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Bridge of preoperative biliary drainage is a useful management for patients undergoing pancreaticoduodenectomy

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ABSTRACT

Background/Objectives: The aims of this study were to clarify the effect of preoperative biliary drainage (PBD) on postoperative outcomes and the role of preoperative intentional exchange from endoscopic nasobiliary drainage (ENBD) to endoscopic retrograde biliary drainage (ERBD) for patients waiting to undergo pancreaticoduodenectomy (PD).
Methods: We evaluated the effect of PBD and intentional exchange of PBD on the perioperative variables in 292 patients.
Results: A total of 179 (61.3%) of 292 patients received PBD. There was no marked difference in the postoperative outcomes between the patients who did and did not receive PBD. Among the 160 patients who initially received endoscopic PBD, 10 (6.3%) underwent stent exchange for stent dysfunction, 59 (36.9%) who did not develop stent dysfunction underwent intentional stent exchange from ENBD to ERBD (bridge PBD group), and 91 (56.9%) did not receive any stent exchange (unchanged PBD group). The bridge PBD group had a longer duration of PBD (37 days) ($p < 0.001$) and a shorter preoperative hospital stay after PBD (32 days) ($p < 0.001$) than the unchanged PBD group (25 and 46 days, respectively); however, there were no significant differences in the postoperative variables. The incidence of stent exchange due to stent dysfunction in the bridge PBD group (11.9%) was lower than that in patients who initially received ERBD (36.0%) ($p = 0.015$).
Conclusions: Bridge PBD worked well for extending the duration of PBD without worsening the postoperative outcomes after PD.

Introduction

Preoperative biliary drainage (PBD) has been generally considered for jaundiced patients, because PBD can relieve the biliary obstruction and associated cholangitis and optimize patients' physical status. Indeed, PBD is indispensable as a "bridge therapy" for patients waiting to undergo pancreaticoduodenectomy (PD), and a high rate of PBD in patients undergoing PD has been shown in most recent reports [1–6], although PBD requires the additional performance of endoscopic retrograde cholangiography, which is potentially invasive and associated with several complications [7]. Though, recent large retrospective studies [3,4] and a meta-analysis [5] reported that PBD increased the rate of postoperative complications after PD. A randomized controlled trial by van der Gaag et al. also revealed that routine PBD in patients undergoing surgery increased the rate of complications, but a significant proportion of complications were related to the PBD procedure itself and pancreatic resection was only performed in 120 (59.4%) cases in 202 enrolled patients [7]. Conversely, contemporary retrospective studies reported that PBD did not affect the overall rate of postoperative complications or mortality of patients undergoing PD [6,8–10]. Thus, the role of PBD for PD has not been clear.

One possible reason for these discrepancies in the effect of PBD on postoperative outcomes after PD might be the different managements of PBD that are applied in each institute. Though only a few reports describe the detailed management of PBD, such as duration of PBD and the frequencies of stent exchange [5,9,10,13,14,18]. In some studies, the frequencies of stent exchange ranged from 9.1% to 36.1% [9,13,14]. In clinical practice, there are three types of PBD: endoscopic nasobiliary drainage (ENBD), endoscopic retrograde biliary stenting (ERBD), and percutaneous

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transhepatic biliary drainage (PTBD). Among these, it was reported that patients who received ERBD more frequently developed biliary drainage dysfunction, bacterobilia, and preoperative cholangitis in comparison to patients who received ENBD and PTBD [11], and it was suggested to increase the risk of postoperative complications [12–17]. In contrast, ERBD has a significant benefit in restoring the entero-hepatic circulation and provides relief from the discomfort of an external drainage tube [13,14]. These benefits of ERBD can lead to a temporary discharge of a patient and the shortening of the preoperative hospital stay.

Stent exchange in PBD is generally performed in cases of stent dysfunction. However, based on clinical demands for temporary discharge of patients and in an effort to shorten the preoperative hospital stay, we sometimes perform intentional stent exchange from ENBD to ERBD for patients who do not develop stent dysfunction, which we have termed “bridge PBD”. In this retrospective study, we analyzed the effect of bridge PBD on the duration of PBD and preoperative hospital stay as well as on the postoperative outcomes, as these have never been evaluated before. The present study sought to clarify the effect of PBD on the postoperative outcomes and to assess the utility of bridge PBD for the preoperative management of patients who wait a long time to undergo PD.

