ORIGINAL ARTICLE

The effect of pre-operative biliary drainage in resectable periampullary lesions: a systematic review and meta-analysis

Efecto del drenaje biliar pre-operatorio en lesiones periampulares resecables: revisión sistemática y metaanálisis

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Abstract

Objective: *The effect of a pre-operative biliary stent on complications after pancreaticoduodenectomy (PD) remains controversial.* **Materials and method***: We conducted a meta-analysis according to the preferred reporting items for systematic reviews and meta-analyses guidelines, and PubMed, Web of Science Knowledge, and Ovid's databases were searched by the end of February 2023. 35 retrospective studies and 2 randomized controlled trials with a total of 12641 patients were included.* **Results***: The overall complication rate of the pre-operative biliary drainage (PBD) group was significantly higher than the no-PBD group (odds ratio [OR] 1.46, 95% confidence interval [CI] 1.22-1.74; p < 0.0001), the incidence of post-operative delayed gastric emptying was increased in patients with PBD compared those with early surgery (OR 1.21, 95% CI: 1.02-1.43; p = 0.03), and there was a significant increase in post-operative wound infections in patients receiving PBD with an OR of 2.2 (95% CI: 1.76-2.76; p < 0.00001).* **Conclusions:** *PBD has no beneficial effect on post-operative outcomes. The increase in post-operative overall complications and wound infections urges the exact indications for PBD and against routine pre-operative biliary decompression, especially for patients with total bilirubin < 250 umol/L waiting for PD.*

Keywords: *Pre-operative biliary drainage. Resectable. Periampullary lesions. Meta-analysis.*

Resumen

Objetivo: *El efecto de una endoprótesis biliar pre-operatoria sobre las complicaciones después de la pancreaticoduodenectomía sigue siendo controvertido.* **Materiales y método:** *Se llevó a cabo un metaanálisis siguiendo las directrices PRISMA y se realizaron búsquedas en PubMed, Web of Science Knowledge y la base de datos de Ovid hasta finales de febrero de 2023. Se incluyeron 35 estudios retrospectivos y 2 ensayos controlados aleatorizados, con un total de 12,641 pacientes.* **Resultados:** *La tasa global de complicaciones del grupo drenaje biliar pre-operatorio (PBD) fue significativamente mayor que la del grupo no-PBD (odds ratio [OR]: 1.46; intervalo de confianza del 95% [IC 95%]: 1.22-1.74; p < 0.0001), la incidencia de vaciado gástrico retardado posoperatorio fue mayor en los pacientes con PBD en comparación con los de cirugía precoz (OR: 1.21; IC95%: 1.02-1.43; p = 0.03), y hubo un aumento significativo de las infecciones posoperatorias de la herida en los pacientes que recibieron PBD (OR: 2.2; IC 95%: 1.76-2.76; p < 0.00001).* **Conclusiones:** *El drenaje biliar pre-operatorio no tiene ningún efecto beneficioso sobre el resultado posoperatorio. El aumento de las complicaciones posoperatorias globales y de las infecciones de la herida urge a precisar las indicaciones de PBD y a desaconsejar la descompresión biliar pre-operatoria sistemática, en especial en pacientes con bilirrubina total inferior a 250 μmol/l en espera de pancreaticoduodenectomía.*

Palabras clave: *Drenaje biliar pre-operatorio. Resecable. Lesiones periampulares. Metaanálisis.*

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Introduction

Obstructive jaundice is the most common manifestation of pancreatic head and other periampullary lesions, which is related to disturbed coagulation, decreased hepatic function, and the development of cholangitis following pancreaticoduodenectomy (PD)[1].

The management of pre-operative biliary drainage (PBD) in patients undergoing PD is controversial. PBD is mostly performed by placing a biliary stent in the common bile duct or percutaneous transhepatic biliary drainage in the pre-operative diagnosis of endoscopic retrograde cholangiopancreatography[2]. Early studies have suggested a beneficial effect of treating obstructive jaundice with PBD on post-operative outcomes with regard to mortality and morbidity. However, previous data and systematic reviews have shown that PBD for distal biliary obstruction leads to increased perioperative complications after PD[3].

