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Original Article

Clinical efficacy of percutaneous transhepatic biliary drainage for obstructive jaundice in pancreatic cancer and risk factors for postoperative pancreatitis

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Abstract: Objective: To investigate the clinical efficacy of percutaneous transhepatic biliary drainage (PTBD) for obstructive jaundice in pancreatic cancer and identify the independent risk factors for postoperative pancreatitis after PTBD. Methods: A retrospective cohort study included 145 consecutive patients with pancreatic cancer admitted to Shanghai Seventh People's Hospital from June 2022 to June 2024, assigned to either the endoscopic retrograde biliary drainage (ERBD, n=72) group or the PTBD (n=73) group. The PTBD group was further subdivided into pancreatitis (n=11) and non-pancreatitis (n=62) subgroups. Clinical data were compared between groups. Univariate and Firth multivariate logistic regression analyses identified independent factors, with ROC curves evaluating predictive value. Results: Baseline data were balanced between groups (all P>0.05). PTBD yielded more significant improvements in liver function and a shorter jaundice resolution time (all P<0.05), yet was associated with a significantly higher incidence of postoperative pancreatitis (P<0.05). High body mass index (BMI), Oddi sphincter dysfunction, and difficult intubation were independent risk factors (P<0.05), while external drainage was a protective factor (OR=0.064, P=0.023). A multivariate combined predictive model constructed from these factors exhibited excellent predictive efficacy (area under the curve (AUC) =0.960, 95% CI: 0.918-1.000). Conclusion: PTBD effectively relieves obstructive jaundice and improves liver function. High-risk patients (elevated BMI, Oddi sphincter dysfunction, difficult intubation) require close monitoring, and prioritizing external drainage may reduce postoperative pancreatitis risk.

Keywords: Percutaneous transhepatic biliary drainage (PTBD), pancreatic cancer, obstructive jaundice, pancreatitis

Introduction

Previous studies have reported that pancreatic cancer is the 12th most common cancer worldwide and it has an extremely poor prognosis. It is the 7th leading cause of cancer-related deaths, accounting for 12.7% of deaths related to gastrointestinal cancers [1]. The incidence of pancreatic cancer is showing an upward annual trend. Its main type is ductal cell adenocarcinoma. As the disease progresses, patients may experience clinical manifestations such as abdominal pain, obstructive jaundice, and cholangitis [2, 3]. Obstructive jaundice is a major cause of poor prognosis and mortality in patients with pancreatic cancer. Due to the mechanical obstruction of the bile duct system caused by malignant lesions inside or outside the bile duct or the bile duct wall, the distal bile duct expands, the permeability of the capillary bile duct increases, and bile components reflux into the blood and lymph fluid, thereby causing jaundice [4-7]. Surgical resection of lesions and biliary bypass are curative treatments for malignant obstructive jaundice. However, most patients with pancreatic cancer are diagnosed at an advanced stage and are ineligible for curative surgery. Failure to effectively treat jaundice can directly reduce survival time and significantly impair quality of life [8-10]. Percutaneous transhepatic biliary drainage (PTBD) and endoscopic retrograde biliary drainage (ERBD)

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are currently the first-line palliative treatment modalities for obstructive jaundice, which can effectively alleviate liver failure caused by obstructive jaundice and prolong patient survival [11, 12]. At present, their application in high-level obstructive jaundice such as pancreatic cancer remains controversial [13]. PTBD is an invasive surgical procedure that may cause certain damage to the patient's pancreas, resulting in a relatively high risk of complications such as pancreatitis. Based on this, this study aimed to compare and evaluate the clinical efficacy of PTBD in the treatment of obstructive jaundice caused by pancreatic cancer by comparing it with ERBD, and to retrospectively analyze and explore the risk factors for pancreatitis in patients treated with PTBD, in order to provide a theoretical basis for clinical identification of high-risk populations.

Materials and methods

General information

A retrospective analysis of 145 patients with pancreatic cancer in Shanghai Seventh People's Hospital from June 2022 to June 2024 was conducted. Patients were divided into ERBD group (n=72) and PTBD group (n=73) according to the surgical plan, and the clinical effects were evaluated. Risk factor analysis was performed on patients with PTBD, and they were divided into the Pancreatitis group (n=11) and non-Pancreatitis group (n=62) according to whether patients had pancreatitis after PTBD operation. Inclusion criteria: (1) Patients with pancreatic cancer; (2) Obstructive jaundice was confirmed by clinical manifestations, laboratory examination, B-ultrasonography, CT or MR Examination; (3) Complete clinical data; (4) The serum amylase level was normal before operation. Exclusion criteria: (1) Patients with severe biliary infection; (2) Patients with chronic pancreatitis before operation; (3) The presence of any bile duct perforation. This study was approved by the Ethics Committee of Shanghai Seventh People's Hospital. Written informed consent was waived due to the retrospective design, and all patient data were anonymized to ensure privacy protection.