Materials and methods

Patients

This study was reviewed and approved by the Institutional Review Board of Jichi Medical University [S17-62]. Before surgery, we communicated fully with the patients and their families and explained the advantages of surgery and possible complications, and written informed consent was obtained from all patients according to our institutional guidelines. A total of 343 consecutive patients undergoing PD in our hospital between 2006 and 2016 were considered for the study. Forty-eight patients who underwent combined resection of other organs and 3 patients who underwent urgent PD were excluded. Thus, a total of 292 patients were analyzed in this study. The indications for PD are shown in Table 1.

Management of PBD and the perioperative course

The majority of patients who were being treated in association with jaundice and obstruction of biliary tract were referred for surgery with PBD after undergoing diagnostic endoscopic retrograde cholangiography at our institution or outside our institution. The method of endoscopic PBD was decided by the endoscopists. Plastic stents were used for ERBD. Only one patient received a metallic stent instead of a plastic one for stent exchange after initial ERBD. When endoscopic PBD was unsuccessful, PTBD was performed under ultrasonic guidance. When preoperative cholangitis due to stent dysfunction occurred, patients were initially treated with appropriate antibiotics, and if this was not effective, stent exchange was performed. After the preoperative evaluation was completed and jaundice had been improved, the patients who received ERBD were discharged temporarily and waited to undergo their operation at home, while those who received ENBD and PTBD waited for their operation while hospitalized due to the difficulty of their management. However, when the time to surgery after the completion of the preoperative evaluation exceeded two weeks, the patients with ENBD who did not develop stent dysfunction underwent exchange of ENBD to ERBD and were also discharged temporarily. We termed this exchange of ENBD to ERBD as “bridge PBD” for PD with the intent of reducing the preoperative hospitalization duration. Conventional PD or subtotal stomach-preserving PD were performed. Cephalosporin was prophylactically administered for 3 days, and antibiotics were administered as necessary to treat postoperative infectious conditions. During this period, a team specializing in hepato-biliary-pancreatic surgery performed PD procedures and provided postoperative care [19–23]. Therefore, the backgrounds of PD in this period including the patient selection, were homogeneous, hopefully limiting any bias in the postoperative outcomes. The details regarding surgical procedures and postoperative patient care, and the criterion for discharge have been described previously [19–23].

Table 1
The pathological characteristics of the whole study population (n = 292).

Variables	
Pancreatic cancer	106 (36.3%)
Bile duct cancer	76 (26.0%)
Intraductal papillary mucinous neoplasm	41 (14.0%)
Cancer of the ampulla of Vater	36 (11.3%)
Duodenal cancer	12 (4.1%)
Neuroendocrine tumor	6 (2.1%)
Solid and pseudopapillary tumor	4 (1.4%)
Chronic pancreatitis	4 (1.4%)
Metastatic cancer	3 (1.0%)
Duodenal gastrointestinal stromal tumor	1 (0.3%)
Pancreatic invasion of gastric cancer	1 (0.3%)
Cholangitis	1 (0.3%)
Autoimmune pancreatitis	1 (0.3%)

Clinical parameters

The preoperative and postoperative data were collected by a review of the patients’ medical records. The preoperative variables included gender, age, body mass index (BMI), the pathological diagnosis, serum albumin content, total bilirubin at the time of surgery, presence and type of PBD, and general comorbidities including hypertension, coronary artery disease, cerebral artery disease, diabetes mellitus, and chronic kidney disease. Intraoperatively, the operator judged the texture of the pancreatic parenchyma to be soft or hard, and main pancreatic duct (MPD) dilatation was deemed to be absent when the size of the main pancreatic duct was <3 mm; these variables were also included in the intraoperative variables. The intraoperative variables also included operative time, estimated blood loss, the need for blood transfusion, and portal vein or superior mesenteric vein resection.