In order to evaluate the incidence of complications and mortality, we conducted a meta-analysis to compare surgery after PBD and single surgery.

Materials and methods

Using the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines, PubMed, Web of Science, and Ovid's database were searched for studies published by the end of February 2023. The search terms used were "preoperative biliary drainage," "pancreaticoduodenectomy," "resectable periampullary lesions," "complication", and "mortality."

Manually check the reference list of relevant studies to locate any missing studies. The two co-authors independently chose to include and exclude studies and reached a consensus when they did not reach an agreement at first.

Inclusion criteria and exclusion criteria

The inclusion criteria are as follows: (1) Study of patients with periampullary lesions undergoing PD; (2) Comparison of prognosis between PBD and no-PBD; (3) Mortality or complications were mentioned. Exclusion of a study using the following criteria: (1) summary, correspondence, editorial, expert opinion, review, case report; (2) no data or control studies are available; (3) including studies of unresectable periampullary lesions; and (4) patients with palliative R2 resection.

Study selection

By reviewing the titles, abstracts, keywords, and full text of each retrieved record, we evaluated whether the identified studies were qualified to be included in the review. The research is limited to papers published in English.

Data extraction

Data were extracted from two independent observers (Tiequan Yang and Yangjun Li) using standardized tables. Record the following variables: author, journal and publication year, number of patients, total sample size, age, gender, tumor size, complications, re-operation, and mortality. If necessary, contact the corresponding authors of the study to obtain supplementary information.

Quality assessment

Review Manager 5.3 by the Cochrane Collaboration was used for analysis. The risk of bias was assessed using the Cochrane Risk of Bias 2.0 assessment tool for randomized controlled trials (RCTs)[4] and the Cochrane Risk of Bias in non-randomized studies of interventions tool for non-RCTs[5].

Statistical analysis

A formal meta-analysis was carried out for all included studies for periampullary lesions with or without PBD. The outcomes of our study were complications, re-operation, and mortality. Outcomes were encoded as dichotomous variables, and odds ratios (OR) were calculated by assessing the incidence of respective outcomes. The Mantel–Haenszel statistical method with a randomized or fixed effects model was not based solely on statistical heterogeneity but also on clinical heterogeneity between the trials. Sensitivity analyses were also performed by removing individual studies from the data set and analyzing the effect on the overall results to identify sources of significant heterogeneity.

Potential publication bias was assessed by the application of contour-enhanced funnel plots[6], Egger's linear regression test[7], and Begg's rank correlation

test at the $p < 0.05$ level of significance[8]. If publication bias was indicated, we further evaluated the number of missing studies in a meta-analysis by the application of the trim and fill method and recalculated the pooled risk estimate with the addition of those missing studies. Except where otherwise specified, a $p < 0.05$ was considered significant.

Results

We followed the PRISMA guidelines to conduct the literature search and the selection of included studies, as presented in the PRISMA flow diagram (Fig. 1). Finally, 37[9-45] studies met the requirements and were included in this meta-analysis. Of these, 35 were retrospective studies, and 2 were RCTs (Table 1).

The basic characteristics of the included studies are shown in table 1. All the included studies demonstrated a relatively high quality.

The 27 included studies comprised 10376 patients, of whom 6380 received PBD and 3996 proceeded directly to surgery. Overall complications were significantly higher in the PBD group (46.3%) than in the no-PBD group (40.8%), with an OR of 1.46 (95% CI 1.22-1.74; $p < 0.001$). In the RCTs, the OR for the incidence of overall complications in the PBD group versus the no-PBD group was 2.69 (95% CI: 0.84-8.63; $p = 0.1$) (table 2).

