Original Article

Value of preoperative biliary drainage in pancreatic head cancer patients with severe obstructive jaundice: A multicenter retrospective study

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Abstract

Background: Pancreatic head cancer accompanied by obstructive jaundice is a common clinical situation. The aim of this study was to assess the impact of preoperative biliary drainage (PBD) on clinical outcomes in patients with severe obstructive jaundice.

Methods: Patients with a bilirubin level of ≥250 μmol/L at diagnosis who underwent PBD were included. The primary endpoints and secondary endpoints were the postoperative severe complications rates. Secondary endpoints were the degree of improvement in general condition, predictors of severe postoperative complications, and the impact of PBD on patients with bilirubin levels >300 μmol/L.

Results: In total, 289 patients were included, and 188 patients (65.1%) underwent PBD. The patients who met the American Society of Anesthesiologists (ASA) classification II–III stages decreased from 119 to 100 ($P = 0.047$) after PBD. The overall severe complications were significantly more frequent in the direct surgery (DS) group than in the PBD group (34.7% vs. 22.9%, $P = 0.031$), especially the postoperative hemorrhage (6/43 [14.0%] vs. 9/35 [25.7%], $P = 0.038$) and intra-abdominal infection (6/43 [14.0%] vs. 10/35 [28.6%], $P = 0.018$). The ASA classifications II–III (odds ratio [OR] = 2.89, 95% confidence interval [CI]: 1.38–4.31), $P = 0.01$) and DS (OR = 3.65, 95% CI: 1.45–7.08; $P = 0.003$) were independently associated with severe postoperative complications. The occurrence rate of severe postoperative complications in patients with a bilirubin level >300 μmol/L who underwent PBD was significantly lower than in patients who underwent DS (25.6% vs. 40.6%, $P = 0.028$), but the benefit of PBD was not observed in patients who had a bilirubin level between 250 and 300 μmol/L.

Conclusion: PBD is useful in reducing severe postoperative complications, especially in patients with bilirubin levels >300 μmol/L.

Keywords: Bilirubin level, postoperative complications, obstructive jaundice, pancreatic head cancer, preoperative biliary drainage

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INTRODUCTION

In the next 20 to 30 years, pancreatic cancer, which already has a high mortality rate, is expected to overtake lung cancer as the second biggest cause of cancer death in the USA.[1] The tumor's location in the pancreatic head is where it is discovered in over 75% of patients.[2] Surgical resection with pancreatoduodenectomy is the only way to achieve long-term survival. However, only 15–20% of patients are identified as surgery candidates at the time of diagnosis. Even in the surgery candidate patients, some of them have to postpone the surgery due to complications caused by the pancreatic head tumor. Obstructive jaundice is often the case.

Obstructive jaundice was associated with suboptimal liver function. Moreover, it was shown to be related to a pro-inflammatory condition with elevated levels of endotoxins and cytokines in the systemic circulation due to bacterial translocation.[3,4] Theoretically, complications and mortality may be reduced after preoperative biliary drainage (PBD). However, the benefits of PBD are controversial in clinical studies. In 2010, a multicenter, randomized trial study concluded that patients who underwent PBD had no advantage, but the rate of postoperative complications increased. In 2017, a meta-analysis with 6,214 patients showed that PBD does not improve the outcome of the patients.[5] As a result, guidelines[6,7] advise avoiding regular PBD in patients with pancreatic head cancer and obstructive jaundice, based on the findings mentioned above and other studies.[8-10]

However, in patients with symptoms of cholangitis or fever, severe symptomatic jaundice (intense pruritus), and delayed surgery, PBD is still recommended. The 200–250 μmol/L limit of bilirubin levels is frequently considered a preoperative drainage indication, but the evidence level is limited.[11] The results from previous studies were also not consistent.[9,12,13] Moreover, few studies have explored the role of PBD in patients with extremely high bilirubin levels (>300 μmol/L). Therefore, we conducted this retrospective study to further present the clinical outcomes and postoperative complications of pancreatic head cancer patients with severe obstructive jaundice who underwent PBD. Notably, the impact of PBD on patients with extremely high bilirubin levels was explored.

