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Comparison of The Initial Endoscopic Versus Percutaneous Approach Biliary Drainage for Palliative Perihilar Cholangiocarcinoma

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1. Abstract

1.1 Background: Percutaneous Transhepatic Biliary Drainage (PTBD) and endoscopic retrograde biliary drainage (ERBD) had been widely used for unresectable perihilar cholangiocarcinoma (PHC). The optimal type of biliary drainage is still a matter of debate. We aim to compare the efficacy and complications of PTBD and ERBD in the unresectable PHC.

1.2. Patients and Methods: From January 2013 to December 2020, 1145 patients were diagnosed with cholangiocarcinoma or gall bladder cancer in a tertiary hospital cancer registry. We excluded those with resectable tumor, combination intrahepatic tumor or without any treatment. Twenty-seven patients received initial ERBD (n = 18) or PTBD (n = 9) for palliative treatment of unresectable PHC.

1.3. Results: Age, gender, tumor stage, or Bismuth type were similar between the two groups. The clinical successful rates of drainage were similar between the PTBD and the ERBD groups (66.7% vs. 50.0%, p = 0.683). Two groups had similar complication rates. The PTBD group had a longer survival time in trend (p = 0.184) than ERBD group in the 1-year follow-up. There was a higher dislocation rate in the PTBD (55.5%) than the ERBD (14.3%) group in trend (p = 0.066), as the consequence of shorter patency time in the PTBD than ERBD group (47.0 ± 32.8 days vs. 156 ± 151.1 days, p = 0.083)

1.4. Conclusions: ERBD and PTBD were used as therapeutic options to improve obstructive jaundice in palliative PHC patients with similar complications and could be each other's rescue method if initial drainage approach had no clinical response.

2. Introduction

Cholangiocarcinomas are rare, with a prevalence of 0.01%–0.46% in autopsy studies [1]. In the recent study, the age-standardized incidence rates between 2008 and 2012 were 0.26–2.8 and 0.08–2.24 per 100,000 person-years in Intrahepatic Cholangiocarcinoma (ICC) and Extrahepatic Cholangiocarcinoma (ECC), respectively. ICC and ECC incidence increased in majority of the countries worldwide in 20 years, with the highest rates in Asia [2]. Hilar cholangiocarcinoma (HC) is the most common type of bile duct cancer, constituting 50%–55% of all bile duct cancers compared with distal extrahepatic and intrahepatic tumors [3, 4], which is often diagnosed at a terminal stage and is unresectable because of no obvious early symptom and poor image enhancement. Unresectable HC has a poor prognosis with a 5-year survival rate of 7%–16%, with Japan having the best results [5]. Many patients with an unresectable HC suffered from obstructive jaundice. Therefore, the palliative drainage of this obstructive jaundice became an important issue for improvement of life quality for these patients. Various strategies have been applied for biliary drainage, including percutaneous drainage, endoscopic decompression by nasobiliary drainage, or internal biliary stenting.

Rare studies were also found to distinguish which drainage is better in Bismuth types III and IV of malignant hilar strictures, which need to be modulated according to local experts [6]. In this study, we compared Percutaneous Transhepatic Biliary Drainage (PTBD) and Endoscopic Retrograde Biliary Drainage (ERBD) in unresectable HC, aiming to determine which is better for palliative Perihilar Cholangiocarcinoma (PHC).

3. Materials and Methods

3.1. Patients and Assessments

This was a retrospective study trial conducted at Kaohsiung Chang Gung Memorial Hospital, which was approved by the institutional review board and the Ethics Committee of Chang Gung Memorial Hospital (IRB-202001348B0D001). A waiver for patient consent was granted due to the retrospective nature of the study. A total of 1145 patients were diagnosed with cholangiocarcinoma or gall bladder cancer in the Kaohsiung Chang Gung Memorial Hospital cancer registry between January 2013 and December 2020: 584 (51.0%), intrahepatic cancer; 109 (9.5%), common bile duct cancer; 113 (9.9%), perihilar cancer(PHC); 140 (12.2%), ampulla cancer; 100 (8.7%), combined with hepatocellular carcinoma; and 99 (8.6%), gallbladder cancer (Figure 1). A total of 78 (69.0%) patients were diagnosed with PHC during follow-up treatment course in our hospital, and the other 35 (31.0%) did not undergo treatment in our hospital after diagnosis or just went there for second opinions. Patients who had resectable tumor (n = 22), with previous history of hepatectomy or gallbladder surgery (n =8), with combined intrahepatic tumor (n = 5), or without any treatment (n = 15) were excluded. Twenty-seven patients had received initial ERBD (n = 18) or PTBD (n = 9) for the palliative treatments (Figure 2), the baseline characteristics of whom (age, gender, infection of chronic hepatitis B or C, tumor stage, Bismuth type, pre-procedure prothrombin time (PT), active prothrombin time (aPTT), and serum bilirubin level) were recorded. Successful rates of clinical drainage, technical procedures, and complications were evaluated.