In the 29 included studies, 1154 out of 6640 (17.4%) patients with PBD developed a pancreatic fistula in contrast to 701 of 4921 (14.2%) patients in the no-PBD group with an OR of 1.1 (95% CI: 0.9-1.35; $p = 0.34$), showing no significant difference in the incidence of post-operative pancreatic fistulas between patients receiving PBD and the no-PBD group. In the RCT, pancreatic fistula rates were 8/102 (7.8%) and 11/94 (11.7%) in the PBD and no-PBD groups, respectively, resulting in an OR of 0.64 (95% CI: 0.25-1.67; $p = 0.36$) (Table 2).

In the 20 included studies, biliary fistulas were 117/3404 (3.4%) and 116/2944 (3.9%) in the PBD and no-PBD groups, respectively, with an OR of 0.87 (95% CI: 0.66-1.15; $p = 0.32$). In the RCT, biliary fistula rates were 1/102 (1.0%) and 3/94 (3.2%) in the PBD and no-PBD groups, respectively, resulting in an OR of 0.3 (95% CI: 0.03-2.94; $p = 0.3$) (Table 2).

We elucidated the incidence of intra-abdominal abscess, intraperitoneal bleeding, and digestive tract bleeding. No significant differences were observed between the groups in terms of intra-abdominal abscess (OR 0.88, 95% CI: 0.53-1.46; $p = 0.63$), intraperitoneal bleeding (OR 1.11, 95% CI: 0.65-1.88; $p = 0.7$), and digestive tract bleeding (OR 0.79, 95% CI: 0.58-1.08; $p = 0.14$) (Table 2).

We investigated the influence of PBD on the incidence of post-operative delayed gastric emptying. As demonstrated in our study, the incidence of post-operative delayed gastric emptying was increased in patients with PBD (12.7%) compared those with early surgery (11.9%), with an OR of 1.21 (95% CI: 1.02-1.43; $p = 0.03$) (Table 2). In the RCT, 18 out of 102 (17.6%) and 9 out of 94 (9.6%) patients suffered post-operative delayed gastric emptying in the PBD and no-PBD groups, respectively, resulting in an OR of 2.02 (95% CI: 0.86-4.76; $p = 0.11$) (Table 2).

A total of 26 included studies revealed 1144 wound infections in 6373 patients in the PDB group (18.0%) in comparison to 363 in 4203 patients in the no-PBD group (8.6%), with an OR of 2.2 (95% CI:1.76-2.76; $p < 0.00001$) in favor of the no-PBD group, indicating that post-operative wound infection in PBD patients increased significantly. The incidence of wound infections in the RCT was 13 of 102 (12.7%) and 7 of 94 (7.4%) in the PBD and no-PBD groups, respectively, resulting in an OR of 1.82 (95% CI: 0.69-4.77; $p = 0.23$) (Table 2).

17 studies assessed patients for re-operation. The prevalence of re-operation was 5.3% (165/3094) in the PBD group versus 5.9% (148/2513) in the no-PBD group. However, this difference was not statistically significant (OR 0.78, 95% CI: 0.61-1.0; $p = 0.05$). In the RCT, re-operation rates were 12/102 (11.7%) and 13/94 (13.8%) in the PBD and no-PBD group, respectively, resulting in an OR of 0.83 (95% CI: 0.36-1.92; $p = 0.67$) (Table 2).

We evaluated the effect of PBD on post-operative mortality within 30 days after surgery. Among the 24 included studies, 126 (2.1%) of the 5774 cases in the PBD group died, while 103 (2.4%) of the 4051 cases in the no-PBD group died, with an OR of 0.84 (95% CI: 0.63-1.11, $p = 0.22$) (Table 2).