PATIENTS AND METHODS

Design and study population

We performed a retrospective, multicenter cohort study in three hospitals (one academic and two regional: Suzhou Hospital of Nanjing University School of Medicine, Shanghai Armed Police Force Hospital, and Rudong County People's Hospital). Between January 2010 and May 2021, all pancreatic head cancer patients who were eligible for curative surgery and had obstructive jaundice were included. The data on patients were obtained from the medical databases of two centers. The exclusion criteria were as follows: (1) recent biliary drainage before diagnosis; (2) PBD performed by percutaneous transhepatic cholangiography (PTC) instead of endoscopic retrograde cholangiopancreatography (ERCP); and (3) the medical records that were not fully obtained. The decisions for surgical resection were made in multidisciplinary oncology meetings. If the tumor was borderline resectable in accordance with the National Comprehensive Cancer Network (NCCN) standards, patients were eligible for curative resection. Pancreatoduodenectomy was performed by surgeons with experience in >200 cases. The study protocol was approved by the ethics committees of the two hospitals.

Data collections

The baseline characteristics, laboratory test results, PBD-related data, surgery-related data, and complications were collected.

Baseline variables such as Age, sex, American Society of Anesthesiologists (ASA) classification, clinical tumor, node, and metastasis (TNM) classification, white blood cell count (WBC), C-reaction protein (CRP), bilirubin level at diagnosis, alanine aminotransferase (ALT), prothrombin time (PT), creatinine, and comorbid disease (hypertension and diabetes mellitus), and laboratory test results were collected. Tumors were staged according to the eighth edition of the TNM cancer staging manual of the American Joint Committee on Cancer.[14] The following PBD-related data were obtained: bilirubin level before PBD, stent type, and PBD-related complications and mortality. According to the international consensus definition,[15] PBD consequences were categorized as mild, moderate, or severe.

The following surgery-related data were collected: timing of surgery in relation to date of diagnosis and date of PBD, duration of surgery, type of surgery (open or minimally invasive pancreaticoduodenectomy), estimated blood loss, bilirubin level before surgery, length of postoperative hospital stay days, and final histology data. Complications were measured before discharge. The complications with Clavien–Dindo classification grade ≥3 were considered severe.

Procedure of ERCP

All the ERCPs were performed by experienced endoscopists (>200 cases per year). To perform ERCP, patients were placed in the left lateral recumbency under conscious sedation with propofol. After endoscopic sphincterotomy, a catheter was placed, and a contrast agent (iodixanol) was injected into the bile duct to show the location and morphology of the bile duct. Then, a guidewire was advanced through the stricture under fluoroscopic guidance. A plastic or metal stent was placed to perform drainage.

Study endpoints

Patients were grouped according to their bilirubin level at diagnosis (<250 μmol/L and ≥250 μmol/L). On subgroup analysis, the impact of PBD on patients with bilirubin level >300 μmol/L was compared to patients with bilirubin levels ≥250 μmol/L but <300 μmol/L.

The primary endpoints were the postoperative severe complications rate. Secondary endpoints were the degree of improvement in general condition after PBD, predictors of severe postoperative complications, and the impact of PBD on patients with bilirubin levels >300 μmol/L.

Statistical analysis

Continuous variables with a normal distribution are represented by means and standard deviation (SD), while categorical variables are represented by numbers (%). Non-normally distributed variables are represented by the median and the interquartile range (IQR). Student's unpaired *t*-test for normally distributed continuous variables and the Mann–Whitney U-test for non-normally distributed variables were used to compare demographic data and imaging findings between the clinical significance and insignificance groups. For categorical data, we utilized the χ^2 test, and for cell counts less than 5, we used Fisher's exact test. The independent high-risk factors related to severe postoperative complications were calculated using univariate analysis and logistic regression analysis. A statistically significant *P* value of 0.05 was used. Using the Statistical Package for the Social Sciences (SPSS) 22.0 software, the data were examined (SPSS, Chicago, Illinois, USA).

