practice guidelines of the Society of Interventional Radiology (SIR).[11] The exclusion criteria were insufficient patient data or poor imaging quality that interfered with the evaluation or statistical analysis.

2. Procedures

1) PTBD

The treatment strategy of MHBO was based on a multidisciplinary discussion between hepatobiliary surgeons, endoscopists, oncologists, and interventional radiologists. PTBD was performed using the Seldinger technique. The targeted bile duct was selected under ultrasound guidance using a 21G Chiba needle (Cook Medical, Bloomington, IN, USA). A 0.018" wire, 5F catheter, and 5F sheath (Cook Medical) were then exchanged into the selected bile duct to perform a direct cholangiography and assess the biliary tree anatomy, degree of dilatation, and obstruction characteristics. The obstruction site was crossed using a 0.035" glidewire (Terumo, Tokyo, Japan) and a 5F diagnostic catheter (Cobra; Terumo). The tract was dilated with an 8F dilator followed by the placement of an 8.5F pigtail drainage catheter (Sungwon Medical, Cheongju, Korea) over-the-wire. Unilateral or bilateral, number of side-holes, and Y- or T-configured drainage were decided based on the site, level, etiologies of the obstruction, and treatment purposes.

2) Percutaneous transhepatic biliary stent placement

An Amplatz stiff wire (Boston Scientific, Natick, MA, USA) was placed through the previous access route for the delivery of a balloon, when necessary, and a stent. Self-expandable, metallic, non-covered biliary stents were deployed over the wire. The diameter, length, and configuration (unilateral stent, T-stent, Y-stent, and kissing stent) of the stents were selected according to the abovementioned drainage. Finally, 8.5F drainage catheters were temporarily placed for irrigation. A post-dilated balloon bilioplasty was not a routine practice. One interventional radiologist with 15 years of experience performed all the procedures.

3. Data collection

The patients' data were collected, including age, sex, clinical manifestations, laboratory tests (serum bilirubin and liver enzymes), cause of the biliary obstruction (histological findings), and imaging characteristics (CT and MRI). The post-procedure parameters included post-procedure laboratory test (serum bilirubin level), types of PTBD procedure performed, drainage or stent configuration, and PTBD-related complications.

Technical and clinical success were defined according to the SIR guidelines.[11] For PTBD, technical success was defined as the placement of drainage tubes into the biliary tree with external or internal free flow of bile. Clinical success was defined as a ≥20% decrease in the serum bilirubin level within seven days post-procedure compared to the pre-intervention level.[12] For percutaneous transhepatic biliary stent placement, technical success was defined as stent deployment in an adequate position across the stenosis with the good passage of contrast agent through the stents. The clinical success rate was defined as the resolution of signs and symptoms of biliary obstruction. The 30-day morbidity, mortality, and re-intervention were documented.

Post-procedural complications were classified into the following: minor complications that required no or minor therapy, including overnight admission for observation only and had no consequence; major complications that required major therapy and hospitalization (≥48 hours) or an unplanned increase in level of care or resulted in permanent adverse sequelae or death.[11,12]

4. Statistical analysis

The continuous data are presented as the mean±SD if the variables were normally distributed or as the median and range if the variables were not normally distributed. The categorical data are reported as the counts and percentages. A paired-samples t-test was used to compare the mean bilirubin levels between pre- and post-PTBD groups. Pearson's Chi-square test was run to determine the association between the site (left vs. right) and the number of drainages with clinical success. Binary and multivariate logistic regressions were performed to determine the correlation between the success rate and demographic factors, pre-procedural PTBD level, diameter of the peripheral intrahepatic duct (IHD), degree of obstruction, and drainage configuration. All analyses were performed using SPSS 20.0 (IBM Co., Armonk, NY, USA) software. p-values <0.05 were considered significant for all comparisons.

RESULTS

This retrospective study included 112 patients with MBHO who underwent PTBD between 2019 and 2024 at the authors' institution. The patients had a mean age of 62.6±12.3 years (range, 28–91 years) and a female-to-male ratio of 2:3.