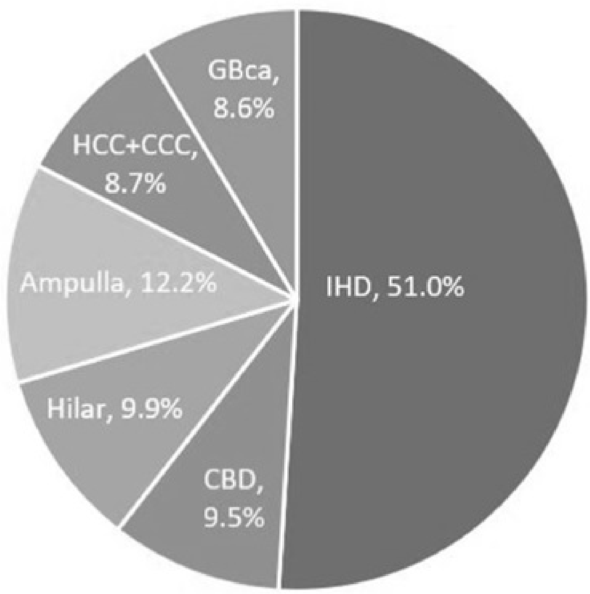

Figure 1: Ratio of location in cholangiocarcinoma and gall bladder cancer.

3.2. Procedure

Endoscopic retrograde cholangiopancreatography was performed using duodenoscopes to characterize the biliary stricture (Olympus; JF-260V, TJF-260V). If cannulation to CBD (common bile-duct) is difficult, endoscopic sphincterotomy was performed. We inserted a 7F or 8.5F plastic stent by a transpapillary approach after confirmation of guidewire passage through the stricture, the proper placement across the stricture of which was confirmed by fluoroscopy [7]. For PTBD, local anesthesia was performed before the procedure. The appropriate intrahepatic bile ducts or common hepatic/common bile ducts were accessed using a fine needle under ultrasound and fluoroscopy guidance. After dilator insertion, 8F or 8.5F pigtail catheter was inserted over the guidewire and positioned in the appropriate intrahepatic duct or common hepatic/common bile duct for external drainage [8].

3.3. Definitions

Biliary obstruction is defined as > 3mg/dl bilirubin with evidence of biliary tract dilatation and obstruction at imaging study before drainage [8]. Technical success is defined as appropriately positioned stent/catheter insertion across the stricture with immediate biliary decompression. Successful biliary drainage (clinical success) is defined as a decrease in serum bilirubin levels (< 50%) of the pretreatment value or < 2mg/dL serum bilirubin levels within 2 weeks without rescue PTBD/ERBD after the drainage procedure [8, 9]. The drainage complications were compared with cholangitis, pancreatitis, cholecystitis, and post-procedure bleeding. The symptoms of cholangitis are fever of ≥38°C, abdominal pain, and worsening biochemical parameters, within 7 days of drainage; cholecystitis, fever of ≥38°C, abdominal pain, worsening biochemical parameters, and confirmatory finding (new-onset gall bladder wall thickness) on imaging study within 7 days of drainage; and pancreatitis three times above normal limits serum lipase or amylase and abdominal pain following the procedure [8-10]. Significant bleeding is defined as a > 2mg/dL drop in hemoglobin level or requiring blood transfusion of > 2 units or for a hemostatic procedure after a drainage procedure [8, 9]. Stent patency was measured by the elapsed days between the procedure and either the condition (dislocation, obstruction) requiring reintervention or the date of patient death [8-10].

