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RESEARCH

Whether preoperative biliary drainage leads to better patient outcomes of pancreaticoduodenectomy: a meta-analysis and systematic review

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Abstract

Objective To investigate whether preoperative biliary drainage is beneficial for patients undergoing pancreaticoduodenectomy.

Methods The PubMed, Cochrane Library and the Web of Science were systematically searched for relevant trials that included outcome of pancreaticoduodenectomy with and without preoperative biliary drainage from January 2010 to May 2024. The primary outcomes are postoperative pancreatic fistula and intra-abdominal infection. Data is pooled using the risk ratio or standardized mean difference with 95% confidence interval. The study protocol was registered prospectively with PROSPERO (CRD42022372584).

Results A total of 39 retrospective cohort studies with 33,516 patients were included in this trial. Compared with no preoperative biliary drainage, the preoperative biliary drainage group had a longer hospital stay (SMD, 0.14). Performing preoperative biliary drainage significantly increases the risk of postoperative pancreatic fistula (RR, 1.09), intra-abdominal infection (RR, 1.09), surgical site infection (RR, 1.84), and sepsis (RR, 1.37). But preoperative biliary drainage lowers risk of bile leak (RR, 0.74).

Conclusion Preoperative biliary drainage before pancreaticoduodenectomy increases the risk of postoperative complications without clear overall benefits. Routine PBD is not recommended for younger patients with mild to moderate jaundice but may be considered for high-risk patients, such as those with severe infections or progressive jaundice. Optimizing preoperative biliary drainage duration and timing may help reduce complications. Further research is needed to refine patient selection and perioperative strategies.

Keywords Preoperative biliary drainage, Obstructive jaundice, Meta-analysis, Pancreaticoduodenectomy

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Introduction

Obstructive jaundice is a frequent clinical manifestation of hepatobiliary and pancreatic tumors, often arising as a consequence of malignancies such as pancreatic cancer, bile duct cancer, and ampullary cancer [1]. For these patients, preoperative biliary drainage (PBD) through endoscopic or percutaneous biliary stenting before pancreaticoduodenectomy (PD) may be considered as an option to relieve symptoms.

PD was first introduced by Whipple et al. [2]. in 1935. At the time, they believed that preoperative obstructive jaundice had a significant impact on postoperative recovery, a perspective that has been supported by several subsequent studies [3, 4]. As the duration of jaundice prolongs and the severity of the disease worsens, patients may develop a range of physiological and metabolic disorders, ultimately reducing their tolerance to surgery [5]. However, as clinical research on PBD has advanced, some scholars have found that while PBD does not reduce patient mortality, it may increase the risk of postoperative complications. Moreover, the invasive nature of PBD itself can lead to procedure-related complications, potentially impacting the patient's postoperative prognosis [6, 7].

Although some guidelines advise against the routine use of PBD before PD, they do recommend it for patients experiencing symptoms such as fever or cholangitis who require a delay in surgery. While these guidelines outline the indications for PBD, they do not clearly define its necessity [8, 9]. Therefore, exploring the impact of PBD on postoperative complications and mortality after PD is of great clinical significance, as it can help further clarify the necessity of PBD. Given that previous studies are relatively outdated, this study incorporates more recent research to provide updated insights and reassess earlier perspectives.

Methods

This study was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA) statement [10]. We also registered this protocol in the International Prospective Systematic Reviews Registry database (CRD42022372584).

Data sources and search

The PubMed, Web of Science and Cochrane Library were searched from January 2010 to May 2024. Relevant search terms are as follows: [(Preoperative Biliary Drainage) OR (Cholangiopancreatography, Endoscopic Retrograde)] AND [(Jaundice, Obstructive) OR (Pancreaticoduodenectomy) OR (Cholangiocarcinoma) OR (Bile Duct Neoplasms) OR (Pancreatic Neoplasms) OR (Ampullary Cancer)] in the title/abstract. In addition, citations of articles were searched to supplement relevant studies not included in the initial literature search results. Detailed search strategies are presented in the eAppendix in Supplement 1 in word format.