RESULTS

Patient characteristics

From January 2010 to May 2021, a total of 668 patients with pathologically identified cancer of the pancreatic head and obstructive jaundice were included in this study. Among them, 353 patients had bilirubin levels >250 μmol/L. After exclusion criteria were applied, 289 patients were included in our study [Figure 1].

Among them, 188 patients (65.1%) underwent PBD, and were included in the PBD group. One hundred and one patients (34.9%) underwent DS, and were included in the DS group. Of all the study cohorts, 190 were male (65.7%), and the mean age was 63.1 ± 10.6 years. Median serum levels of total bilirubin were 308 (272–389) μmol/L. The other baseline characteristics and laboratory test results stratified by groups are presented in Table 1. After comparison between the two groups, no significant difference in variables was identified, which indicated that no obvious selection bias was observed.

Treatment efficacy of PBD

The mean elapsed time from diagnosis to PBD was 3.0 ± 1.2 days. Among the 188 patients who received

Table 1: Baseline characteristics and laboratory test results of the study cohort

	PBD (*n*=188)	DS (*n*=101)	*P*
Age, years	62.5±10.4	63.5±9.8	0.436
Sex (M: F)	122/66	68/33	0.678
Hypertension	75 (39.9)	35 (34.7)	0.382
Diabetes mellitus	43 (22.9)	32 (31.7)	0.103
ASA classification		0.232	
I	69 (36.7)	30 (29.7)	
II–III	119 (63.3)	71 (70.3)	
TNM staging		0.258	
Stage I	10 (5.3)	10 (9.9)	
Stage II	85 (45.2)	39 (38.6)	
Stage III	93 (49.5)	52 (51.5)	
White blood cell count	10.9^10⁹±2.6^10⁹	9.2^10⁹±2.1^10⁹	0.085
CRP, ng/ml	22.5 (15.0–30.0)	19.0 (14.0–24.0)	0.324
Total bilirubin level at diagnosis, μmol/L	326 (260–405)	305 (270–370)	0.171
Alanine aminotransferase, U/L	150 (62–265)	135 (50–240)	0.206
Prothrombin time, s	11.90±1.42	12.50±1.68	0.301
Creatinine, μmol/L	85 (68–118)	82 (67–115)	0.715

Data presented as *n* (%), mean ± standard deviation, or median (interquartile range), as appropriate. SD=Standard deviation, IQR=Interquartile range, ASA=American Society of Anesthesiologists, CRP=C-reaction protein