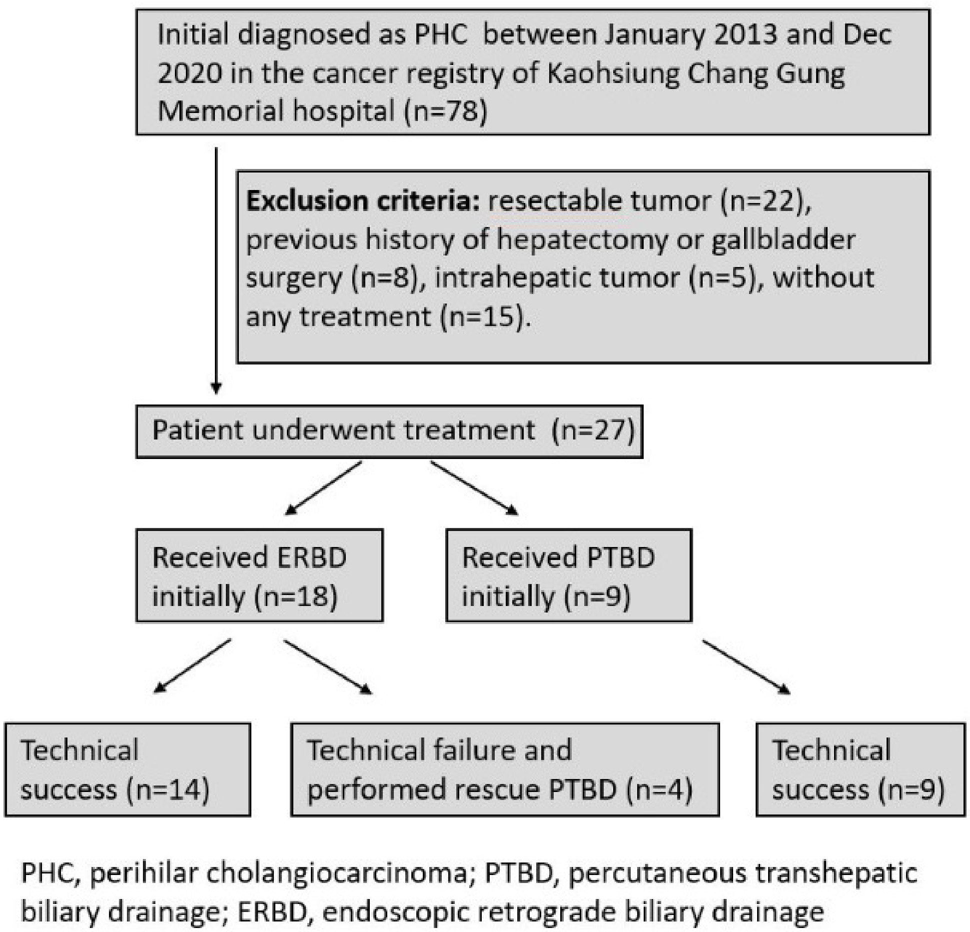

Figure 2: Flow chart of patients eligible for study in the period from January 2013 and Dec 2019.

3.4. Statistical Analysis

Statistical analysis was performed with SPSS version 22 for Windows. The treatment group variables were compared, assuming a 95% probability for rejection of the null hypotheses. The standard deviation is a measure of the amount of variation of a set of values. The Student's t-test and Fisher's exact test were used to calculate the statistical significances of different demographic and clinical variables. P-value < 0.05 was considered statistically significant.

4. Results

4.1. Patient Characteristics

(Table 1) shows the baseline characteristics of 9 and 18 patients undergoing PTBD and ERBD, respectively, as the primary procedure. The age, gender, infection of chronic hepatitis B or C, tumor stage, Bismuth type, pre-procedure serum bilirubin, PT, and a PTT were similar between two groups.