Definitions

Severe PBD-related complications included stent dysfunction and dislocation, perforation of intestine, and bleeding. Stent dysfunction was defined as recurrent obstructive jaundice and cholangitis necessitating stent exchange. Cholangitis was determined according to the definition and classifications in the 2013 Tokyo guidelines (TG13) [24]. Overall morbidity was defined as any complication. Intraabdominal abscess was defined as intra-abdominal fluid collection with a positive culture or organ/space surgical site infection in the abdominal cavity [25]. The presence of postoperative pancreatic fistula (POPF) was determined according to the updated International Study Group of Pancreatic Surgery criteria [26], and Grade B and C POPF were designated as clinically relevant (CR)-POPF. The duration of PBD was calculated from the day of the initial placement of the PBD to the day of the operation. The duration of ERBD was calculated from the day of the placement of the ERBD to the day of the operation or stent exchange due to its dysfunction. The duration of preoperative hospital stay was calculated from the day of the initial placement of the PBD to the day of the operation or the day of temporary hospital discharge to home

to wait for surgery. The duration of the postoperative hospital stay was calculated from the day of the operation to the day of hospital discharge. Perioperative death was defined as any death occurring in the hospital or within 30 days after the operation.

Statistical analyses

Categorical variables were reported as the number and percentage. Continuous variables were reported as the median and range. Categorical variables were compared using a chi-squared test or Fisher's exact test, as appropriate. Continuous variables were compared using Student's *t*-test or Wilcoxon's rank-sum test. P values of <0.05 were considered to indicate statistical significance. All statistical analyses were conducted using the EZR software program [27].

Results

Management of PBD

Among 292 patients, a total of 179 (61.3%) patients received PBD and were assigned to the PBD group and 113 (38.7%) patients who did not receive PBD were assigned to the non-PBD group. A total of 259 PBD procedures (ENBD, n = 153; ERBD, n = 87; PTBD, n = 19) were preoperatively performed for 179 patients in the PBD group. Furthermore, 109 (60.9%) patients received only 1 PBD procedure, 60 (33.5%) received PBD procedures twice, and 10 (5.6%) received PBD procedures ≥3 times. The median of duration of PBD was 30 days (7–437 days). In this series, no patients received neoadjuvant therapy before PD, and the pathology of the patient who had received PBD for 437 days was refractory cholangitis due to intrapancreatic bile duct stricture. The complications related to the PBD, and types of PBD in which they occurred, were as follows: stent dysfunction (n = 15; 8.4% [ERBD, n = 11; ENBD, n = 3; PTBD, n = 1]), stent dislocation (n = 7; 3.9% [ERBD, n = 1; ENBD, n = 3; PTBD, n = 3]), cholecystitis (n = 3; 1.7% [ERBD, n = 1; ENBD, n = 2]), and bleeding (n = 2; 1.1% [PTBD, n = 2]). Thus, complications related to PBD occurred in 27 (15.1%) of 179 patients and 27 (10.4%) of 259 procedures. Eighteen (66.7%) of 27 cases in which complications related to PBD developed required further stent exchanges, but conservative treatment or only observation was applied in the other 9 cases. There were no cases of associated mortality.

In the PBD group, 19 (10.6%) of 179 patients received PTBD, and 160 (89.4%) patients initially received endoscopic PBD; these included 135 patients who received ENBD and 25 who received ERBD. Fig. 1 shows the flow of endoscopic PBD management. A total of 69 (43.1%) of 160 patients who received endoscopic PBD underwent stent exchange after initial PBD. Nine (36.0%) of the 25 patients who had initially received ERBD and 1 (1.7%) of the 135 patients who had initially received ENBD underwent stent exchange due to stent dysfunction or other complications related to PBD; therefore, 10 (6.2%) of 160 patients who received endoscopic PBD underwent initial stent exchange due to stent dysfunction or other complications related to the PBD. Fifty-nine (43.7%) of the 135 patients who had initially received ENBD and did not develop stent dysfunction were converted to ERBD for temporary discharge (bridge PBD group). Conversely, 91 (56.9%) of the 160 patients in the PBD group did not receive any stent exchange (unchanged PBD group).

Overall postoperative short-term morbidity and mortality

With regard to the short-term outcomes, the overall postoperative morbidity and mortality rates were 46.6% and 1.0%, respectively. Eighty-eight (30.1%) of the 292 patients developed intraabdominal abscess, while 51 (17.5%) developed CR-POPF. The duration of postoperative hospital stay was 24 days.