Etiologies of MHBO were cholangiocarcinoma (n=77; 68.8%), perihilar lymphadenopathy (n=8; 7.2%), hepatocellular carcinoma (n=8; 7.2%), gallbladder carcinoma (n=7; 6.2%), liver metastasis (n=6; 5.4%), invasive pancreatic adenocarcinoma (n=3; 2.6%), and invasive gastroduodenal carcinoma (n=3; 2.6%). Obstructions were classified according to the Bismuth–Corlette classification as follows: type 1, n=20 (17.9%); type 2, n=26 (23.2%); type 3a, n=29 (25.9%); type 3b, n=18 (16.0%); type

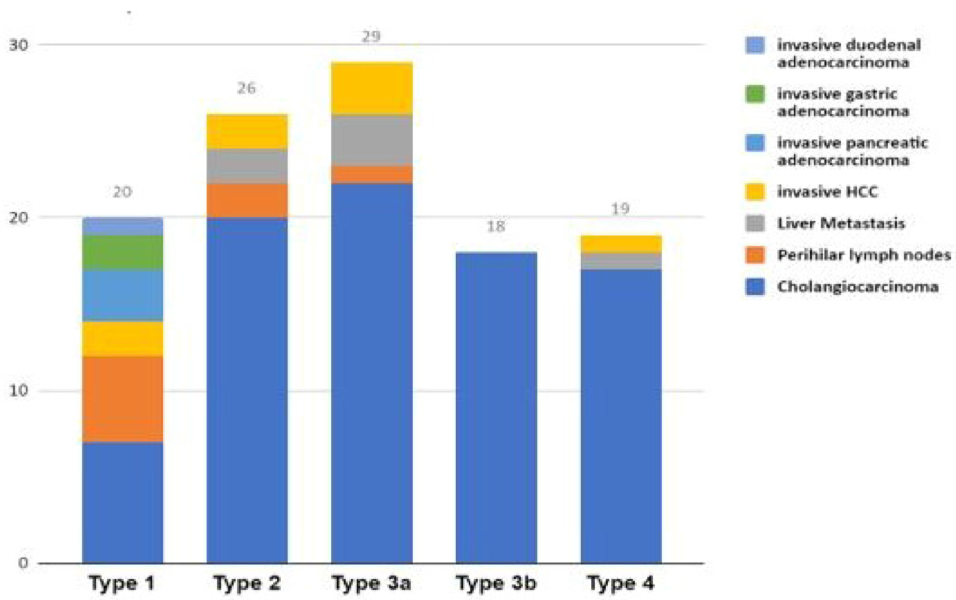

Fig. 1. Distribution of biliary obstruction according to the etiologies and Bismuth and Corlette classification. HCC, hepatocellular carcinoma.

4, n=19 (17.0%) (Fig. 1).

The technical success rate was 99.1%, of which 58.6% was unilateral drainage and 41.4% was bilateral drainage (Table 1). Ten patients (8.9%) had a minimal or non-dilated intrahepatic duct, defined as a peripheral IHD <2 mm in diameter. The internal–external, external, and mixed drainage rates

Table 1. Procedure Success Rate (n=112)

Parameters			Number (%)
Technical success rate			111 (99.1)
Unilateral drainage (n=65; 58.6%)	Left side (n=36; 55.4%)	Internal-External drainage	23 (63.9)
		External drainage	13 (36.1)
	Right side (n=29; 44.6%)	Internal-External drainage	28 (96.6)
		External drainage	1 (3.4)
Bilateral drainage (n=46; 41.4%)		Internal-External drainage	22 (47.8)
		External drainage	8 (17.4)
		Combined	16 (35.8)
Stent placement (n=39; 35.1%)		Single stent	20 (51.3)
		Y-stent	9 (23.1)
		Kissing stent	8 (20.5)
		T-stent	2 (5.1)