Treatment outcomes and complications

(Table 2) shows the outcomes of two groups. Univariate analysis revealed that the overall technical success and clinical successful drainage was similar between the PTBD and the ERBD groups. (technical, 9 (100.0%) vs. 14 (77.8%), p = 0.268; clinical, 6 (66.7%) vs. 9 (50.0%), p = 0.683, respectively). Four patients with technically ERBD all underwent rescue PTBD. The mean time of pigtail patency in the PTBD group was 47.0 ± 32.8 (6–90) days, while that of stent patency in the ERBD group was 156 ± 151.1 (3–419) days, showing a trend of longer time of stent patency in the ERBD than the PTBD group (p = 0.083) (Table 3). The complication rates were similar between the PTBD and ERBD groups (hemorrhage, 11.1% vs. 5.6%, p = 1; cholangitis, 0% vs. 5.6%, p = 1), with a higher cholecystitis and post-procedure pancreatitis rate in the ERBD group but no statistical significance (PTBD vs ERBD: 0% vs. 11.1%, p = 0.538; 0% vs 11.1%, p = 0.538) and a higher dislocation rate in the PTBD (5/9 (55.5%)) than the ERBD group (2/11 (14.3%)) in trend (p = 0.066) (Table 3).

The patients were all followed up until December 31, 2020: 15 of 18 patients died in the ERBD group, while 7 of 9 patients died in the PTBD group. (Figure 3) shows the 1-year Kaplan–Meier time-to-survival curves for both types of drainage, wherein the PTBD group had a higher survival probability in trend than the ERBD group (p = 0.184).

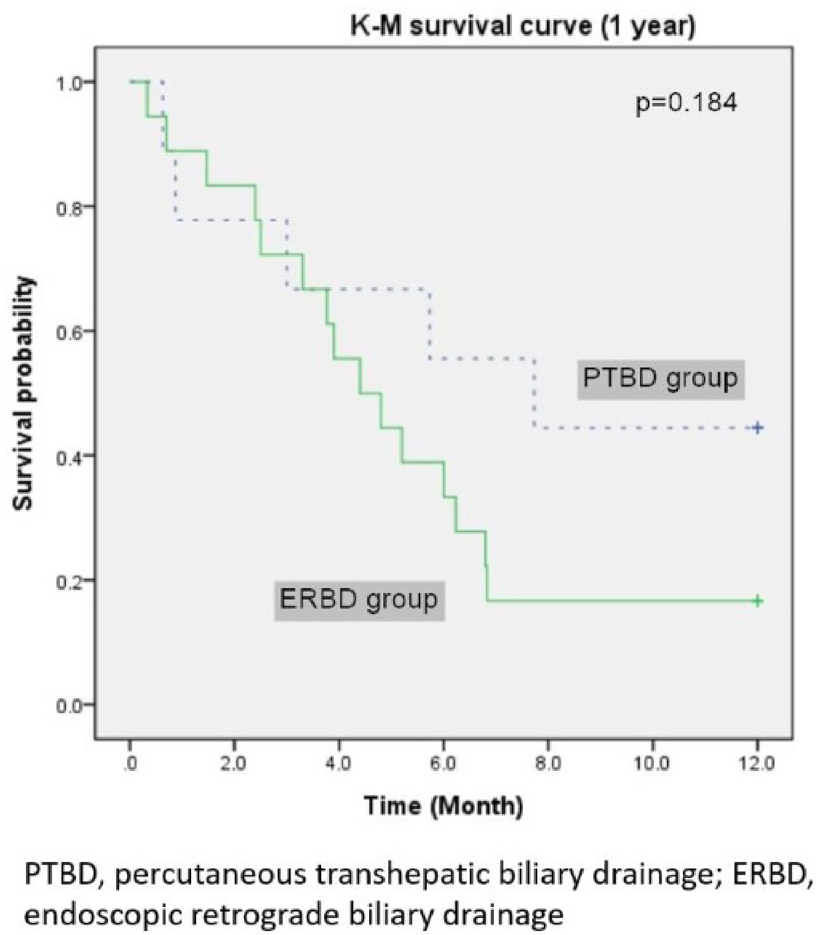

Figure 3: The two-year Kaplan–Meier time-to- survival curves for the both types of drainage

Table 1: Clinical baseline characteristics of two groups.

Characteristics		PTBD n =9 (n, %)	ERBD n =18 (n, %)	P-value
Age (year) (mean ± SD)		63.8±12.3	69.9±14.	0.272
Gender (F/M)		3/6(33.3/66.7)	8/10(44.4/55.6)	0.692
Cirrhosis		0(0)	4(22.2)	0.268
HBV		2(22.2)	5(27.8)	1
HCV		0(0)	4(22.2)	0.268
Bismuth type				0.582
	II	2(22.2)	2(11.1)	
	III-IV	7(77.8)	16(88.9)	
PT(sec) (mean ± SD)		11.29±2.3	12.1±2.2	0.4
APTT(sec) (mean ± SD)		28.5±4.2	28.4±4.7	0.953
Bilirubin (mg/dl) (mean ± SD)		10.0±5.7	13.5±10.3	0.392
Platelet (10^3/uL) (mean ± SD)		273.0±55.3	271.6±109.2	0.973

PTBD, percutaneous transhepatic biliary drainage; HBV, chronic hepatitis B; HCV, chronic hepatitis C; ERBD, endoscopic retrograde biliary drainage; PT, prothrombin time; APTT, activated partial thromboplastin time; SD, standard deviation.