Inclusion and exclusion criteria

Inclusion criteria were strictly formulated according to the PICOS approach. Inclusion criteria: (1) Literature needs to include the intervention group that received PBD and the control group that did not receive PBD. (2) All patients had periampullary tumors, including pancreatic, ampullary, distal bile duct, and duodenal tumors, all requiring PD. (3) Patients were over 18 years old, in good overall health, free from severe comorbidities (such as terminal illness or severe cardiopulmonary insufficiency), and capable of tolerating surgery. Exclusion criteria: (1) Reviews, conference papers, case reports, etc. are not our type of research. (2) Patients with unclear PBD and non-pancreatic diseases, such as other types of tumors, non-pancreatic surgery. (3) No data available or data cannot be converted into usable form. Based on the above inclusion and exclusion criteria, the two authors (LW and LZK) independently conducted the screening process, and consulted WZF for different opinions.

Data collection and quality assessment

Data extraction was done independently by two authors (ZKX and LW). Inconsistent opinions shall be discussed by everyone or consulted by WZF. Extracted information included: first author, year of publication, sample size, age, bilirubin level, disease type, and all primary and secondary outcomes.

The included studies were assessed for bias according to the the Newcastle-Ottawa Scale (NOS) by two independent authors (ZB and LZK). The evaluation content includes selection bias, comparability bias, and exposure bias. There are evaluation items under each item, and each item is indicated by stars. The highest score for the comparability bias and outcome bias is two stars. The highest total score is eight stars. Any discrepancies were resolved by discussion. We also used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to assess the quality of the evidence. With the GRADE approach, each outcome was classified as 'high,' 'moderate,' 'low,' or 'very low' in terms of the quality of the evidence. According to GRADE, observational studies start with a low level of evidence. However, this level may be further downgraded based on limitations in five key areas: risk of bias, consistency, indirectness, imprecision, and publication bias. Conversely, large magnitude of effect and potential confounding factors that could affect the efficacy and dose-response gradient can upgrade the quality of the evidence [11].

Outcomes and definitions

Primary outcomes are postoperative pancreatic fistula and bile leak. Secondary outcomes are some common complications including sepsis, surgical site infection, post pancreatectomy hemorrhage, delayed gastric emptying and intra-abdominal infection. Other outcomes are overall mortality and hospital stay. The definition of postoperative pancreatic fistula refers to the definition of Bassi et al. [12]. Bile leak was confirmed either by postoperative radiological examination or by measuring bilirubin levels that were three times higher in the drain output or fluid aspirated from a clinically significant intra-abdominal collection compared to serum levels. The surgical site infection was confirmed when an infection involving the skin and subcutaneous tissue of the incision occurred within 30 days of the operation, characterized by purulent drainage, positive cultures, pain or tenderness, swelling, or heat. Delayed gastric emptying and post pancreatectomy hemorrhage were defined according to the International Study Group of Pancreatic Surgery [13, 14].

Statistical analysis

All statistical analyses were performed using Review Manager (RevMan) version 5.4 (The Cochrane Collaboration, Copenhagen, Denmark) and Stata SE 16.0 (Stata Corporation, TX, USA). The risk ratio (RR) with 95% confidence intervals (CI) were used for dichotomous data, and standard mean difference (SMD) with 95% CI for continuous data. The Q-test and I^2 statistic were calculated to assess the heterogeneity of studies. The fixed-effects model was used when $I^2 < 50\%$; otherwise, we would use random-effects model. Significant heterogeneity was considered when $p < 0.1$ or $I^2 > 50\%$. Meta-regression analysis were conducted to explore the source of heterogeneity. Risk of publication bias for studies will be assessed using funnel plots, and the Egger's test was employed to examine the publication bias when there were at least 10 studies. We used TSA 0.9.5.10 beta software to conduct trial sequential analysis (TSA) of clinical efficacy. This helped reduce the occurrence of random errors, determine the reliability of the conclusions, and estimate the sample size required for the meta-analysis. A significance level of $\alpha = 0.05$ was set for all analyses. Sensitivity analysis was used to assess whether the results were stable and also to assess sources of heterogeneity.

Results

Study selection results

A total of 1267 articles were retrieved from the database. After removing duplicate articles, 980 article titles and abstracts were evaluated, and 924 articles were excluded. The remaining 56 articles were then read in full-text, 6 studies were excluded due to lack of PBD as an intervention, 4 studies were excluded because of lack of a control group without PBD, and 7 studies were excluded because of lack of relevant results or results that could not be translated into usable results. In the end, 39 studies were confirmed for inclusion [15–53]. All are observational studies. The specific screening process is shown in Fig. 1.