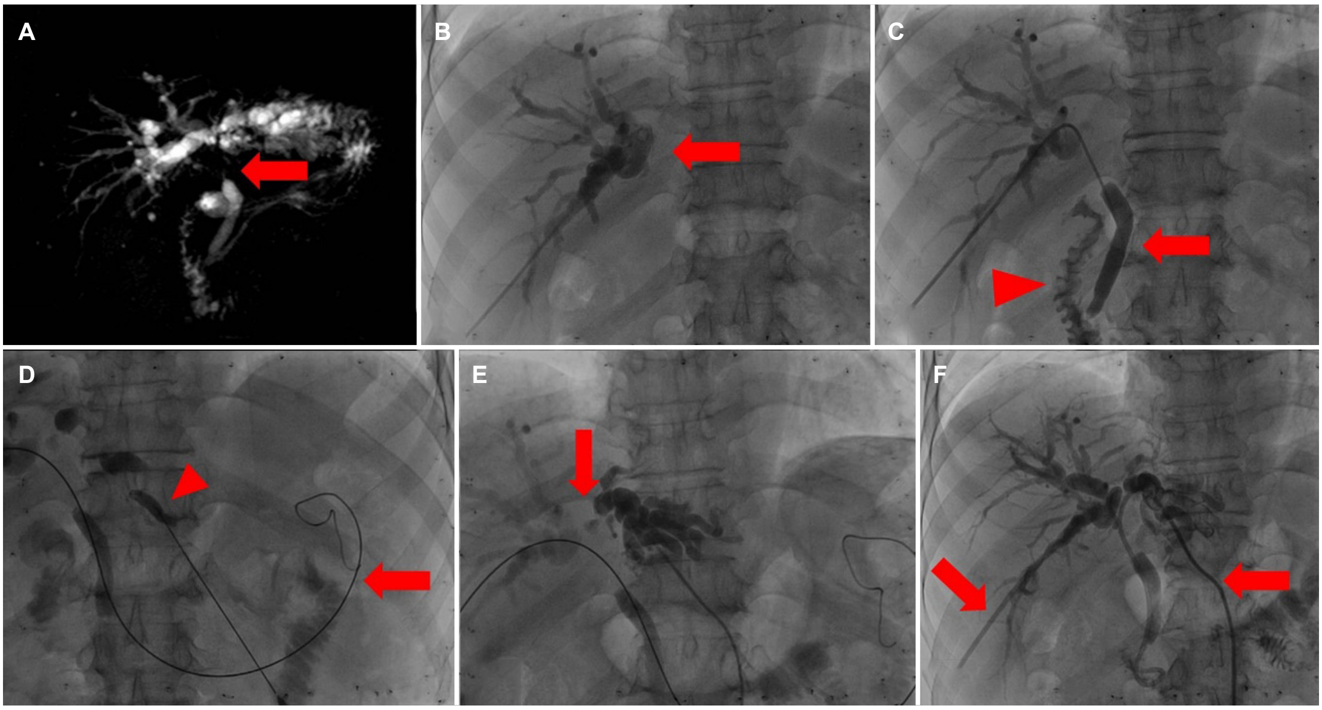

Fig. 2. Bilateral external-internal drainage (Y-configuration PTBD) for palliative treatment in an 81-year-old male patient diagnosed with Klatskin type 2 Cholangiocarcinoma. (A) The MRCP image shows dilatation of bilateral intrahepatic bile duct (IHD) with abrupt hilar occlusion (arrow) consistent with hilar cholangiocarcinoma. (B) Fluoroscopic cholangiogram of the right IHD confirms the complete occlusion at the right hepatic duct (arrow). (C) Cholangiogram obtained from a 5F catheter after crossing the obstruction site reveals hilar biliary filling defect consistent with tumor invasion, opacification of the common bile duct (arrow) and duodenum (arrowhead). (D) A stiff wire was exchanged into the proximal jejunum for later placement of the drainage tube (arrow). Puncture of the left biliary duct (arrowhead). (E) Cholangiography of the left IHD also confirms the abrupt occlusion of the left hepatic duct (arrow), compatible with Klatskin type II cholangiocarcinoma. (F) Bilateral 8.5F drainage catheters with multiple side holes were placed to ensure external-internal drainage. MRCP, magnetic resonance cholangiopancreatography; IHD, intrahepatic duct.

were 65.8%, 19.8%, and 14.4%, respectively (Fig. 2). Biliary stents were implanted in 39 patients (35.1%), in which 23.1%, 20.5%, 5.1%, and 51.3% of patients received Y-stents (Fig. 3), kissing stents (Fig. 4), T-stents, and unilateral stents, respectively.

A significant reduction (26.5%) in the mean total serum bilirubin levels was observed between pre- and post-PTBD (256.1±158.9 μmol/L vs. 188.3±110.6 μmol/L, $p<0.05$) of the entire cohort. Among these, 78 patients (69.6%) had ≥ 20% total bilirubin reduction within seven days post-procedure, which was defined as clinical success. In this clinical success group, the mean serum bilirubin levels of the pre- and post-PTBD groups were 299.9±161.9 μmol/L and 182.7±97.8 μmol/L, respectively, corresponding to an average reduction of 39.1% ($p<0.05$). By contrast, the mean serum bilirubin levels of the clinical unsuccessful group were 161.9±105 μmol/L and 200.6±135.9 μmol/L, respectively, corresponding to a 24.2% increase ($p<0.05$). Table 2 lists the change in bilirubin level after PTBD according to the Bismuth–Corlette classification.