Treatment method

PTBD group: The specific operation was 2% lidocaine local anesthesia and intravenous sedation of midazolam or fentanyl from subcutaneous to subcapsular liver. If the patient is unable to cooperate, general anesthesia may also be used. Percutaneous transhepatic cholangiography (PTC) was performed for intrahepatic bile duct puncture under fluoroscopy to understand the obstruction status of bile duct, and bile duct puncture was selected, guide wire and cannula were introduced, the narrow segment was explored with guide wire, and the narrow length was determined by angiography again. Stent was selected according to the length and catheter was pulled out, and balloon catheter was introduced to dilate the narrow segment. After expansion, the stent was introduced and the conveyor reached the appropriate position to release the stent, the guide wire was retained, and the external drainage tube was introduced. The swelling and bile flow of the stent were examined, and the external drainage tube was removed after 1 week.

Definition and grouping criteria of PTBD drainage modalities

To ensure objectivity, reproducibility and accuracy of the study, the following definitions and grouping criteria were formulated based on the clinical operation specifications of our center and intraoperative records: External drainage: After percutaneous transhepatic stent implantation, an external drainage tube was routinely retained, with its distal end connected to a sterile closed drainage bag. Bile was directly drained outside the body for continuous biliary decompression. The external drainage tube was retained for ≥7 days postoperatively and removed only after confirming unobstructed stent drainage and normalized liver function (e.g., total bilirubin ≤34.2 μmol/L).

Internal drainage: After percutaneous transhepatic dilatation of the biliary stricture and implantation of a self-expandable metal stent, no external drainage tube was placed or retained during/after the operation. Bile was rerouted to flow into the duodenum through the metal stent, establishing a physiological intrabiliary drainage pathway.

Grouping criteria: Patients were grouped strictly according to the actual drainage modality implemented intraoperatively by the attending surgeon, with no cross-grouping or retrospective adjustment. The specific drainage modali-

ty, stent parameters, and grouping information were recorded in real time in the operative record and electronic medical record, which served as the sole objective basis for subsequent data collection and statistical analysis.

ERBD group: The patients were placed in the left lateral decubitus position, and were given intramuscular injection of conventional sedatives before surgery, general anesthesia if necessary, and endoscopic slow entry into the duodenum to avoid injury to the pharynx. After entering the descending part of the duodenum, the duodenal papilla was located, with carefully observation of the morphology of the papilla, the duodenal papilla was intubated with an incision knife and guide wire, and selective bile duct intubation was performed with a guide wire. If intubation was difficult, pre-sphincterotomy of the papillary sphincter could be performed, followed by guiding the guide wire through the narrow segment of bile duct under the guidance of X-ray. After successful intubation of the nipple, angiography was performed to measure and evaluate the length of the narrow segment, the guide wire was introduced, catheter was withdrawn, bile duct stent of appropriate length was placed along the guide wire and released, and fluoroscopy was performed after release to observe the relationship between the metal stent and the narrow segment as well as bile drainage. The position of the stent could be adjusted up and down according to the actual situation.

Definition of difficult intubation

Difficult intubation was defined as ≥3 cannulation attempts or a total cannulation duration >10 minutes by an experienced interventional radiologist during biliary duct intubation for PTBD/ERBD, in accordance with the modified criteria of the American Society of Interventional Radiology (ASIR) [14].

Clinical diagnosis of pancreatitis

The diagnosis of acute pancreatitis was established according to widely accepted international criteria (the revised Atlanta classification) [15, 16], which requires the presence of at least two of the following three features: (1) Abdominal pain consistent with acute pancreatitis (typically acute, persistent, severe epigastric pain often radiating to the back). (2) Serum amylase and/or lipase activity at least three times greater than the upper limit of normal (serum amylase: 35-135 U/L; lipase: 0-60 U/L). (3) Characteristic imaging findings of acute pancreatitis on contrast-enhanced computed tomography (CECT), magnetic resonance imaging (MRI), or transabdominal ultrasonography. All other potential causes of acute abdomen were excluded prior to diagnosis.

Observation index

(1) Clinical effect: Age, sex, and tumor stage of patients in the ERBD group and the PTBD group were recorded, and the following data were collected before and two weeks after surgery: Direct bilirubin (DBIL), serum bilirubin (TBIL), indirect bilirubin (IBIL), alanine aminotransferase (ALT), alkaline phosphatase (ALP), glutamyl transpeptidase (GGT), albumin (ALB), white blood cell count (WBC), platelet count (PLT). The treatment of jaundice in the two groups was collected: success rate of surgery. After successful implantation of biliary duct metal stent, the results were judged as success of surgery, yellow regression time, operation duration and jaundice treatment effect: According to the reduction of total bilirubin (TBIL) before and after the operation, as well as the improvement of abdominal pain and quality of life, they were classified as effective (TBIL decrease degree >1/2 before surgery 1 week after surgery), effective (TBIL decrease degree <1/2 before surgery 1 week after surgery), and ineffective (TBIL almost unchanged or higher than before surgery 1 week after surgery). Total effective rate = (obvious + effective) cases/total cases × 100%. Complications within two weeks after surgery were recorded in both groups. (2) Risk factor analysis: Age, gender, body mass index (BMI), tumor stage, preoperative WBC, ALP, DBIL, surgical drainage mode, Oddi sphincter dysfunction, difficulty in intubation, history of pancreatitis, and operation duration of patients in the PTBD group were recorded, and risk factors were analyzed according to postoperative complications of pancreatitis.