Regarding the patients with mean total bilirubin > 150 umol/L and < 250 umol/L, 5 studies were included for overall complications, and 3 studies were included for mortality. The prevalence of overall complications was 56.1% (202/360) in the PBD group versus 40.9% (143/350) in the no-PBD group. However, this difference was not statistically significant (OR 1.75, 95% CI: 0.99-3.11; $p = 0.06$) (Fig. 2). In the RCTs, the OR for the incidence of overall complications in the PBD group versus the no-PBD group was 2.69 (95% CI: 0.84–8.63; $p = 0.1$), depicting an overall complication rate of 120/197 (60.9%) and 70/184 (38.0%) in the PBD and no-PBD groups, respectively. A total of 3

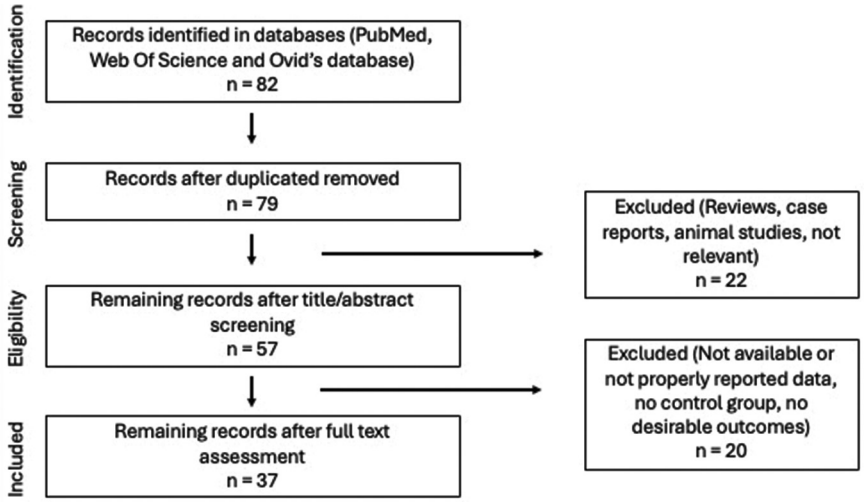

Figure 1. *Flowchart of the results of the literature search.*

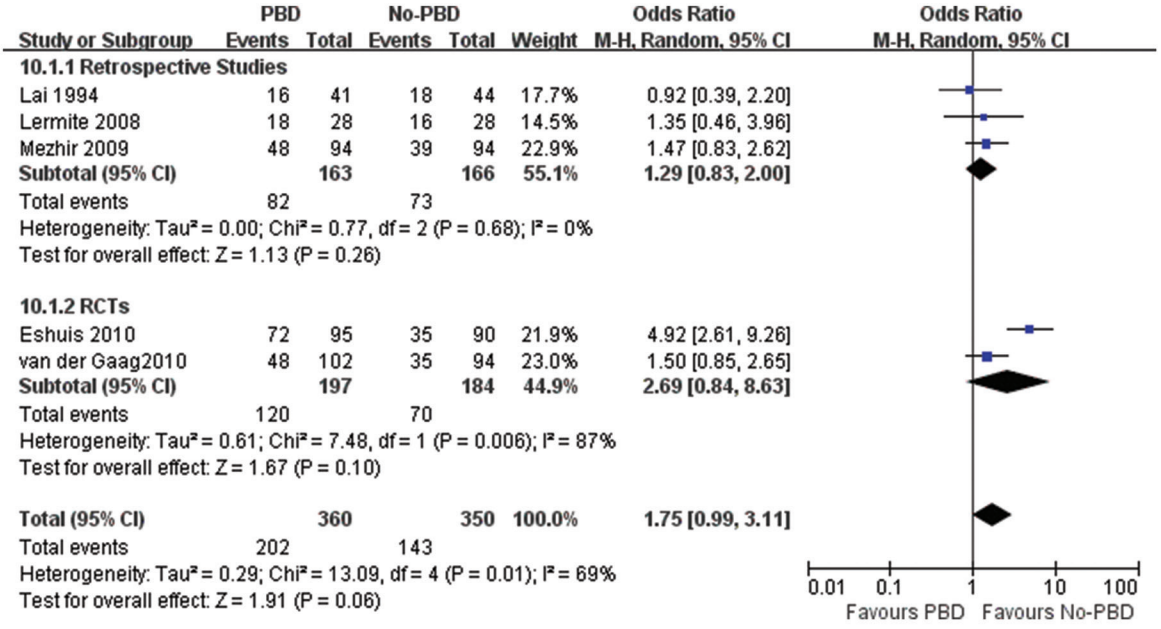

Figure 2. *Forest plots of the comparison of the overall complications between pre-operative biliary drainage (PBD) and no-PBD with patients' mean total bilirubin between 150 umol/L and 250 umol/L.*