For 91 patients with a non-type I obstruction, 46 and 45 patients had unilateral and bilateral drainage, respectively. For the unilateral drainage subgroup, 31/46 patients (67.4%) achieved clinical success. The total bilirubin levels pre- and post-PTBD were 283.7±174.4 μmol/L and 173.6±108.8 μmol/L, respectively, corresponding to a 38.1% reduction. For the bilateral drainage subgroup, 32/45 (71.1%) had clinical success. The total bilirubin levels pre- and post-PTBD were 318.2±154.6 μmol/L and 194.2±87.3 μmol/L, respectively, corresponding to a 38.6% reduction. No significant difference in the clinical success rate and percentage of bilirubin reduction was observed between the two subgroups.

Multivariate logistic regression analysis showed that pre-procedural PTBD total bilirubin level was a predictive factor of clinical outcomes after PTBD (Table 3). Higher pre-procedural bilirubin levels were associated with a lower likelihood of clinical success. For type I MHBO, the drainage side (right vs. left) was not a predictive factor of the clinical outcomes

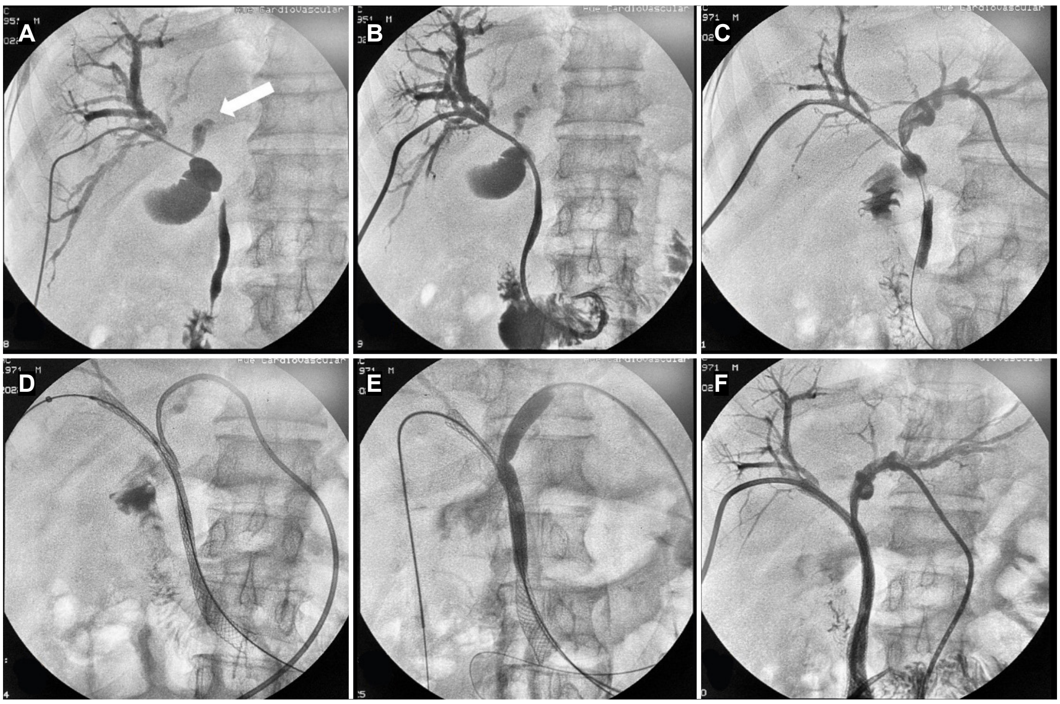

Fig. 3. Y-stent placement in a 70-year-old male with end-stage Klatskin type IV. (A) Cholangiogram obtained from a 5F catheter reveals multiple obstructions at the right IHD, common hepatic duct, and common bile duct. Note the faint opacification of the left IHD (arrow). (B) An 8.5F drainage catheter was inserted into the duodenum with multiple side holes produced along the tube. (C) Left IHD cholangiogram confirms a severe stenosis at the hilum with a filling defect in the left IHD, consistent with type IV Klatskin tumor. (D) A 10×100 mm SEMS was deployed from the right IHD to the duodenum. (E) After the wire was manipulated through the mesh of the first stent, balloon dilatation was performed, followed by the placement of a 10×60 mm SEMS from the left IHD to the CBD. (F) Completion cholangiogram from bilateral temporary drainage tubes confirmed patent biliary outflow. The tubes were removed several days later. IHD, Intrahepatic duct; SEMS, self-expandable metallic stent; CBD, common bile duct.