Statistical analysis

Statistical software SPSS 26.0 was used for all statistical analyses. For continuous variables, the Shapiro-Wilk test was first performed to assess normality and the Levene's test for homogeneity of variance, with the detailed

Table 1. Comparison of general data ($\overline{x}$ ± s, [n (%)])

Index		ERBD group (n=72)	PTBD group (n=73)	*t*	*P*
Age (years)		57.46±9.29	56.95±9.50	0.329	0.743
Gender	Male	37 (51.37)	39 (53.42)	0.060	0.806
	Female	35 (48.61)	34 (46.58)		
BMI		22.89±3.95	22.97±3.86	0.125	0.901
Tumor staging	Stage I	1 (1.39)	0 (0.00)	1.441	0.696
	Stage II	10 (13.90)	11 (15.07)		
	Stage III	26 (36.11)	23 (31.51)		
	Stage IV	35 (48.61)	39 (53.42)		

Note: ERBD: Endoscopic Retrograde Biliary Drainage; PTBD: Percutaneous Transhepatic Biliary Drainage; BMI: body mass index.

results of these tests and the intergroup comparison findings for the total study population and PTBD subgroup presented in Table S1. Normally distributed continuous variables were expressed as mean ± standard deviation ($\overline{x}$ ± s), and the independent-samples t-test was applied for intergroup comparisons of variables with normal distribution and homogeneous variance. Categorical data were presented as numbers and percentages [n (%)], and the chi-square test was used for their intergroup comparisons. Firth multivariate logistic regression analysis was employed to identify the independent risk factors for pancreatitis in patients undergoing PTBD. Receiver operating characteristic (ROC) curves were constructed to determine the optimal cut-off values of continuous variables for predicting pancreatitis. A two-tailed *P* value <0.05 was considered statistically significant for all analyses.

Results

Comparison of general data

ERBD patients ranged in age from 45 to 75 years, with an average age of (57.62±9.33) years. There were 37 males and 35 females. Patients in the PTBD group ranged in age from 39 to 80 years, with an average age of (57.46±9.52) years. There were 39 males and 34 females. There was no significant difference in age, gender and tumor stage between the two groups (P>0.05), as shown in **Table 1**.

Serum index liver function comparison

ALB level in both groups was significantly increased after treatment, and the PTBD group was significantly higher than that in the ERBD group after treatment (*P*<0.05). After treatment, WBC, DBIL, TBIL, IBIL, ALT, ALP and GGT in both groups were significantly lower than before treatment, and the levels of DBIL, TBIL, ALT, ALP and GGT in the PTBD group were significantly lower than those in the ERBD group after treatment (*P*<0.05), as shown in **Figure 1**.

Comparison of jaundice treatment

No statistically significant difference was observed in the surgical success rate between the two groups (P>0.05). However, the effective rate of jaundice treatment, the proportion of patients with intraoperative bile drainage volume ≥300 ml, and the proportion of patients with jaundice resolution time ≤7 days in the PTBD group were significantly higher than those in the ERBD group (all P<0.05), as shown in **Table 2**.

Comparison of complications

There were no statistically significant differences in patients with cholangitis, biliary fistula, biliary peritonitis and intestinal obstruction between the two groups (P>0.05). Patients with pancreatitis in the PTBD group were significantly higher than those in the ERBD group (*P*<0.05), as shown in **Figure 2**.

Single factor analysis of complicated pancreatitis

Univariate analysis results of patients in the pancreatitis group and non-pancreatitis group showed that there were statistically significant differences between the two groups in terms of BMI, drainage method, presence of Oddi sphincter dysfunction, difficulty in intubation, history of pancreatitis, and operative time (all P<0.05), as shown in **Table 3**.

Multifactor analysis

Taking the occurrence or non-occurrence of postoperative pancreatitis as the dependent variable, and the factors with significant differences identified in the univariate analysis as