Table 2: Clinical outcomes of two groups.

	PTBD n =9 (n, %)	ERBD n =18 (n, %)	*P*-value
Technical success	9(100.0)	14(77.8)	0.268
Clinical success	6(66.7)	9(50)	0.683
Complications			
Cholangitis	0(0)	1(5.6)	1
Cholecystitis	0(0)	2(11.1)	0.538
Pancreatitis	0(0)	2(11.1)	0.538
Hemorrhage	1(11.1)	1(5.6)	1

PTBD, percutaneous transhepatic biliary drainage; ERBD, endoscopic retrograde biliary drainage.

Table 3: The rates of dislocation and stent patency of the two groups**.**

	PTBD n = 9 (n, %)	ERBD n = 18 (n, %)	*P*-value
Dislocation	5(55.5%)	2(14.3%)	0.066
Stent patency(day) (mean ± SD)(range)	47.0 ±32.8 (6-90)	156.0±151.1 (3-419)	0.083

PTBD, percutaneous transhepatic biliary drainage; ERBD, endoscopic retrograde biliary drainage.

5. Discussion

PTBD and ERBD had been widely used in obstructive jaundice for cholangiocarcinoma either in preoperative drainage of malignant hilar strictures or palliative drainage in unresectable tumors. Which method is better for palliative drainage in unresectable HC is still in debate [8-12]. In 2012, ESGE suggested that PTBD was better than ERBD in patients with a ≥ 2 malignant hilar stricture of Bismuth type, due to fewer infective complications [13]. The ESGE (2018) had revised and suggested ERBD for Bismuth types I and II HC and PTBD or PTBD with ERBD for Bismuth types III and IV (weak recommendation and low-quality evidence). Only a few studies directly compared the outcomes between PTBD and ERBD in unresectable HC [6, 14]. The patients enrolled in our study were mostly using Bismuth type III or IV (n =23/27, 85.2%).

The technical successes were slightly higher with PTBD than ERBD groups (100.0% vs. 77.8%, p = 0.268). For hilar tumor, previous studies had reported better successful drainage using the percutaneous method [9, 10] in gall bladder cancer and PHC. Moreover, Jong kyoung Choi et al. (2012) reported a higher successful drainage rate in the ERBD group in hilar HCC [8]. Jang et al. (2017) showed similar technical and clinical successes [15]. Pinol et al. (2002) reported a higher therapeutic success in PTBD with more frequent major complications in all hilar cancers [16]. Overall, based on the systemic analysis result, in patients with advanced unresectable hilar malignancies, PTBD seems to be superior to ERBD with higher successful drainage rates (odd ratio (OR) of 2.53) [14].

The different outcomes may be due to various PTBD techniques. Saluja et al. reported the use of standard 8F pigtail for internal-external drainage PTBD in the first step, followed up by another 10F plastic stent for internal drainage few days later, and then the first pigtail (external drainage) was removed [9]. Paik et al. performed a two-step procedure (PTBD followed by percutaneous self-expended metallic stents (SEMS) few days later) [10]. Jang et al. (2017) firstly used an external tube for external drainage and then followed by bilateral SEMS for internal drainage few days later and then external tube removal [15]. The previous study had reported a higher infection rate in internal-external group than the external group in malignant obstructive jaundice [17]. However, more studies are needed to prove this.