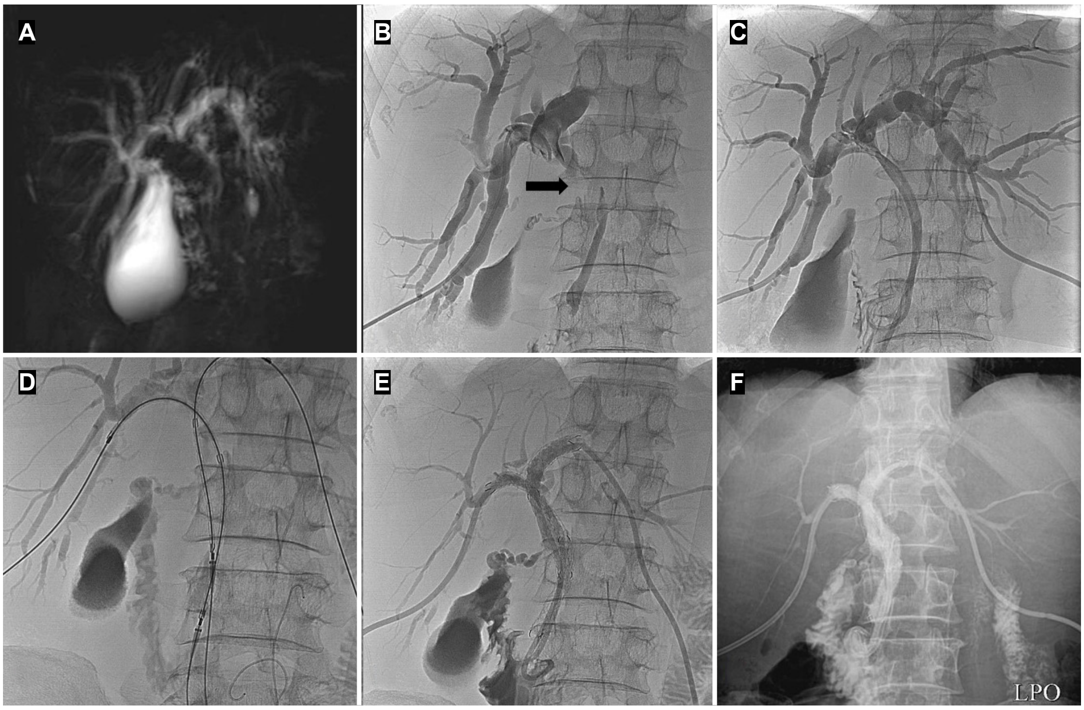

Fig. 4. Kissing stent placement in a 68-year-old male with hilar obstruction due to a pathologically confirmed hepatocellular carcinoma. (A) MRCP showed a separate dilatation of the bilateral IHD. (B) Cholangiogram obtained from a 5F sheath shows a filling defect at the common hepatic duct (arrow) extending to the bilateral IHD, consistent with type II Bismuth–Corlette classification. (C) Bilateral 8.5F drainage catheters with multiple side holes are placed. (D) A few days later, bilateral self-expandable metallic stents 10×80 mm are deployed simultaneously. (E) All IHDs were collapsed. (F) Follow-up cholangiogram shows complete recanalization of the bile flow, and the drainage tubes are removed. MRCP, magnetic resonance cholangiopancreatography; IHD, intrahepatic duct.

Table 2. Bilirubin Changes after the Procedure

Post-PTBD bilirubin	Total, n (%)	Type 1	Type 2	Type 3		Type 4
				3A	3B	
Decrease	77 (69.6)	11 (14.3)	24 (31.2)	17 (22.1)	13 (16.9)	12 (15.5)
Non-decrease	35 (30.6)	9 (25.7)	2 (5.7)	12 (34.3)	5 (14.3)	7 (20.0)
Total	112 (100)	20 (17.9)	26 (23.2)	29 (25.9)	18 (16.0)	19 (17.0)

PTBD, percutaneous transhepatic biliary drainage.