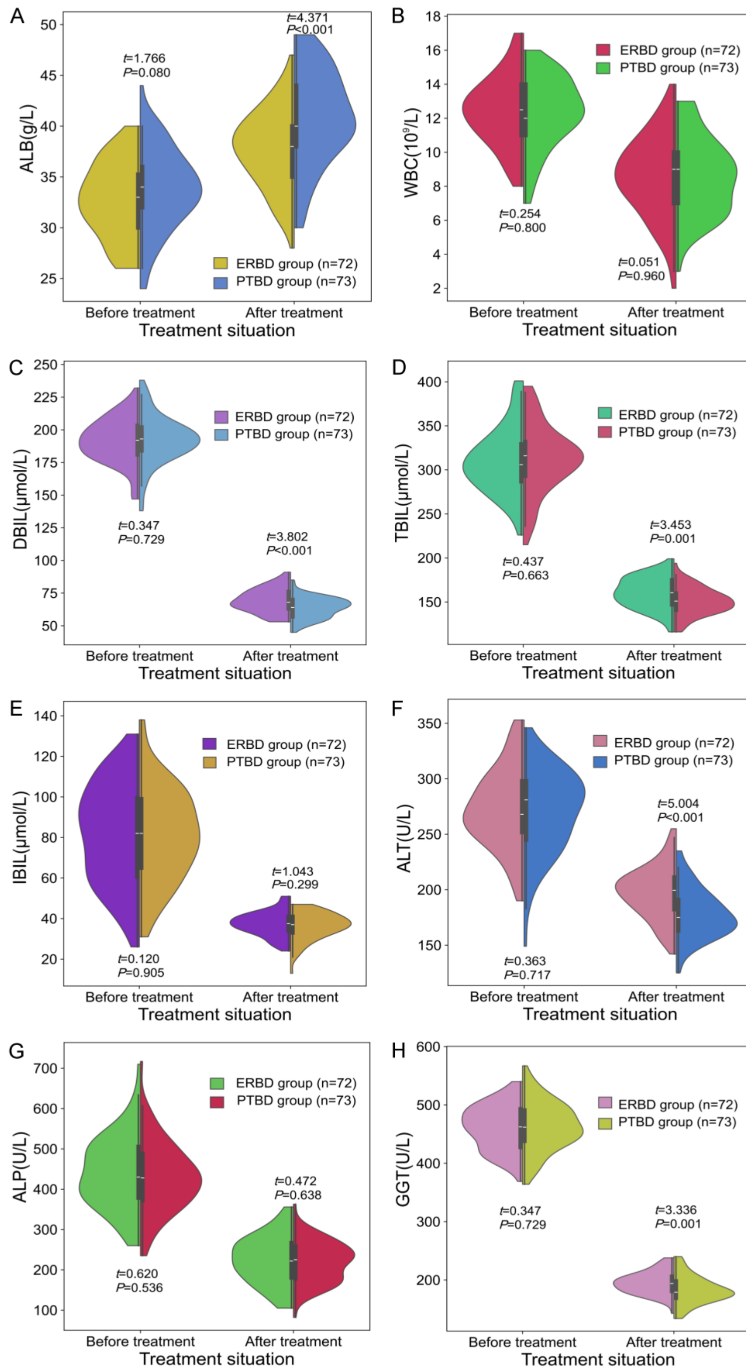

Figure 1. Comparison of serum indicators and liver function indicators. Notes: (A) ALB, (B) WBC, (C) DBIL, (D) TBIL, (E) IBIL, (F) ALT, (G) ALP, (H) GGT. ERBD: Endoscopic Retrograde Biliary Drainage; PTBD: Percutaneous Transhepatic Biliary Drainage; ALB: Albumin; WBC: White blood cell count; DBIL: Direct bilirubin; TBIL: Total bilirubin; IBIL: Indirect bilirubin; ALT: Alanine aminotransferase; ALP: Alkaline phosphatase; GGT: Glutamyl transpeptidase. All indicators were detected preoperatively and 2 weeks postoperatively; $P<0.05$ indicated a statistically significant difference in intergroup comparisons, and all statistical analyses were based on independent-samples t-test after normality and homogeneity of variance tests.

independent variables. History of pancreatitis, difficulty in intubation, Oddi sphincter dysfunction, and drainage method were included in the multivariate Firth logistic regression analysis as dichotomous variables, while the continuous variable BMI was included as raw values. The results of binary Firth logistic regression analysis showed that higher BMI, presence of Oddi sphincter dysfunction, and difficulty in intubation were independent risk factors for postoperative pancreatitis in patients with pancreatic cancer complicated by obstructive jaundice treated with PTBD, whereas external drainage (PTBD) was an independent protective factor (all P<0.05). Notably, history of pancreatitis was not statistically significant in the multivariate analysis (P>0.05), as shown in **Table 4**.

ROC curve diagnostic value analysis

ROC curve analysis was conducted to evaluate the predictive value of individual factors and the multivariate combined model for postoperative pancreatitis in the PTBD group. As shown in **Table 5**, BMI exhibited an AUC of 0.713 (95% confidence interval [CI]: 0.551-0.875, P=0.037) with an optimal cut-off value of 25.1 kg/m^2. For the categorical variables, difficult intubation, dysfunction of Oddi sphincter, and external drainage method showed AUC values of 0.681 (95% CI: 0.503-0.859, P=0.057), 0.665 (95% CI: 0.486-0.843, P=0.083), and 0.670 (95% CI: 0.500-0.840, P=0.074), respectively, with no optimal cut-off values available.

Table 2. Comparison of jaundice treatment outcomes [n (%)]

Variable	ERBD group (n=72)	PTBD group (n=73)	χ^2	P
Surgical success rate	67 (93.06)	69 (94.52)	0.134	0.715
Total effective rate	36 (50.00)	50 (68.49)	5.137	0.023
Markedly effective	18 (25.00)	30 (41.10)	-	-
Effective	18 (25.00)	20 (27.40)	-	-
Ineffective	36 (50.00)	23 (31.51)	-	-
Intraoperative bile drainage volume ≥300 ml	32 (44.44)	54 (73.97)	13.096	<0.001
Duration of jaundice regression ≤7 days	60 (83.33)	69 (94.52)	4.621	0.032

Note: ERBD: Endoscopic Retrograde Biliary Drainage; PTBD: Percutaneous Transhepatic Biliary Drainage; TBIL: Total bilirubin. ① Efficacy grading criteria: Markedly effective: TBIL decreased by >1/2 of the preoperative level 1 week after surgery; Effective: TBIL decreased by <1/2 of the preoperative level 1 week after surgery; Ineffective: TBIL remained almost unchanged or higher than the preoperative level 1 week after surgery; ② Total effective rate = (Markedly effective + Effective) cases/Total cases × 100%; ③ Data are presented as n (%).