PBD and the perioperative variables

The demographics and perioperative variables of the PBD and non-PBD groups are compared in Table 2. Preoperatively, the PBD group had a male predominance (69.3%) (p = 0.002), low BMI (20.8 kg/m^2) (p = 0.007), a high incidence of pancreatic cancer (41.9%) (p = 0.013), low serum albumin (3.7 g/dl) (p < 0.001), high total bilirubin at the time of surgery (1.1 mg/dl) (p < 0.001), preoperative cholangitis (20.1%) (p < 0.001), and high CRP (0.16 mg/dl) (p = 0.002) in comparison to the non-PBD group; in contrast, the values in the non-PBD group were 52.2%, 21.9 kg/m^2, 27.4%, 4.1 g/dl, 0.5 g/dl, 0%, and 0.1 mg/dl, respectively. All patients with preoperative cholangitis were included in the PBD group. Intraoperatively, the PBD group had a long operation time (428 min) (p = 0.007) and a high estimated blood loss (750 g) (p < 0.001) in comparison to the non-PBD group (404 min and 580g, respectively). There were no significant differences in the postoperative variables.

The demographics and perioperative variables of the bridge PBD and unchanged PBD groups are compared in Table 3. Preoperatively, the bridge PBD group had a higher incidence of preoperative cholangitis (30.5%) (p = 0.003), longer duration of PBD (37 days) (p < 0.001), and shorter preoperative hospital stay from PBD (32 days) (p < 0.001) than the unchanged PBD group (11.0%, 25 days, and 46 days, respectively). With regard to the intraoperative and postoperative variables, there were no significant differences.

Comparisons of ERBD in the bridge PBD group and initial ERBD

The duration and incidence of stent exchange due to stent dysfunction among patients who initially received ERBD and those who received ERBD as bridge PBD were compared in Table 4. There was no marked difference in the duration of ERBD between the 2 groups; however, the incidence of stent exchange due to stent dysfunction in the bridge PBD group (11.9%) was lower than that in patients who initially received ERBD (36.0%) (p = 0.015).

Discussion

The PBD group had a long operation time and a high level of estimated blood loss in comparison to the non-PBD group; this was in line with previous reports [5,9]. In contrast to these intraoperative results, there were no significant differences in the postoperative variables. There is no high-quality evidence to support the indication of PBD for jaundiced patients undergoing PD or an optimal cut-off value of preoperative bilirubin that predicted a high incidence of postoperative complications after PD [1,5]. Most recently, two large retrospective studies that analyzed the 1500 and 1200 cases of PD, revealed that patients with a preoperative bilirubin value of >7.5 mg/dl showed a higher incidence of postoperative complications [3,28]. In our series, in the PBD group, the median value of preoperative total bilirubin at the time of surgery after PBD treatment was 1.1 mg, and only one of the 179 (0.1%) cases showed a level of >7.5 mg/dl, respectively. Thus, jaundice was considered to have been treated well in the PBD group. Jaundice was also well treated in previous reports showing that PBD did not affect the overall rate of postoperative complications [6,8–10]. Some reports demonstrated that PBD itself was not correlated with a high incidence of postoperative complications, but preoperative cholangitis was significantly correlated with them [12,13]. The incidence of preoperative cholangitis in the PBD group was 20.1%, which was in line with previous reports [2–14,16]. Recently, Kaneko et al. revealed a preoperative bilirubin value of >2.9 mg/dl

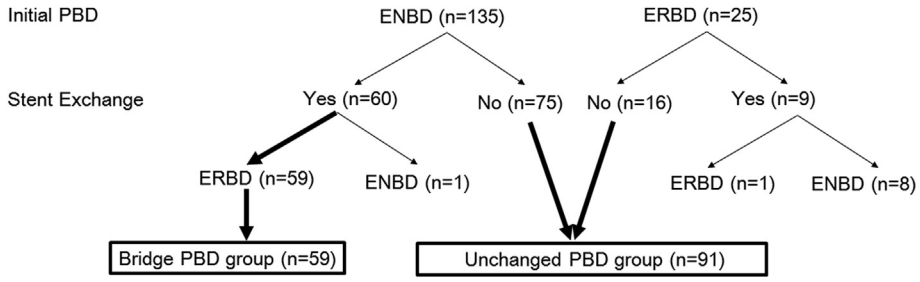

Fig. 1. The management flow of endoscopic preoperative biliary drainage (PBD) for pancreaticoduodenectomy. Exchange from ENBD to ERBD was performed for patients without stent dysfunction as "bridge PBD".

Table 2
The demographic characteristics and clinical outcomes of the PBD and non-PBD groups.