Table 3. Predictors of Clinical Success

Factors	Univariate				Multivariate			
	B	ExpB	95% CI	p-value	B	ExpB	CI 95%	p-value
Age	0.001	1.001	0.965–1.039	0.937	–0.001	0.999	0.949–1.051	0.961
Sex	–0.223	0.800	0.300–2.132	0.655	0.249	1.283	0.317–5.193	0.727
Degree of Obstruction	–0.383	0.682	0.156–2.989	0.612	–0.442	0.643	0.109–3.784	0.625
Number of drainage sites	–0.235	0.719	0.317–1.971	0.615	0.852	2.345	0.420–13.097	0.331
Drainage type	–0.062	0.94	0.168–5.256	0.944	0.602	1.826	0.221–15.115	0.576
Pre-PTBD bilirubin level	–0.007	0.993	0.988–0.997	0.001	–0.010	0.990	0.984–0.995	0.001
Minimal or non-dilated IHD	–0.519	0.595	0.124–2.859	0.517	–1.375	0.253	0.023–2.792	0.262

IHD, intrahepatic duct; CI, confidence interval.

Table 4. Procedure-related Complications

Complications	Number of cases	Percentage (%)
Patients with one complication	5	4.5
Patients with ≥2 complications	16	14.3
Major complications	8	7.1
- Acute cholangitis	3	2.7
- Acute pancreatitis	4	3.6
- Multiorgan failure	1	0.9
Minor complications	21	18.8
- Mild-to-moderate pain	15	13.5
- Bile leakage	13	11.6
- Puncture site infection	10	8.9
- Transient hemobilia	8	7.1
- Catheter dislodgement	3	2.7
- Subcapsular hematoma	2	1.8
- Catheter occlusion	2	1.8
30-day mortality	2	1.8
30-day re-intervention	17	15.2

($p>0.05$, Fisher's Exact test). For types II, III, and IV MHBO, the number of drainage sites was not associated with the clinical outcomes ($p>0.05$, Pearson Chi-square test).

Mild complications were observed in 21 patients (18.8%), with five patients experiencing one complication and 16 having two or more complications. Major complications were observed in eight patients (7.1%), including three cases of acute cholangitis, four cases of acute pancreatitis, and one case of multiorgan failure. Among these, two patients died: one due to acute severe pancreatitis and one due to multiorgan failure, corresponding to a 30-day mortality of 1.8%. Seventeen patients (15.2%) required simple re-intervention within 30 days because of catheter dislodgement and occlusion (Table 4). After PTBD, 28.6% patients received a surgical resection, while 71.4% received palliative care.

DISCUSSION

MHBO is a severe clinical condition that is difficult to treat and has a poor prognosis, particularly in the advanced stage. This study showed that PTBD is a highly effective and safe procedure for managing MHBO, particularly in patients who were ineligible for a surgical resection or endoscopic approaches.

Common malignant causes of hepatic hilar biliary obstruction include Klatskin tumors (65%), gallbladder cancer (12.5%), hepatocellular carcinoma (10%), and metastases (12.5%).[1,2] This study showed similar findings, where the majority of cases were cholangiocarcinoma (n=77; 68.8%), perihilar lymphadenopathy (n=8; 7.2%), hepatocellular carcinoma (n=8; 7.2%), gallbladder carcinoma (n=7; 6.2%), liver metastasis (n=6; 5.4%), invasive pancreatic head tumor (n=3; 2.6%), and invasive gastroduodenal carcinoma (n=3; 2.6%).

The overall technical success rate of this study was 99.1%, which was in line with the literature, highlighting the reliability of PTBD even in complex MHBO.[13] According to the SIR guidelines, the reported technical success rate of PTBD was 90–100% for dilated ducts and 67–97% for non-dilated ducts.[11] A case of non-dilated IHD failed in a patient with mass-forming cholangiocarcinoma (Klatskin type 3B), where a 0.018" hairwire could not be manipulated into the IHD.

A substantial proportion of patients required bilateral drainage, reflecting the intricate nature of hilar obstructions where unilateral drainage may be insufficient. The stent placement success rate was 100% in 39 cases (35.1%). The successful deployment of Y-stents, kissing stents, and T-stents in a significant number of patients further underscored the versatility of PTBD in addressing complex biliary strictures.