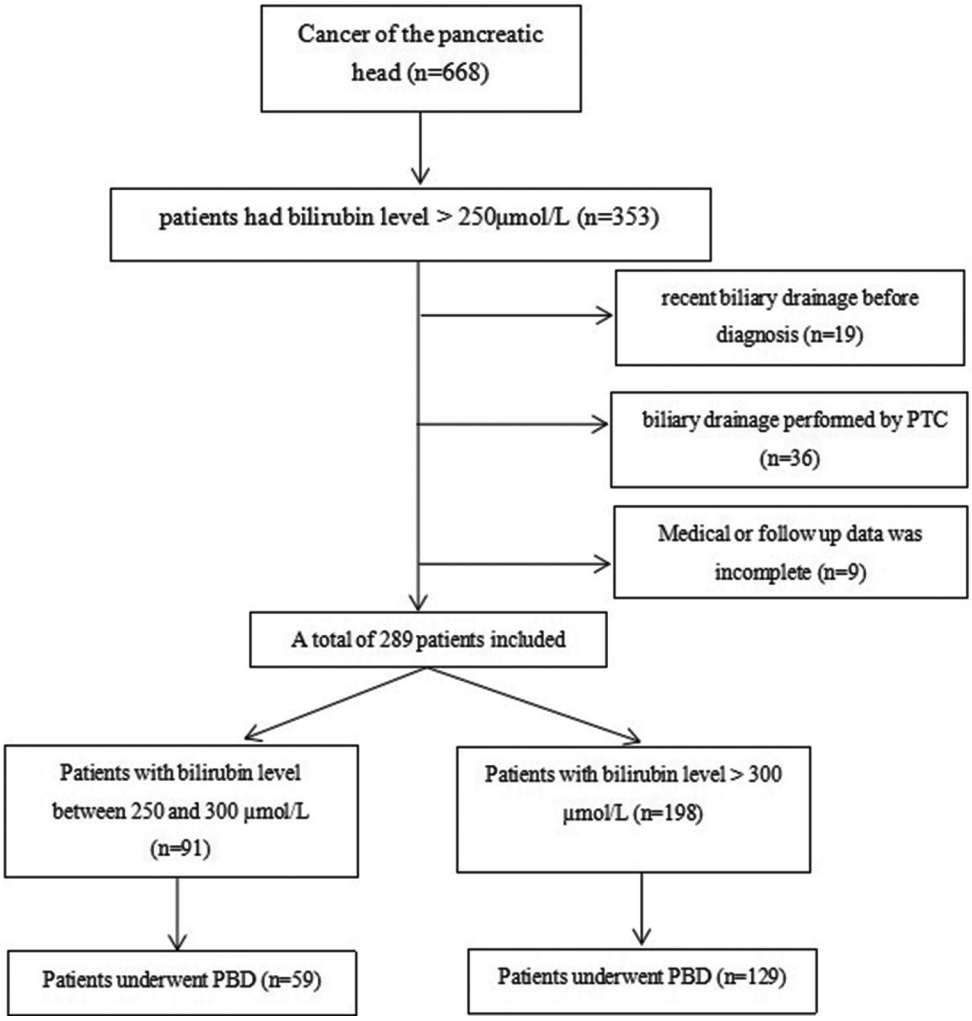


Figure 1: Patient inclusion flow chart

PBD, 76 (40.4%) underwent drainage using a plastic stent, 102 (54.3%) using a self-expandable metallic stent (SEMS), and 10 (5.3%) of them using covered metallic stents. Seventeen patients (9.0%) developed mild pancreatitis, and 11 patients (5.9%) developed post-ERCP infections. All of them recovered after proper treatments. No severe complications occurred within our study cohort.

The mean elapsed time from PBD to surgery was 21.2 ± 5.3 days. Before surgery, the mean WBC in the PBD group decreased from 10.9^10^9 to 9.0^10^9 ($P = 0.07$), the median CRP level decreased from 22.5 ng/ml to 13.3 ng/ml ($P = 0.02$), the median total bilirubin level decreased from 326 μmol/L to 133 μmol/L ($P < 0.001$), the median ALT decreased from 150 U/L to 68 U/L ($P = 0.01$), and the mean PTC decreased from 11.90s to 11.50s ($P = 0.75$). The number of patients who met the ASA classification II–III stages decreased from 119 to 100 ($P = 0.047$). The results indicated that the preoperative condition was significantly improved due to PBD [Table 2].

The surgery-related parameters and postoperative complications

Regarding intraoperative conditions, the mean operating time (285.6 ± 49.2 min *vs.* 298.2 ± 53.4 min, $P = 0.167$) and estimated median blood loss (350 (200–550) min *vs.* 300 (200–500) ml, $P = 0.268$) between the PBD and DS groups showed no statistical difference.

The overall postoperative complication occurred in 104 patients (55.3%) in the PBD group and in 59 patients (58.4%) in the DS group, and there was no statistical difference between the two groups ($P = 0.247$). However, the severe complications were significantly more frequent in the DS group than in the PBD group (34.7% vs. 22.9%, $P = 0.031$). Regarding specific severe complications, postoperative hemorrhage (6/43 [14.0%] vs. 9/35 [25.7%], $P = 0.038$) and intra-abdominal infection (6/43 [14.0%] vs. 10/35 [28.6%], $P = 0.018$) were more common in the DS group. Other complications, such as postoperative pancreatic fistula (POPF), biliary fistula, intestinal fistula,

Table 2: Treatment efficacy of PBD (*n*=188)