Study characteristics and quality assessment

Table 1 summarizes some of the characteristics of the included studies, although some data are missing due to different focus of different studies. The sample size for a single experiment varies from 51 to 5845. A total of 33,516 patients who underwent PD were included, with a mean age of 64.6 years. Most of these patients were pancreatic duct adenocarcinoma and ampullary cancer, followed by bile duct cancer.

After quality evaluation, we found that all included studies were on the upper-middle quality by NOS. Each has a score greater than five stars and met the criteria for inclusion in the meta-analysis. The final result is shown in eTable 1 in Supplement 2. The GRADE evaluation results are shown in Table 2.

Main outcomes

Compared with PBD, not performing PBD significantly reduced patients' risk of postoperative pancreatic fistula (RR, 1.09; 95% CI, 1.03 to 1.15; $p = 0.03$; $I^2 = 33\%$, Fig. 2A), intra-abdominal infection (RR, 1.09; 95% CI, 1.01 to 1.17; $p = 0.02$; $I^2 = 39\%$, Fig. 3A), surgical site infection (RR, 1.84; 95% CI, 1.71 to 1.98; $p < 0.00001$; $I^2 = 49\%$, Fig. 3B) and sepsis (RR, 1.37; 95% CI, 1.24 to 1.51; $p < 0.00001$; $I^2 = 25\%$, Fig. 4B). At the same time, not performing PBD also shortened the patient's hospital stay (SMD, 0.14; 95% CI, 0.05 to 0.23; $p = 0.002$; $I^2 = 82\%$, Fig. 4A). However, no significant differences were observed between the two groups in delayed gastric emptying, pneumonia, post pancreatectomy hemorrhage and overall mortality (Table 3). However, performing PBD may reduce the risk of postoperative bile leak (RR, 0.74; 95% CI, 0.60 to 0.91; $p = 0.004$; $I^2 = 45\%$, Fig. 2B). Table 3 shows the results for other outcomes.

Meta-Regression

To explore potential sources of heterogeneity, we performed a meta-regression analysis in this study to examine the impact of multiple covariates on effect size. We selected sample size, mean age and gender as covariates and used a random effects model to analyze sources of heterogeneity in postoperative pancreatic fistula, bile leak, intra-abdominal infection, surgical site infection and hospital stay. Results suggest that age may be a major source of heterogeneity in postoperative pancreatic fistula and intra-abdominal infection. The results of the