included studies revealed 7 died in 165 patients in the PDB group (4.2%) in comparison to 13 in 166 patients in the no-PBD group (7.8%), with an OR of 0.53 (95% CI:0.21-1.36; p = 0.19) (Fig. 3).

Discussion

Biliary drainage increases patient comfort by reducing bilirubin levels, thereby alleviating the common problem symptoms of pruritus. In addition, biliary drainage can be used as a temporary measure to allow liver function tests and normalization of liver function if the operation is delayed for a considerable period of time. However, biliary stents induce bacterial contamination and enhance the risk of cholangitis because a connection between the bowels and the bile ducts is created.

Table 1. Demographic characteristics of patients and study design as reported in the included studies

Author, year	Country	Groups	No. of patients	Sex (male/female)	Mean age (year)	Total bilirubin (umol/L)	Tumor diameter (cm)	Perioperative antibiotic prophylaxis	Study design
Liu et al. 2015[9]	China	PBD No-PBD	47 288	28/19 166/122	59 ± 2 57 ± 1	363.2 ± 18.0 136.0 ± 8.4	3.5 ± 0.2 4.3 ± 0.4	-	Retrospective
Pisters et al. 2000[10]	USA	PBD No-PBD	172 93	102/70 45/48	-	-	-	Cephalosporin or ciprofloxacin	Retrospective
Howard et al. 2006[11]	USA	PBD No-PBD	86 52	52/34 33/19	61 ± 13 59 ± 14	-	-	-	Retrospective
Coates et al. 2009[12]	USA	PBD No-PBD	56 34	31/25 17/17	66 ± 12 65 ± 15	236 ± 142 101 ± 147	2.8 ± 1.5 3.3 ± 2.0	-	Retrospective
Mullen et al. 2005[13]	USA	PBD No-PBD	170 92	-	-	-	-	Cephalosporin or ciprofloxacin	Retrospective
Lai et al. 1994[14]	China	PBD No-PBD	43 44	31/12 28/16	67 66	266 209	-	-	Retrospective
Morris-Stiff et al. 2011[15]	UK	PBD No-PBD	118 162	-	-	-	-	Cephalosporin	Retrospective
Huang et al. 2015[16]	China	PBD No-PBD	100 170	- 113/57	- 57.8 ± 8.6	- 209.9 ± 136.7	- 2.2 ± 1.1	-	Retrospective
Eshuis et al. 2010[17]	Netherlands	PBD No-PBD	95 90	51/44 63/27	64.7 ± 10.3 64.6 ± 9.5	160 ± 57.9 149 ± 54.5	-	-	RCT
Singhirunnusorn et al. 2013[18]	France	PBD No-PBD	38 62	22/16 30/32	68 68	114 17	-	-	Retrospective
Arkadopoulos et al. 2014[19]	Greece	PBD No-PBD	76 76	50/26 45/31	57 ± 12 58 ± 11	-	-	-	Retrospective
Hodul 2003[20]	USA	PBD No-PBD	154 58	95/59 33/25	66 ± 11 64 ± 10	92.34 ± 102.6 157.3 ± 135.1	-	-	Retrospective
Mezhir et al. 2009[21]	USA	PBD No-PBD	94 94	48/46 47/47	68 ± 10 69 ± 9	201.78 191.52	-	-	Retrospective
Van der Gaag et al. 2010[22]	Netherlands	PBD No-PBD	102 94	53/49 66/28	64.7 ± 10.5 64.7 ± 9.5	154 ± 59.5 151 ± 58.7	-	-	RCT
Abdullah et al. 2009[23]	Singapore	PBD No-PBD	35 47	14/21 26/21	65 62	112.4 ± 116.1 91.6 ± 110.2	1 12	-	Retrospective
Agalianos et al. 2016[24]	Greece	PBD No-PBD	99 105	58/41 62/43	67.1 65.2	- -	- -	-	Retrospective
Barnett and Collier 2006[25]	Australia	PBD No-PBD	49 52	- -	- -	- -	- -	-	Retrospective
Bhati et al. 2007[26]	India	PBD No-PBD	21 27	10/11 15/12	50 48	134.24 ± 95.59 201.11 ± 154.76	- -	-	Retrospective
Cavell et al. 2013[27]	USA	PBD No-PBD	220 289	120/100 149/140	- 65	- -	- -	-	Retrospective
De Pastena et al. 2018[28]	Italy	PBD No-PBD	714 258	419/295 147/111	66 65	22.1 100.89	- -	Ampicillin/ sulbactam	Retrospective
El Nakeeb et al. 2018[29]	Egypt	PBD No-PBD	314 274	183/131 169/105	- -	239.4 138.5	- -	-	Retrospective
Gavazzi et al. 2016[30]	Italy	PBD No-PBD	89 91	57/32 51/40	- -	- -	- -	Cefazolin	Retrospective