	Before PBD	Before surgery	*P*
White blood cell count	10.9 ^ 10⁹±2.6 ^ 10⁹	9.0 ^ 10⁹±1.8 ^ 10⁹	0.07
CRP, ng/ml	22.5 (15.0–30.0)	13.3 (6.5–19.5)	0.02
Total bilirubin level, μmol/L	326 (260–405)	133 (45–286)	<0.001
Alanine aminotransferase, U/L	150 (62–265)	68 (22–151)	0.01
Prothrombin time, s	11.90±1.42	11.50±1.36	0.75
ASA classification		0.047	
I	69 (36.7)	88 (46.8)	
II–III	119 (63.3)	100 (53.2)	

Data presented as *n* (%), mean ± standard deviation, or median (interquartile range), as appropriate. SD=Standard deviation, IQR=Interquartile range, ASA=American Society of Anesthesiologists, CRP=C-reaction protein

incision complication, delayed gastric emptying (DGE), organ complications, perioperative mortality, and postoperative hospital stay days, showed no significant difference between the two groups [Table 3]. Moreover, although the surgery was prolonged due to PBD, the R0 resection rate showed no difference between the two groups (93.1% vs. 91.1%, $P = 0.542$).

Risk factors for severe postoperative complications

Univariate and multivariate analyses were performed to find independent risk factors for severe postoperative complications [Table 4]. In the univariate analysis, history of diabetes, DS, and ASA classification II–III were significantly associated with the development of complications, and they were included in the multivariate analysis. In the multivariate logistic regression analysis, ASA classification II–III (odds ratio [OR] =2.89, 95% confidence interval [CI]: 1.38–4.31), $P = 0.01$) and DS (OR = 3.65, 95% CI: 1.45–7.08; $P = 0.003$) were independently associated with severe postoperative complications.

The impact of PBD on severe postoperative complications of patients with extremely high bilirubin level

In total, 198 patients with bilirubin levels >300 μmol/L were identified in our study. Among them, 129 (65.2%) underwent PBD.

Severe complications occurred in 61 (30.8%) cases with a bilirubin level >300 μmol/L, which was significantly higher than those who had a bilirubin level between 250 and 300 μmol/L (17/91, 18.7%, $P = 0.031$), which indicated that a high bilirubin level may be associated with poor surgery outcomes.

Of the 129 cases, 33 patients (25.6%) developed severe postoperative complications. The remaining 28 (40.6%) severe postoperative complications occurred in the 69 patients who underwent DS. The occurrence rate of severe postoperative complications in patients who underwent PBD was significantly lower than in patients who underwent DS ($P = 0.028$). However, the benefit of PBD in decreasing severe postoperative complications was not observed in patients with bilirubin levels between 250 and 300 μmol/L (PBD 9/59 [15.3%] vs. DS 8/32 [25.0%], $P = 0.255$) [Table 5].

DISCUSSION

In this multiple-center retrospective study, we analyzed the impact of PBD on pancreatic head cancer patients with severe obstructive jaundice. First, we identified that PBD can significantly improve the ASA classification conditions but does not affect the R0 resection rates. Second, we found that PBD may decrease the incidence rate of severe postoperative complications. However, patients with bilirubin levels >300 mol/L may benefit more from PBD. Third, we found that ASA classification II–III and DS were independently associated with severe postoperative complications. These results suggest that PBD before pancreaticoduodenectomy is appropriately indicated in severe obstructive jaundice patients, especially in patients with extremely high bilirubin levels. Our study is one of the rare papers that focuses on individuals with pancreatic