The radiologists performed the simple external drainage (catheter positioned in the appropriate intrahepatic or common hepatic duct) for PTBD in this study, which was similar with the technique by Choi et al. (2012) [8], associated with easy dislocation by the unwilling movement of the patient. Choi et al. (2012) also reported a longer patency in the ERBD (plastic stent) than in the PTBD group (ERBD vs PTBD: 82 days' vs 37 days) [8]. In our study, the stent patency time in the ERBD was longer in trend than in the PTBD groups (156.0 ± 151.1 days' vs 47.0 ± 32.8 days, p = 0.083). One case of the ERBD group died in 13 days due to disease progression, while two had stent dislocation and underwent rescue ERBD or PTBD. It is easy to be monitored the daily total amount and color of bile juice in PTBD with external bag, which could directly detect the tube obstruction and dislocation, leading to earlier PTBD revision, before sepsis development. Nonetheless, in clinical situations, the alertness with ERBD obstruction or dislocation is often heightened until jaundice or sepsis is seen. The delay revision may involve a poor survival outcome. However, the PTBD is similar to ERBD in the 30-day mortality of the systemic review studies [12, 14, 18].

Studies that figured out the long-term survival times of PHC, comparing the ERBD and PTBD groups, were rare. Saluja et al. showed that PTBD and ERBD groups had a similar survival time [9]. Paik et al. showed the percutaneous SEMS group had a longer median survival than the endoscopic SEMS group (8.7 months' vs 6.2 months), but without significance difference [10]. However, Choi et al. showed that the ERBD group had a significantly longer median survival time than the PTBD group [8]. In this study, the PTBD group had a trend of higher survival probability than the ERBD group (p = 0.184) in the 1-year Kaplan–Meier time-to-survival curves (Figure 3).

Performing PTBD is feasible in unstable patients who cannot tolerate anesthesia. However, PTBD is associated with pain and discomfort at the skin puncture site. Cholangitis, biliary peritonitis, hemorrhage, pancreatitis, dislodgement, and obstruction were also reported in PTBD [12, 19, 20]. Malignant disease had been associated with a high risk of cholangitis and PTBD occlusion [21]. The American Society for Gastrointestinal Endoscopy guideline and previous studies reported the adverse events of ERBD: post-ERCP pancreatitis rate of about 9.7% with an increased incidence of 14.7% in high-risk patients; 0.3% to 2% rate of hemorrhage; 1.9% to 12% rate of cholecystitis following biliary SEMS placement; 0.5% to 3% rate of cholangitis and sepsis; and higher risk in patients with incomplete biliary drainage (i.e., HC) [22].

In the three systemic review studies, both ERBD and PTBD have advantages and disadvantages. Cholangitis and pancreatitis following PTBD were lower than following ERBD (OR 0.48 and 0.16, respectively). Incidences of bleeding and tube dislocation in PTBD were higher than in ERBD (OR 1.81 and 3.41, respectively) [12, 14, 18].

The papilla manipulation by catherization would enhance the risk of papilla edema and retrograde infection as the consequence of pancreatitis and cholangitis in the ERBD method. In our study, the ERBD complication rates are similar to the previous reports (cholecystitis, 11.1%; pancreatitis, 11.1%; hemorrhage, 5.6%; and cholangitis, 5.6%). No complications (cholecystitis, pancreatitis, and cholangitis) were found except one hemorrhagic event (11.1%) after PTBD.

It may be helpful in selecting the method of biliary drainage by identifying the risk factors of ERBD failure. Jang et al. reported that percutaneous approach had a higher technical success rate than the ERBD in Bismuth III/IV patient, suggesting that the acute left intrahepatic duct–common bile-duct angulation predicts endoscopic stenting failure [15]. Wiggers et al. reported that the factors of Bismuth 3a or 4 or > 8.8 mg/dL total bilirubin level in patients with potentially resectable PHC indicated the inadequate drainage with ERBD methods (plastic stent) alone [23]. In our study, the mean total bilirubin level before ERBD is 13.46 mg/dL; 11 patients had a > 8.8 mg/dL total bilirubin level before ERBD with a clinical failure rate of 50%, which is compatible with the result (62%) of Wiggers et al.'s study [23].

There are some limitations in this study. First, the number of patients in this study was small, so a significant difference was not achieved. In fact, the unresectable PHC was relatively rare in the cholangiocarcinoma. Second, the selection bias may exist in the patients' need and the decision-making of clinicians.

6. Conclusion

ERBD and PTBD could be the initial treatment option to improve obstructive jaundice in palliative PHC patients with similar complications and could be each other's rescue method if the initial drainage approach had no clinical response. Either option has its pros and cons, and the clinicians should choose the method that best suits the patient's needs and clinical circumstances.

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