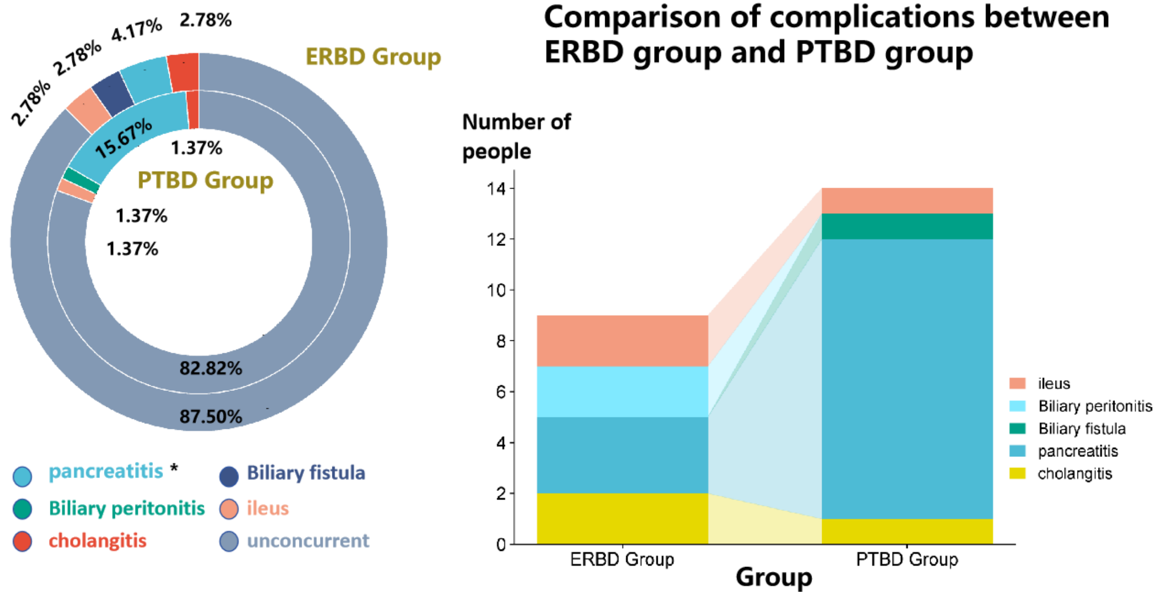

Figure 2. Comparison of complications after the two treatments. Note: ERBD: Endoscopic Retrograde Biliary Drainage; PTBD: Percutaneous Transhepatic Biliary Drainage. Comparison between the two groups of patients with cholangitis after treatment (χ^2=0.335, P=0.552); Pancreatitis was compared between groups (χ^2=4.939, P=0.026). Comparison between the groups complicated with biliary fistula (χ^2=0.993, P=0.319); Comparison of biliary peritonitis between groups (χ^2=2.056, P=0.152); The comparison between groups complicated with intestinal obstruction (χ^2=0.335, P=0.552); Total complications were compared between the two groups (χ^2=1.211, P=0.271). *indicates statistically significant difference between groups, *P<0.05.

The multivariate combined model achieved a significantly higher predictive performance with an AUC of 0.960 (95% CI: 0.918-1.000, P<0.001). At the optimal cut-off value of 0.038, the combined model presented a sensitivity of 0.730, a specificity of 0.778, and a Youden index of 0.508, which were all better than those of any single predictor, as shown in **Table 5** and **Figure 3**.

Discussion

Due to the latent early symptoms of obstructive jaundice, the disease is often more serious when clinically detected, and the general condition of patients is poor [17, 18], making it difficult to carry out radical surgery. The key point of clinical treatment is to improve the quality of life of patients, alleviate their symptoms, and

Table 3. Single factor analysis of postoperative pancreatitis ($\bar{x} \pm s$, [n (%)])

Group		Pancreatitis group (n=11)	Non-Pancreatitis group (n=62)	t/χ^2	P
Age (years)		60.55±10.37	61.23±9.90	0.209	0.835
Gender	Male	6 (54.54)	33 (53.23)	0.007	0.936
	Female	5 (45.45)	29 (46.77)		
BMI (kg/m^2)		26.45±3.11	23.94±3.22	2.391	0.019
Present with hypertension		3 (27.27)	15 (24.19)	0.040	0.827
Hyperglycemia		2 (18.18)	12 (19.35)	0.009	0.927
Tumor staging	Stage I	0 (0.00)	0 (0.00)	0.538	0.764
	Stage II	1 (9.10)	11 (17.74)		
	Stage III	4 (36.36)	19 (30.65)		
	Stage IV	6 (54.54)	32 (51.61)		
Preoperative Hb (g/L)		115.73±17.33	118.47±15.29	0.537	0.593
Preoperative WBC (10^9/L)		12.27±2.13	12.31±2.10	0.098	0.922
Preoperative ALP (U/L)		432.55±83.10	429.87±83.23	0.049	0.961
Preoperative DBIL (U/L)		191.73±18.43	191.55±18.94	0.098	0.922
Drainage mode	Internal drainage	8 (72.73)	24 (38.71)	4.391	0.036
	External drainage	3 (27.27)	38 (61.29)		
Oddi sphincter dysfunction	Yes	7 (63.64)	19 (30.65)	4.434	0.035
	No	4 (36.36)	43 (69.35)		
Difficulty in intubation	Yes	7 (63.64)	17 (27.42)	3.947	0.047
	No	4 (36.36)	45 (72.58)		
History of pancreatitis	Yes	10 (90.91)	35 (56.45)	4.691	0.030
	No	1 (9.09)	27 (43.55)		
Operation duration (min)		74.45±10.69	69.85±9.30	1.479	0.144

Note: BMI: body mass index; Hb: hemoglobin; WBC: white blood cell count; ALP: alkaline phosphatase; DBIL: direct bilirubin.