(Continues)

Table 1. Demographic characteristics of patients and study design as reported in the included studies *(continued)*

Author, year	Country	Groups	No. of patients	Sex (male/female)	Mean age (year)	Total bilirubin (umol/L)	Tumor diameter (cm)	Perioperative antibiotic prophylaxis	Study design
Heslin et al. 1998[31]	USA	PBD	39	17/22	67 ± 2	160 ± 14	-	-	Retrospective
		No-PBD	35	24/11	62 ± 2	118 ± 18	-		
Jagannath et al. 2004[32]	India	PBD	74	50/24	50	140	-	-	Retrospective
		No-PBD	70	48/22	50	70	-		
Lermite et al. 2008[33]	France	PBD	28	22/6	64.8 ± 9.3	200 ± 158	-	Cefazolin	Retrospective
		No-PBD	28	17/11	64.4 ± 9.5	169 ± 155	-		
Marcus et al. 1998[34]	USA	PBD	22	13/9	67.5	23.94	-	-	Retrospective
		No-PBD	30	19/11	71.5	189.81	-		
Martignoni et al. 2001[35]	Switzerland	PBD	99	52/47	69	145	-	-	Retrospective
		No-PBD	158	86/72	64	14	-		
Ng et al. 2017[36]	Australia	PBD	30	19/12	66.5	24.5	-	-	Retrospective
		No-PBD	21	9/11	64	7.0	-		
Pešková and Gürlich 2005[37]	Czech Republic	PBD	144	-	63	118	-	Cefoperazone	Retrospective
		No-PBD	160	-	53.2	81	-		
Sahora et al. 2016[38]	USA	PBD	500	273/227	66	18.81	-	Cefoxitin	Retrospective
		No-PBD	500	237/263	61	6.84	-		
Shaib et al. 2020[39]	Lebanon	PBD	1803	1055/748	66.52 ± 10.26	107.6 ± 77.5	-	-	Retrospective
		No-PBD	503	272/231	66.43 ± 10.14	48.1 ± 49.1	-		
Sohn et al. 2000[40]	USA	PBD	408	220/188	63.8 ± 0.6	-	-	-	Retrospective
		No-PBD	159	78/81	61.4 ± 1.2	-	-		
Yanagimoto et al. 2014[41]	Japan	PBD	112	73/39	-	-	-	-	Retrospective
		No-PBD	73	42/31	67	10.26	-		
Ozgun et al. 2021[42]	Turkey	PBD	574	236/206	59.43 ± 11.27	104.3	-	-	Retrospective
		No-PBD	231	131/100	59.24 ± 12.87	17.1			
di Mola et al. 2014[43]	Italy	PBD	53	33/20	67	-	-	-	Retrospective
		No-PBD	40	29/11	66.5				
Ray et al. 2021[44]	India	PBD	175	115/60	52.46 ± 9.90	234.6 ± 118.5	-	-	Retrospective
		No-PBD	229	139/90	48.23 ± 11.22	115.3 ± 129.6			
Wu et al. 2019[45]	Taiwan	PBD	237	136/101	65.2 ± 12.7	179.55 ± 141.93	-	Cefmetazole	Retrospective
		No-PBD	662	346/316	60.4 ± 13.5	47.88 ± 87.21	-		