	PBD group (n = 179)	non-PBD group (n = 113)	*p* value
Preoperative variable			
Gender, male	125 (69.3%)	59 (52.2%)	0.002
Age	69 (29-85)	68 (24-90)	0.343
BMI (kg/m^2)	20.8 (14.0-31.1)	21.9 (14.6-35.2)	0.007
Disease, pancreatic cancer	75 (41.9%)	31 (27.4%)	0.013
Albumin (g/dl)	3.7 (1.7-4.5)	4.1 (1.8-5.0)	<0.001
Bilirubin at the time of surgery (mg/dl)	1.1 (0.21-10.9)	0.5 (0.13-1.63)	<0.001
Preoperative comorbidities, present	103 (57.5%)	65 (57.5%)	0.997
Preoperative cholangitis, present	36 (20.1%)	0 (0%)	<0.001
WBC (/μl)	5770 (2730-19540)	5410 (2790-13370)	0.357
CRP (mg/dl)	0.16 (0.01-17.7)	0.1 (0.01-5.01)	0.002
Intraoperative variables			
Soft pancreatic parenchyma	105 (58.7%)	68 (60.2%)	0.56
Pancreatic duct dilatation, present	91 (50.8%)	64 (56.6%)	0.333
Operative time (min)	428 (234-687)	404 (214-702)	0.007
Estimated blood loss (g)	750 (180-3850)	580 (100-2656)	<0.001
Blood transfusion, present	26 (14.5%)	11 (9.7%)	0.231
Portal vein or SMV resection, present	36 (20.1%)	18 (15.9%)	0.222
Postoperative variables			
All morbidity	81 (45.6%)	55 (48.7%)	0.568
Intraabdominal abscess	50 (27.9%)	38 (33.6%)	0.302
CR-POPF	29 (16.2%)	22 (19.5%)	0.474
Mortality	2 (1.1%)	1 (0.9%)	0.848
Postoperative hospital stay (days)	24 (14-93)	25 (11-180)	0.249

was a risk factor for preoperative cholangitis in patients who received PBD [12], and only 19 (10.6%) of the 179 cases in the PBD group had a preoperative bilirubin value of >2.9 mg/dl. Regarding inflammatory signs, the CRP level at the time of surgery in the PBD group was significantly higher than that in the non-PBD group; however, it was still within the normal range. The WBC counts at the time of surgery were within the normal range and did not differ to a statistically significant extent. Thus, it is considered that preoperative cholangitis was also treated well, and that it did not affect the incidence of postoperative complications. Accordingly, there was no significant difference in the postoperative variables.

The analyses of the correlation between the type of PBD and the postoperative outcomes after PD were complex, because stent exchange with a change in the type of PBD was performed frequently for the treatment of PBD-related complications, as described in previous reports [5,9,10,14,18], and for preoperative temporary discharge in this series. ERBD was associated with higher rates of stent dysfunction (which require stent exchange) than ENBD and PTBD [11]. Indeed, in the PBD group, 9 (90.0%) of 10 patients who experienced stent dysfunction after initial PBD were patients who received ERBD. However, ERBD has the advantage of relieving the patient from the discomfort of an external drainage tube and prevents the external loss of fluid and electrolytes [13,14]. Indeed, some cases in the PBD group required stent exchange from ENBD to ERBD due to acute renal dysfunction caused by massive external loss of fluid and electrolytes in bile juice. In addition, ENBD and PTBD are associated with a risk of dislocation as the drainage tube may accidently be pulled out [13,14]. Thus, patients who received ENBD or PTBD were not suitable for temporary preoperative discharge to await surgery at home. In this series, 59 (43.7%) of 135 patients who initially received ENBD or PTBD underwent bridge PBD for temporary preoperative discharge. And we found that there were no significant differences in the postoperative variables of the bridge PBD and unchanged PBD groups. Furthermore, preoperative hospital stay of the bridge PBD group was significantly shorter in comparison to unchanged PBD group. Thus, bridge PBD might lead to shortening the preoperative hospital stay without a worsening of postoperative outcomes after PD.

Few studies have evaluated the correlation between the duration of PBD and postoperative complications after PD. Clinically, the accepted timing from PBD to surgery is between 4 and 6 weeks [1,3,5,7]. The median duration of PBD in this series was 30 days, and this was in line with these previous reports. However, Kaneko et al. showed that PBD for ≥29 days was a risk factor for preoperative cholangitis in patients with PBD [12]. Fujii et al. also revealed that ERBD for ≥29 days was a risk factor for POPF after PD [14]. The

Table 3
The demographic characteristics and clinical outcomes in the bridge PBD and unchanged PBD groups.