Table 4. Risk analysis of pancreatitis complication after PTBD surgery

Variable name	B	Standard error	Z	P	OR	OR (95% confidence interval)
Intercept	-15.741	5.720	-2.752	0.006	-	-
History of pancreatitis	1.288	1.188	1.084	0.278	3.626	[0.353, 37.217]
BMI	0.460	0.202	2.275	0.023	1.584	[1.066, 2.354]
Difficult intubation	3.008	1.397	2.153	0.031	20.249	[1.310, 313.094]
Disfunction of Oddi sphincter	3.279	1.239	2.647	0.008	26.557	[2.342, 301.097]
External drainage method	-2.749	1.211	-2.269	0.023	0.064	[0.060, 0.688]

Note: OR: odds ratio; CI: confidence interval; BMI: body mass index.

Table 5. Diagnostic value of risk factors for postoperative pancreatitis complications

Factors	Optimal cut-off	AUC	AUC 95% confidence interval	P	Sensitivity	Specificity	Youden index
BMI	25.1 kg/m^2	0.713	[0.551, 0.875]	0.037	0.636	0.774	0.411
Difficult intubation	-	0.681	[0.522, 0.840]	0.007	0.636	0.726	0.362
Disfunction of Oddi sphincter	-	0.665	[0.505, 0.825]	0.042	0.636	0.694	0.330
External drainage method	-	0.670	[0.519, 0.821]	0.004	0.727	0.613	0.340
	0.038	0.960	[0.918, 1.000]	<0.001	0.730	0.778	0.508

Note: AUC: area under the curve; CI: confidence interval; BMI: body mass index.

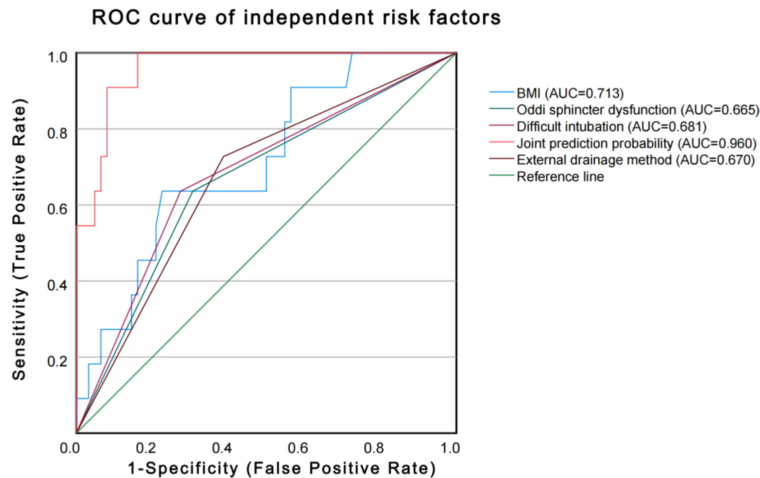

Figure 3. ROC curve of pancreatitis after diagnosis of PTBD by risk factors. Note: AUC: area under the curve; CI: confidence interval; BMI: body mass index.

prolong their survival time [19]. As a palliative treatment for obstructive jaundice, PTBD has a very high success rate, which can effectively open the narrow and obstructed bile duct, and enable bile to be directly drained outside the body to achieve full drainage, with rapid yellow reduction effect. PTBD can reduce bile duct pressure, reduce microvilli damage, restore bilirubin transporter function, relieve bile stasis damage to the liver, and improve the transformation function of liver cells. The yellowing effect is remarkable [20-22]. However, previous studies [23, 24] have reported that postoperative complications of PTBD can not only compromise therapeutic efficacy but also increase the risk of mortality in severe cases. Among them, pancreatitis is one of the more serious postoperative complications.

Our study results showed that the levels of WBC, DBIL, TBIL, IBIL, ALT, ALP, and GGT in both the ERBD and PTBD groups were significantly lower after treatment than those before treatment, indicating that both jaundice reduction methods can effectively decrease serum bilirubin levels and promote liver function recovery. Patients with obstructive jaundice generally have biliary stricture or even occlusion, which leads to abnormal elevation of bilirubin levels and subsequent liver dysfunction [25]. PTBD exhibited a more significant effect in reducing bilirubin and may have a lower risk of infection. Studies have shown [26] that PTBD drains stagnant bile out of the body through a catheter, which can effectively reduce serum bilirubin levels, decrease the incidence of endotoxemia, and lower the risk of fatal complications in patients with obstructive jaundice. The surface of the metal stent implanted during ERBD usually has no coating, which easily leads to tumor tissue embedding in the stent, causing jaundice; while the surface of the plastic stent has a coating, tumor tissue cannot embed in it, but the inner diameter of this stent is smaller and the drainage effect is poorer [27]. Ruan's research found that ERBD significantly increased the positive rate of bacterial culture in the bile duct compared with PTBD, with Enterobacter and Enterococcus being the main types [28]. ERBD causing tumor tissue to block part of the stent can lead to a decrease in bilirubin levels and a slower drainage rate in the later stage of drainage [29, 30]; while the PTBD method can continuously drain bile through the catheter to the outside, and the drainage effect is stable. Therefore, the clinical effect of PTBD is more advantageous, which can quickly relieve the biliary pressure, protect liver function, promote liver metabolism, improve liver blood oxygen supply, enhance digestive system function, and benefit patients significantly, improving their quality of life [31].