The clinical success rate of this study was 69.6%, defined as a serum bilirubin reduction of ≥20% within seven days post-procedure, which was slightly lower than that reported in the SIR guidelines (77–88.5%).[11] In particular, upon subsequent follow-up at 1–3 weeks, this rate improved to 80.2%, indicating an existing discrepancy in the definitions of clinical success, the cut-off values for the bilirubin levels, and the time points of bilirubin testing across studies. Most of the authors advocated for a reduction in the serum bilirubin level of ≥20% within seven days post-procedure, implying clinical success. The optimal timing for bilirubin measurement is unclear. In addition, the slightly lower clinical success rate in the present study may be attributed to the study population, which comprised a majority of complex hilar obstruction; 58.9% were Bismuth–Corlette type 3 and 4. Páez-Carpio et al. reported a one-week clinical success rate of 83.6%.[14] Nevertheless, their study only included patients with cholangiocarcinoma, whereas Korea involved various malignant pathologies causing hilar biliary obstruction. Ratra et al. reported a clinical success rate of 94.6%,[15] but their cohort included biliary obstructions ranging from distal to hilar levels, rather than exclusively perihilar obstructions, as in the present study.

1. Unilateral or Bilateral Drainage

Physiologically, the right hepatic duct, left hepatic duct, and caudate duct drain were approximately 55–60%, 30–35%, and 10% of the liver volume, respectively.[16,17] Unilateral drainage was sufficient in cases of type I obstruction where the lobar confluence was patent. Among 20 patients with type I obstruction, 14 had left-sided drainage and six had right-sided drainage. The clinical outcome of right-sided versus left-sided drainage in these patients was not statistically different, with 66.7% vs. 71.4% (p>0.05). Generally, the choice of the right vs. left approach depended on the dominantly dilated IHD and the availability of safe access. Technically, right-sided access allowed drainage of a larger liver volume in the cases of non-type I obstructions, but it was usually associated with pain caused by intercostal nerve injury or irritation, respiratory difficulties, fatigue, and anorexia. Conversely, left access offered advantages such as the ease of manipulation, better patient comfort, and improved drainage care, making it preferable in cases of ascites, but this approach caused more radiation exposure to the operators' hands.[18,19] One study showed that left lobe entry was associated with a higher technical success rate, higher bilirubin decrease, and lower complication rate compared to right lobe entry.[20]

For severe obstructions (types II, III, and IV), the outcomes of unilateral vs. bilateral drainage remained heterogeneous in terms of palliative care.[6] In the present study, the numbers in the unilateral and bilateral drainage subgroups were comparable, and the clinical success and total bilirubin reduction post-PTBD were similar in both subgroups. Schima et al. analyzed 41 hilar obstruction patients and reported no significant differences in stent patency between unilateral (27 patients) and bilateral (14 patients) drainage.[21] Similarly, Kaiho et al. studied 21 patients with hilar obstruction (three Type II, seven Type III, and 11 Type IV) and observed no differences in outcomes between complete drainage (n=12) and partial drainage (n=9).[22]

Several studies have advocated that the effectiveness of drainage depends on the volume of liver drained, and optimal liver volume drainage significantly improves the treatment outcomes and is considered physiologically ideal.[17] Previous papers have recommended draining of at least 25% of the liver volume for effective biliary drainage.[17,23] More recently, Vienne et al. speculated that the liver drainage volume ≥50% was associated with the drainage effectiveness (odds ratio 4.5, p=0.001), particularly in Bismuth III strictures, and concluded that patients with a ≥50% drainage volume had significantly longer median survival than those with a <50% drainage volume, 119 vs. 59 days, p<0.01.[24] Achieving a >50% liver drainage volume could be challenging in complex obstructions (Bismuth III/IV), especially when the confluence and segmental branches are involved. Bilateral or multiple drainage should be considered if a single stent or drainage system could not achieve the target volume.[25]

The reason for unilateral drainage for non-type I hilar obstruction in this study is as follows. For resectable type II hilar obstruction, temporary unilateral drainage could be acceptable if the confluence was not completely occluded. In these cases, unilateral drainage was performed, and the drainage catheter was modified with multiple side holes. For an unresectable type II lesion, bilateral drainage was preferred for sufficient decompression and further stent placement. In the case of type IIIB and IV Klatskin tumors, where the left hepatic lobe was often atrophic or massive tumor-harboring, it was assumed that left-sided drainage was ineffective and increased the risk of complications. One study reported that intubating an atrophic sector (<30%) was ineffective and increased the risk of cholangitis (odds ratio 3.04, p=0.01).[24]