	Bridge PBD group (n = 59)	Unchanged PBD group (n = 91)	*p* value
Preoperative variable			
Gender, male	40 (67.8%)	65 (71.4%)	0.635
Age	69 (40-85)	68 (40-84)	0.129
BMI (kg/m^2)	20.8 (16.1-31.1)	21.1 (14.0-28.7)	0.302
Albumin (g/dl)	3.7 (2.6-4.5)	3.7 (2.6-4.5)	0.425
Bilirubin at the time of surgery (mg/dl)	0.84 (0.25-3.95)	1.17 (0.27-10.9)	0.099
Disease, pancreatic cancer	29 (49.2%)	40 (44.0%)	0.533
Preoperative comorbidities, present	36 (61.0%)	62 (68.1%)	0.371
Preoperative cholangitis, present	18 (30.5%)	10 (11.0%)	0.003
WBC (/μl)	5225 (2730-19540)	5920 (2940-9780)	0.080
CRP (mg/dl)	0.19 (0.02-8.62)	0.17 (0.01-17.7)	0.090
Duration of PBD (days)	37 (20-437)	25 (9-82)	<0.001
Preoperative hospital stay from PBD (days)	32 (19-79)	46 (20-117)	<0.001
Intraoperative variables			
Soft pancreatic parenchyma	43 (72.9%)	57 (62.6%)	0.194
Pancreatic duct dilatation, present	39 (66.1%)	46 (50.5%)	0.060
Operative time (min)	432 (234-642)	428 (245-687)	0.714
Estimated blood loss (g)	830 (240-2080)	740 (180-3850)	0.244
Blood transfusion, present	6 (10.2%)	14 (15.4%)	0.359
Portal vein or SMV resection, present	11 (18.6%)	19 (20.9%)	0.738
Postoperative variables			
All morbidity	32 (54.2%)	43 (47.3%)	0.403
Intraabdominal abscess	21 (35.6%)	29 (31.9%)	0.636
CR-POPF	12 (20.3%)	17 (18.7%)	0.802
Mortality	0 (0.0%)	2 (2.2%)	0.252
Postoperative hospital stay (days)	22 (16-83)	25 (16-93)	0.107

Table 4
The comparisons between ERBD in the bridge PBD and initial ERBD.

	ERBD in the bridge PBD (n = 59)	Initial ERBD (n = 25)	*p* value
Duration of ERBD (days)	27 (3-118)	30 (1-68)	0.770
Stent exchange, yes	7 (11.9%)	9 (36.0%)	0.015

median duration of PBD in the bridge PBD group was 37 days, which was longer than that in the unchanged PBD group. However, there was no differences in the postoperative outcomes between 2 groups. This may be because bridge PBD worked well. Despite no marked difference in the duration of ERBD, the incidence of stent exchange due to stent dysfunction in the bridge PBD group was lower than that in patients who initially received ERBD. We have no clear evidence explaining this result, but we speculate that, in the bridge PBD group, the issues associated with biliary obstruction were well-treated with initial ENBD, which might have reduced the risk of stent dysfunction in replaced ERBD. Thus, we believe that in addition to shortening the preoperative hospital stay, bridge PBD might have allowed us to perform PBD for a long duration without worsening the postoperative outcomes after PD.

The present study is associated with some limitations due to its retrospective design. Firstly, the indications and type of PBD were decided by endoscopists, and the disease entities were heterogeneous. Secondly, we could not analyze the microbial cultures of bile samples obtained during the perioperative period, or the drainage fluid cultures. Thus, we could not evaluate the correlation between “bridge PBD” and bacterobilia. Thirdly, we could not evaluate the benefits, in terms of the medical cost, of “bridge PBD”. These limitations should be evaluated in prospective study.

In conclusion, bridge PBD worked well for shortening the preoperative hospital stay and allowing PBD to be performed for a long duration without worsening the postoperative outcomes after PD. Bridge PBD may provide surgeons with a useful preoperative management strategy for patients with biliary duct obstruction who are undergoing PD.

Conflicts of interest

The authors declare that they have no conflict of interest.

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Data availability statement

All data generated or analyzed during this study are included within the article.

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