Previous studies have found [32] that compared with ERBD, PTBD has a more significant effect in relieving high-level obstructive jaundice, which is consistent with the results of this study. High-level obstruction is due to more severe blockage conditions. Under endoscopic assistance, a longer guide wire needs to be inserted, and it has many bends, with no effective foothold for the guide wire, greatly reducing its flexibility, making it difficult to reverse and pass through the obstructive site. Therefore, the therapeutic effect of the PTBD procedure is prominent. At the same time, patients with insufficient heart and lung function have difficulty in the prone position, which is not suitable for ERBD. In addition, PTBD is performed by puncturing the bile duct under ultrasound guidance through the skin. The operation is rela-

tively simple and can quickly expel the compressed bile through the drainage tube from the body to prevent the occurrence of obstructive jaundice of the biliary tract. However, in this study, the probability of pancreatic inflammation after PTBD was significantly higher than that after ERBD; the reason for this is that PTBD is a surgical treatment, and the intraoperative operation will cause damage to the pancreatic tissue structure, resulting in a higher risk of pancreatic inflammation after the operation. Therefore, identifying the independent risk factors for post-PTBD pancreatitis is crucial for early stratification of high-risk patients and the implementation of targeted preventive strategies.

The Firth regression analysis revealed a specific clinical profile associated with post-PTBD pancreatitis. External drainage was confirmed as a strong independent protective factor (OR=0.064). In contrast, elevated BMI, Oddi sphincter dysfunction, and difficult intubation were identified as significant independent risk factors. The quantitative data from our cohort provides a clear pathophysiological basis for these statistical associations.

Patients who developed pancreatitis had a significantly higher mean BMI of 26.45±3.11 kg/m^2 compared with those who did not, whose mean BMI was 23.94±3.22 kg/m^2. An ROC-derived cutoff value of 25.1 kg/m^2 further clarified this risk. This finding clinically supports the model in which obesity-related dyslipidemia induces a pro-inflammatory and pro-thrombotic state, and elevated free fatty acids cause direct endothelial injury and pancreatic enzyme activation to lower the threshold for procedural injury [33, 34]. Beran et al. [35] confirmed in a comprehensive meta-analysis that obesity (BMI ≥30 kg/m^2) independently predicts post-procedural pancreatitis, including both PTBD and ERCP cases, which validates the generalizability of metabolic-related risk across biliary drainage procedures. That said, Sbeit et al. [36] did not detect a significant association between BMI and pancreatitis risk. This lack of association may stem from three key factors: their study included a heterogeneous population mixing pancreatic and non-pancreatic etiologies of biliary obstruction, lacked a predefined BMI cutoff value, and featured a wide baseline BMI range, all of which likely diluted the specific correlation observed in pancreatic cancer-related obstruction. Mechanistically, Liu et al. [37] have also reported that dysregulated lipid metabolism impairs pancreatic microcirculation, which aligns with the pathophysiological pathway we proposed.

Oddi sphincter dysfunction was markedly more prevalent in the pancreatitis group (63.64% vs. 30.65%). Naing C, et al. [38] pointed out in the Cochrane systematic review that the incidence of pancreatitis after endoscopic sphincterotomy in patients was as high as 18%, which was consistent with the results of this study. This high incidence strongly implicates pre-existing sphincter abnormality as a key predisposing condition. The associated functional obstruction likely results in chronic pancreatic duct hypertension [39]. The PTBD procedure, involving guidewire manipulation and contrast injection, can then acutely exacerbate this baseline pressure, triggering parenchymal injury and inflammation.

The procedural risk is further underscored by difficult intubation, which was significantly more common in the pancreatitis group (63.64% vs. 27.42%). Repeated cannulation causes local trauma, edema, and sphincter spasm [40], increasing unintended pancreatic duct instrumentation and iatrogenic injury. Mechanistically, this papillary mechanical injury induces Oddi sphincter spasm and outflow obstruction, triggering pancreatic duct hypertension and inflammation [41]. Conversely, external drainage exerts a protective effect via sustained biliary decompression, mitigating bile reflux and pancreatic orifice compression [42] as a modifiable strategy. Compared with internal drainage, it significantly reduces post-procedural pancreatitis by avoiding pancreatic orifice compression and preventing reflux of infected bile or intestinal fluid. Song et al. [43] specifically recommended prioritizing percutaneous transhepatic external drainage for patients with biliary tract infections undergoing transampullary stenting to prevent pancreatitis.