Table 3: Postoperative complications according to the PBD status

	PBD (*n*=188)	DS (*n*=101)	*P*
Overall complications, n (%)	104 (55.3)	59 (58.4)	0.247
Clavien–Dindo classification Grades I–II, *n* (%)	61 (32.4)	24 (23.7)	0.122
Clavien–Dindo classification Grade ≥III, *n* (%)	43 (22.9)	35 (34.7)	0.031
Postoperative hemorrhage, *n* (%)	6 (3.2)	9 (8.9)	0.038
Intra-abdominal infection, *n* (%)	6 (3.2)	10 (9.9)	0.018
Postoperative pancreatic fistula, *n* (%)	8 (4.3)	7 (6.9)	0.328
Biliary fistula, *n* (%)	7 (3.7)	5 (5.0)	0.618
Intestinal fistula, *n* (%)	1 (0.5)	1 (1.0)	1.000
Incision complication, *n* (%)	10 (5.3)	7 (6.9)	0.579
Delayed gastric emptying, *n* (%)	20 (10.6)	18 (17.8)	0.085
Organ complications*, *n* (%)	15 (8.0)	10 (9.9)	0.579
Perioperative mortality, *n* (%)	2 (1.1)	1 (1.0)	1.000
Postoperative hospital stay days, median (IQR)	18 (13–24)	17 (14–20)	0.512
R0 resection, *n* (%)	175 (93.1)	92 (91.1)	0.542

Only Clavien–Dindo classification Grade ≥III complication was recorded; IQR: interquartile range; *hepatic failure, renal failure, cardiovascular event, and pulmonary complications were considered as organ complications

Table 4: Univariate and multivariate analyses for predicting severe postoperative complications

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	*P*	OR (95% CI)	*P*
Age	1.01 (0.98–1.02)	0.356		
Sex M vs. F	1.46 (0.78–2.59)	0.287		
Hypertension, yes vs.no	1.39 (0.92–1.68)	0.118		
Diabetes mellitus, yes vs.no	2.05 (1.02–3.61)	0.037		
ASA classification, II–III vs. I	2.79 (1.35–4.22)	0.012		
TNM staging, I–II vs. III	1.49 (0.94–2.08)	0.112		
White blood cell count	1.03 (0.98–1.07)	0.106		
C-reaction protein	1.02 (0.95–1.10)	0.211		
Total bilirubin level at diagnosis	1.00 (0.99–1.01)	0.564		
Alanine aminotransferase	1.01 (0.98–1.04)	0.689		
Prothrombin time	1.00 (0.99–1.00)	0.886		
Surgery type open vs. minimally	1.49 (0.96–2.14)	0.103		
Operating duration <290 vs. >290 min	0.72 (0.39–1.26)	0.309		
Intraoperative blood loss <320 vs. >320 ml	1.78 (0.98–3.18)	0.071		
DS vs. PBD	3.09 (1.31–6.68)	0.007	3.65 (1.45–7.08)	0.003

ASA=American Society of Anesthesiologists

head cancer who have significant obstructive jaundice. Our study may help gain knowledge about pancreatic head cancer patients with severe obstructive jaundice.

Obstructive jaundice is one of the most common symptoms of pancreatic head cancer and may lead to pruritus, pale stools, and dark urine. Severe obstructive jaundice may cause necrosis of liver cells and even hepatic failure.[16] Several animal tests have revealed the presence of elevated amounts of pro-inflammatory cytokines and endotoxins related to obstructive jaundice.[3,4] Moreover, obstructive jaundice also impairs the function of the intestinal mucosal barrier, which not only promotes bacterial translocation but also increases intestinal permeability.[17] Furthermore, the return of bile to the gastrointestinal system can correct this deterioration of intestinal barrier function.[18] However, the theoretical benefit of PBD was not identified by previous studies.

Bolm *et al*.[19] observed that preoperative biliary stenting significantly enhanced the surgical complication risk in patients with high bilirubin levels (>255 μmol/L). The study by Arkadopoulos *et al*.[20] focused especially on patients with high bilirubin levels (>255 μmol/L) at the time of surgery and discovered a considerably reduced postoperative complication rate in the DS group compared with the PBD group. Another study by van Gils *et al*.[9] found that PBD technical success and complications, including severe postoperative complications, did not differ between patients with a bilirubin level >250 and <250. They concluded that severe bilirubin level should not be recognized as an indicator of PBD. On the contrary, Shen *et al*.[12] conducted a retrospective study with 200 patients. The overall postoperative complications were lower in the PBD group compared with the DS group. They concluded that PBD should be routinely performed in patients with bilirubin levels >250 μmol/L. However, nearly half of the patients in their study underwent PTC instead of ERCP. Our study first reported the impact of PBD on patients with bilirubin levels >300 μmol/L. The indication for PBD may have changed according to our study; however, further prospective studies with large sample size are needed to verify our findings.