PBD: pre-operative biliary drainage.

Through our meta-analysis, we can provide evidence that the overall complications in patients receiving PBD before surgical intervention are higher than those in patients without PBD. In addition, we can indicate that PBD is related to the increase in post-operative wound infection rate and delayed gastric emptying but has no effect on biliary fistula, pancreatic fistula, abdominal abscess, intraperitoneal hemorrhage, gastrointestinal bleeding, and perioperative mortality.

The underlying mechanism of DGE remains unclear, but many authors believe that pancreatic enzyme leakage may play an important role in local inflammation[46,47].

Post-operative wound infection is defined as purulent drainage with or without bacterial culture positive, or any drainage that was culture positive. Bacterial cultures of infected wounds showed a strong correlation with the microorganisms found on bile cultures obtained at the time of surgery. For example, Sahora et al. reviewed a series of patients and reported that the presence of Citrobacter and Enterobacteriaceae in bile culture significantly increased the incidence of wound infection in stent patients[38]. Gavazzi et al.

Table 2. Comparison of outcomes associated with PBD versus no-PBD

Outcomes	No. of studies	No. of patients		OR	95% CI	p-value	I^2
		PBD	No-PBD				
Overall complications							
Retrospective	25	6183	3812	1.39	1.17,1.65	0.0002	67
RCTs	2	197	184	2.69	0.84,8.63	0.1	87
Total	27	6380	3996	1.46	1.22,1.74	< 0.0001	70
Pancreatic fistula							
Retrospective	28	5736	4327	1.12	0.92,1.37	0.27	48
RCT	1	102	94	0.64	0.25,1.67	0.36	-
Total	29	5838	4421	1.1	0.90,1.35	0.34	48
Biliary fistula							
Retrospective	19	3302	2850	0.89	0.67,1.17	0.4	3
RCT	1	102	94	0.3	0.03,2.94	0.3	-
Total	20	3404	2944	0.87	0.66,1.15	0.32	2
Intraabdominal abscess							
Retrospective	18	2540	2508	0.9	0.53,1.51	0.68	76
RCT	1	102	94	0.61	0.1,3.71	0.59	-
Total	19	2642	2602	0.88	0.53,1.46	0.63	75
Intraperitoneal bleeding							
Retrospective	5	757	1016	1.23	0.7,2.15	0.47	0
RCT	1	102	94	0.45	0.08,2.52	0.36	-
Total	6	859	1110	1.11	0.65,1.88	0.7	0
Digestive tract bleeding							
Retrospective	6	1369	1050	0.79	0.58,1.08	0.14	0
Delayed gastric emptying							
Retrospective	16	3039	2436	1.18	0.99,1.4	0.06	0
RCT	1	102	94	2.02	0.86,4.76	0.11	-
Total	17	3141	2530	1.21	1.02,1.43	0.03	0
Wound infection							
Retrospective	25	5469	3609	2.22	1.76,2.81	< 0.00001	40
RCT	1	102	94	1.82	0.69,4.77	0.23	-
Total	26	5571	3703	2.2	1.76,2.76	< 0.00001	37
Re-operation							
Retrospective	15	2817	2190	0.78	0.6,1.01	0.06	0
RCT	1	102	94	0.83	0.36,1.92	0.67	-
Total	16	2919	2284	0.78	0.61,1.0	0.05	0
Mortality							
Retrospective	23	5599	3822	0.84	0.63,1.11	0.22	0