It is worth noting that in this study, patients with pancreatic cancer had a history of pancreatitis with statistical significance in univariate analysis, but this factor was not an independent influencing factor in multivariate Firth regression analysis (P=0.278), thus it was not

included in the final risk factor assessment system. Considering the association between the history of pancreatitis and concurrent cholangitis, which may occur through inducing or accompanying other more direct pathological physiological changes; compared with patients without a history of pancreatitis, those with a previous history of pancreatitis suffered from repeated and frequent episodes of pancreatitis, resulting in pancreatic parenchymal damage, decreased pancreatic secretion function, and a significantly increased risk of postoperative pancreatitis.

Therefore, for patients with Oddi sphincter dysfunction, clinical placement of a pancreatic duct stent can reduce intrapancreatic duct pressure, prevent postoperative pancreatitis, and minimize the number of guidewire insertions to lower the risk of pancreatitis. Postoperatively, enhanced monitoring is necessary to promptly detect and manage pancreatitis. For high-risk patients, comprehensive preoperative evaluation should be performed to assess their specific conditions and surgical risks.

Conclusion

In summary, PTBD is an effective palliative treatment for obstructive jaundice in pancreatic cancer, yielding more significant improvements in liver function and faster jaundice resolution than ERBD. However, PTBD is associated with a significantly higher incidence of postoperative pancreatitis. High BMI (≥25.1 kg/m^2), Oddi sphincter dysfunction, and difficult intubation are independent risk factors for post-PTBD pancreatitis, while external drainage is an independent protective factor (OR=0.064, P=0.023). Clinically, close monitoring and comprehensive preoperative evaluation are recommended for high-risk patients, and external drainage should be prioritized for PTBD to reduce the risk of postoperative pancreatitis. This study was a single-center retrospective cohort study with a relatively small sample size; therefore, further multi-center, prospective studies with larger sample sizes are needed to validate the findings and optimize the predictive model. The multivariate combined predictive model constructed in this study (AUC=0.960) has excellent clinical predictive value for post-PTBD pancreatitis and can provide a quantitative basis for clinical risk stratification.

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Disclosure of conflict of interest

None.

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Table S1. Normality, homogeneity of variance tests and intergroup comparisons of continuous variables in this study

Study Module	Variable Name	Group Comparison	Sample Size per Group	Shapiro-Wilk Normality Test (*P*-value for each group)	Levene's Test for Homogeneity of Variance
Total study population (n=145)	Age (years)	ERBD group vs PTBD group	72/73	ERBD group =0.983; PTBD group =0.476	*F*=0.159, *P*=0.691
	BMI (kg/m^2)	ERBD group vs PTBD group	72/73	ERBD group =0.785; PTBD group =0.284	*F*=0.050, *P*=0.823
PTBD subgroup (n=73)	Age (years)	Pancreatitis group vs Non-Pancreatitis group	11/62	Pancreatitis group =0.351; Non-Pancreatitis group =0.283	*F*=0.000, *P*=0.995
	BMI (kg/m^2)	Pancreatitis group vs Non-Pancreatitis group	11/62	Pancreatitis group =0.855; Non-Pancreatitis group =0.708	*F*=0.113, *P*=0.737
	Preoperative Hb (g/L)	Pancreatitis group vs Non-Pancreatitis group	11/62	Pancreatitis group =0.131; Non-Pancreatitis group=0.175	*F*=1.070, *P*=0.304
	Preoperative WBC (10^9/L)	Pancreatitis group vs Non-Pancreatitis group	11/62	Pancreatitis group =0.586; Non-Pancreatitis group =0.895	*F*=0.000, *P*=0.987
	Preoperative ALP (U/L)	Pancreatitis group vs Non-Pancreatitis group	11/62	Pancreatitis group =0.547; Non-Pancreatitis group =0.828	*F*=0.296, *P*=0.588
	Preoperative DBIL (U/L)	Pancreatitis group vs Non-Pancreatitis group	11/62	Pancreatitis group =0.083; Non-Pancreatitis group =0.185	*F*=0.236, *P*=0.629
	Operation duration (min)	Pancreatitis group vs Non-Pancreatitis group	11/62	Pancreatitis group =0.484; Non-Pancreatitis group =0.887	*F*=0.024, *P*=0.877

Notes: ERBD: Endoscopic Retrograde Biliary Drainage; PTBD: Percutaneous Transhepatic Biliary Drainage; BMI: body mass index; Hb: hemoglobin; WBC: white blood cell count; ALP: alkaline phosphatase; DBIL: direct bilirubin. ① Group definitions: ERBD: Endoscopic Retrograde Biliary Drainage; PTBD: Percutaneous Transhepatic Biliary Drainage; Pancreatitis group: PTBD group with postoperative pancreatitis; Non-Pancreatitis group: PTBD group without postoperative pancreatitis; BMI: body mass index; Hb: hemoglobin; WBC: white blood cell count; ALP: alkaline phosphatase; DBIL: direct bilirubin. ② Normality was assessed by the Shapiro-Wilk test, with a *P*-value >0.05 indicating a normal distribution. ③ Homogeneity of variance was tested by Levene's test, with a *P*-value >0.05 indicating homogeneous variance. ④ Independent-samples *t*-test was used for intergroup comparison of continuous variables with normal distribution and homogeneous variance; a 2-tailed *P*-value <0.05 was considered to indicate a statistically significant difference. ⑤ All statistical analyses were performed using SPSS 26.0 software.