2. Internal-External vs. External Drainage

The decision between internal–external and external drainage depended on the therapeutic goal, patients' general condition, and procedure complexity. Routinely, internal–external drainage was prioritized. This method allowed bile juice to drain into the duodenum, improving digestion in individuals undergoing palliative management. In addition, it facilitated subsequent interventions, such as stricture dilation or biliary stent placement, to restore physiological bile flow without maintaining a drainage tube. On the other hand, this type of drainage resulted in a longer procedure time and more radiation exposure. External drainage was reserved for patients who (i) were surgical candidates, (ii) were in a state of acute cholangitis, or (iii) had a poor general condition that required a prompt procedure. Specifically, no significant difference in the clinical success rates was observed between these two groups: 70.1% for internal–external drainage vs. 71.4% for external drainage.

As previously reported, PTBD had a lower rate of chol-

Table 5. Comparison of Characteristics in this Study and SIR Guideline Thresholds

Characteristics	Our study	SIR threshold
PTBD technical success rate	99.1%	92%*
PTBD clinical success rate	69.6%	75%
Biliary stent placement success rate	100%	95%
Complications		
- Major complications	7.1%	10%
- Minor complications	18.8%	45.2%
+ Transient hemobilia	7.1%	5.7%
+ Puncture site infection	8.9%	18.4%
+ Catheter dislodgement	2.7%	17%
+ Bile leakage	11.6%	8.3%

PTBD, percutaneous transhepatic biliary drainage; SIR, Society of Interventional Radiology.
*The threshold used for cases with intrahepatic duct dilation.

angitis, pancreatitis, salvage biliary drainage, and lower hospitalization costs in patients with types II, III, and IV hilar cholangiocarcinoma compared to ERCP, but ERCP drainage was more durable.[26-28]

The pre-PTBD total bilirubin level was a predictor for the clinical outcome after PTBD, which was in line with previous reports.[12,13] A high serum bilirubin level usually contraindicates surgery as well as other local or systemic therapies. Preoperative PTBD proved to be beneficial in reducing postoperative hepatic insufficiency in patients with a high total serum bilirubin concentration.[29]

The rates of minor and major complications in the present study were 7.1% and 18.8%, respectively, which are below the SIR recommended threshold (Table 5).[11] A slightly higher rate of bile leakage was observed at the puncture site compared to the SIR-suggested thresholds, possibly due to prolonged catheter placement.[11] This could be prevented by improved patient education and routine follow-up of the drainage catheter, allowing the early signs of bile leakage to be detected and promptly managed. The incidence of transient biliary bleeding in this study was relatively high (7.2%), probably due to the high rate of internal-external drainage (80.2%), where the bilateral catheters traverse the malignancies. Meticulous catheter placement and limiting the number of wires and catheter manipulations across the lesion may reduce the risk of this complication.[30] Seventeen patients required simple re-intervention procedures, such as catheter reposition or change, to manage the minor complications of catheter dislodgement and occlusion. The 30-day mortality was 1.8%. These findings are considered acceptable given the complexity of the procedure.

This study had several limitations. First, the study design was retrospective. Second, the inherent heterogeneity of the patient population, which included various types of malignancies, might induce potential bias in evaluating technical and clinical success. Lastly, the short follow-up duration overlooked late complications and was unable to assess stent patency, re-intervention, and overall survival. Future studies could address these limitations by adopting a prospective design and focusing on a more homogeneous patient population to enable a clearer evaluation of the technical and clinical outcomes. In addition, extending the follow-up period would allow an assessment of late complications, stent patency, need for re-intervention, and overall survival, providing a more comprehensive understanding of the long-term efficacy.

In conclusion, these findings reaffirmed the effectiveness and safety of percutaneous transhepatic biliary intervention in managing MHBO, particularly in cases where surgery and ERCP were not feasible. The high technical success rate, combined with a manageable complication profile and significant clinical benefits, highlighted the value of PTBD in the palliative management of MHBO. Further studies will be needed to evaluate the long-term effects of PTBD on patients' overall survival and quality of life.

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