The high postoperative complication rate reported by previous studies may be due to the high incidence of PBD-related complications. In a large clinical randomized controlled trial by van der Gaag *et al*.,[21] the reported PBD-related rate was as high as 46%. Only plastic stents were used in their trial. The PBD-related complications in the study by Gils were about 30%. In our study, about 15% of patients developed post-PBD complications, and no severe

Table 5: Occurrence rate of severe postoperative complications based on bilirubin level

	Bilirubin level >300 μmol/L (*n*=198)		Bilirubin level between 250 and 300 μmol/L (*n*=91)	
	PBD (*n*=129)	DS (*n*=69)	PBD (*n*=59)	DS (*n*=32)
Overall complications, *n* (%)	71 (55.0)	38 (55.0)	34 (57.6)	20 (62.5)
Clavien–Dindo classification Grades I–II, *n* (%)	38 (28.5)	10 (14.5)	25 (42.4)	12 (37.5)
Clavien–Dindo classification Grade ≥III, *n* (%)	33 (25.6)	28 (40.6)	9 (15.3)	8 (25.0)
*P**	0.028		0.255	

DS=Direct surgery, PBD=Preoperative biliary drainage.* comparison results of Clavien–Dindo classification grade ≥III complications in different groups based on bilirubin levels

complications were observed. The possible reasons were as follows: (1) The endoscopists were rich in experience, and our two centers were all high-volume centers. Endoscopists who are qualified to perform PBD have experience with more than 300 cases per year. (2) Almost all the patients in our two centers underwent PBD with ERCP, which was in accordance with guidelines.[22] (3) Most patients received PBD from SEMS. The reported migration rate and subsequent complications were lower than for other types of stents, and the stent patency was higher for SEMS.[23,24] The fewer PBD-related complications did not significantly prolong the timing of surgery. As a result, the severe postoperative complication rates may have been reduced.[25]

Studies to evaluate severe postoperative complications are rare. Although not statistically significant, there was a trend toward fewer complications in the bilirubin >250 μmol/L group (16% and 35%; $P = 0.06$) in the study by van Gils *et al*.[9] We believe that analyzing the severe complications may be more clinically significant because severe complications are life-threatening. The mild and moderate complications can be treated properly.

As jaundice is already a documented independent risk factor for postoperative death, it stands to reason that patients with severe obstructive jaundice may be in worse condition than those with milder cases (e.g., anorexia or delayed care seeking). Our study identified that PBD can significantly improve the liver function of severe obstructive jaundice patients, and the ASA classification also improved. To our knowledge, our study is the first to analyze the treatment efficacy of PBD in detail. The results may depend on the theoretical basis of PBD.

Our study obviously has significant limitations. First, due to the retrospective design, there was clearly a selection bias and inadequate information. The indication of PBD, as well as other facts about past medical history, was particularly lacking. Second, all the patients in this study received internal biliary drainage with ERCP; the effect of PTC was not analyzed in our study. Third, despite the fact that the median bilirubin value significantly decreased in the PBD group, a percentage of patients still had elevated bilirubin levels before surgery. We may assume that if the patients obtained full biliary drainage, the complication rate would be even lower. However, some of these patients may fail to receive surgery owing to tumor progression. Fourth, the optimal cutoff level of bilirubin to perform PBD was not analyzed in our study due to the limited number of cases.

In conclusion, we have demonstrated that PBD significantly improved the ASA classification conditions and did not affect the R0 resection rates. PBD can reduce the rates of severe postoperative complications, especially in patients with bilirubin levels >300 μmol/L. We also identified that ASA classification II–III and DS were independently associated with severe postoperative complications. Further prospective randomized trials are required to properly analyze and verify the influence of PBD on postoperative outcomes.

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Conflicts of interest

There are no conflicts of interest.

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