PBD: pre-operative biliary drainage; OR: odds ratio; CI: confidence interval; RCT: randomized controlled trials.

analyzed 180 patients to explore the risk factors for wound infection after PD. Multivariate analysis showed that biliary stents significantly increased the incidence of wound infection, among which Enterococcus, Escherichia coli, and Klebsiella were the most common bacteria in bile culture[30].

Moreover, we also confirmed that the wound infection rate in the PBD group was higher than that in the no-PBD group, resulting in an increase in overall complications. The longer the time of biliary stent is implanted, the more intestinal bacteria flow back into the biliary tree, thus increasing the risk of bacterial colonization. In addition, biliary drainage itself also has complications, including pancreatitis, cholecystitis, cholangitis, and perforation[33].

One previous study illustrated that overall morbidity and mortality were not influenced by the presence or absence of severe jaundice[35]. Another study reported patients with serum bilirubin levels between 40 and 250 μmol/l had no benefit from PBD in patients with serum bilirubin levels < 170 μmol/l, and only higher values were associated with intraoperative or

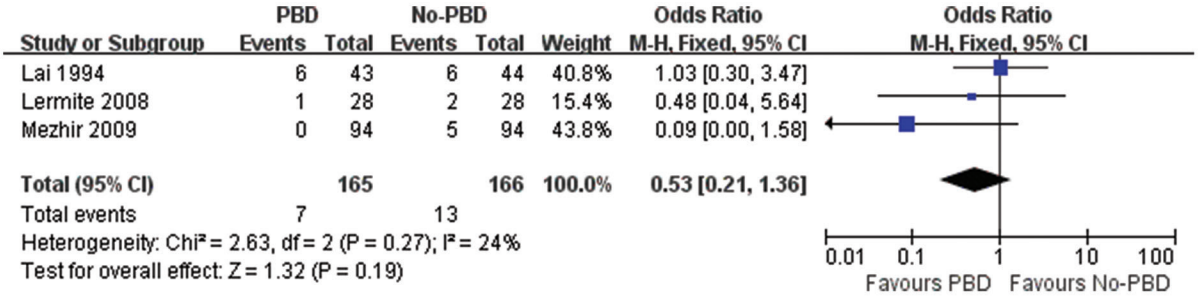

Figure 3. *Forest plots of the comparison of the mortality between pre-operative biliary drainage (PBD) and no-PBD with patients' mean total bilirubin between 150 umol /L and 250 umol /L.*

post-operative complications[17]. In our meta-analysis, patients with mean total bilirubin between 150 umol/L and 250 umol/L showed no statistically significant difference in overall complications and mortality between the PBD and no-PBD groups. However, there was no high-quality evidence for the indication of PBD by serum bilirubin thresholds.

The present analysis also has limitations that should be taken into consideration. First, only two RCTs were included in the meta-analysis. Non-RCTs may exaggerate the effect of the approaches, either by external factors or by intrinsic flaws. Second, heterogeneity was high among the included studies, possibly due to different definitions of complications, ways of stent placement, stent types, and materials. Third, some relevant data, such as stent-related complications, drainage interval, and post-operative hospital stay, were not included in this study. Therefore, more RCTs using standardized assessments, a single pre-operative drainage method, and limited surgical procedures are needed.

Conclusion

In conclusion, the use of PBD has not been proven to be beneficial for patients, especially for patients with total bilirubin < 250 umol/L waiting for PD.

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Conflicts of interest

There are no conflicts of interest exits regarding the submission of this manuscript.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that no patient data appear in this article. Furthermore, they have acknowledged and followed the recommendations as per the SAGER guidelines depending on the type and nature of the study.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript or for the creation of images, graphics, tables, or their corresponding captions.

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