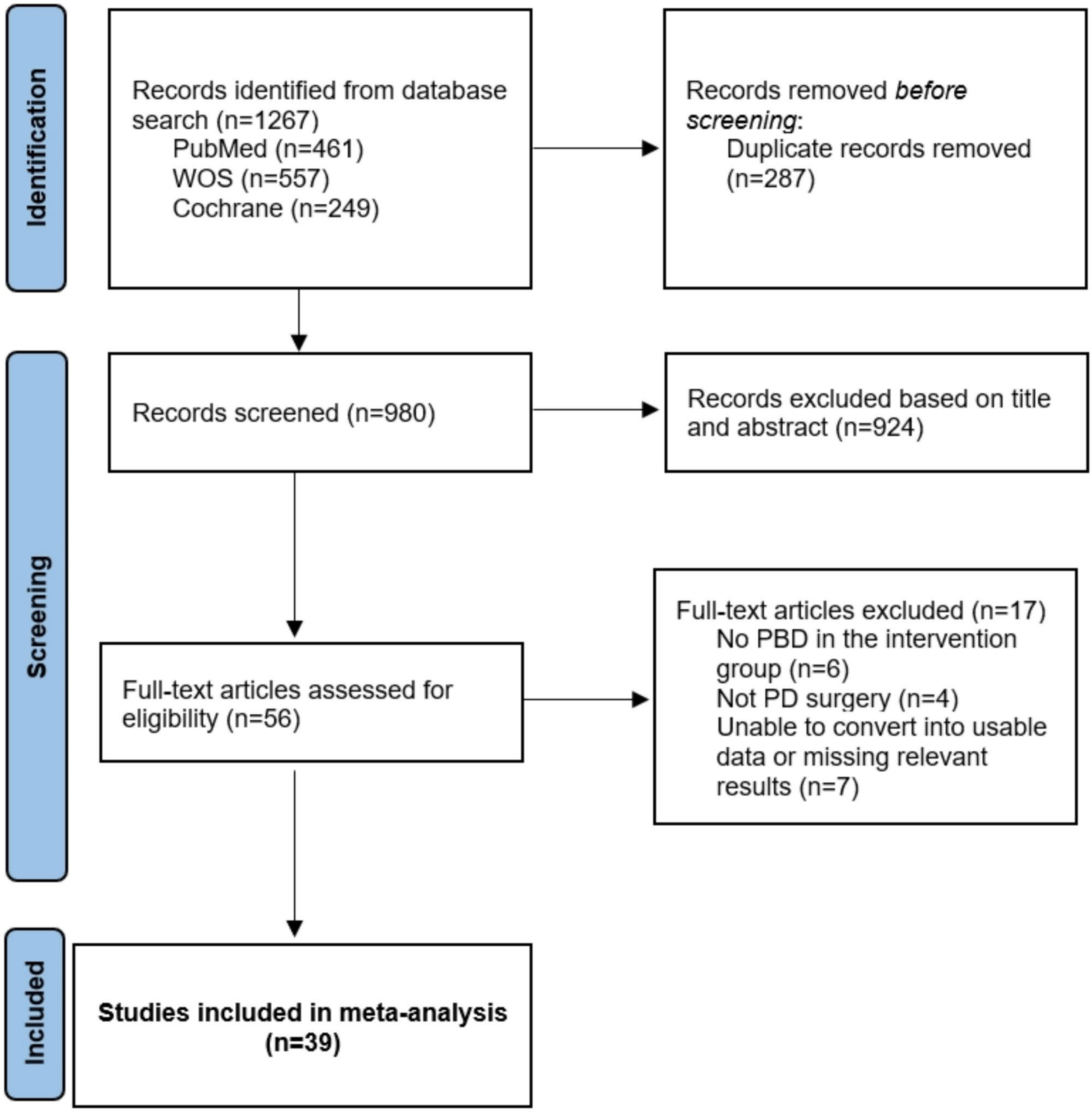


Fig. 1 Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flowchart of selection

meta-regression are shown in eFigure 5–9 in Supplement 3.

Subgroup analysis

Based on the results of meta-regression, we conducted a subgroup analysis of postoperative pancreatic fistula and intra-abdominal infection according to different age groups. The results showed that in those aged < 65 years, not performing PBD reduced the risk of postoperative pancreatic fistula and intra-abdominal infection. However, for patients > 65 years old, there was no statistically significant difference between the two groups. The results are shown in eFigure 10–11 in Supplement 3.

Publication Bias assessment and sensitivity analysis

The funnel plots of the corresponding results did not show obvious publication bias. All funnel plots are shown in eFigure 12–17 in Supplement 3). The results of begg's test and egger's test are shown in eFigure 18–23 in Supplement 3. Based on the results of the funnel plot and

Table 1 Patient condition and some baseline data

Reference	Country	n	Age (year)	Gender (male)	Mean SB of intervention group [BI/AI] (μmol/L)	Mean SB of control group (μmol/L)	Preoperative jaundice reduction	Disease type
Arkadopoulos 2014	Greece	152	57.5	95 (62.5)	340.3/35.9	324.9	ERCP (plastic stent)	periampullary tumor
Bademci 2021	Spain	123	69.0	71 (57.7)	235.0/NA	109.0	ERCP (plastic or metallic stent)	periampullary tumor
Barauskas 2016	Lithuania	64	65.5	28 (43.7)	NA	NA	PEBD (plastic stent)	periampullary tumor
Bhatti 2020	Pakistan	133	57.2	87 (65.4)	116.3/65.0	106.0	ERCP (plastic stent)	NA
Cavell 2013	America	509	65.7	269 (51.3)	NA	NA	PBS (plastic or metallic stent)	mainly pancreatic cancer
Cazauran 2017	France	106	64.9	66 (62.3)	273.3/73.2	NA	PEBD	mainly pancreatic cancer and bile duct cancer
Chen 2021	China	1365	60.7	830 (60.8)	72.5/NA	54.3	ERCP	NA
Endo 2019	Japan	292	67.6	184 (63.0)	NA/24.5	9.2	ERCP	mainly pancreatic cancer and bile duct cancer
Farooqui 2022	Denmark	722	68.5	374 (51.8)	204.0/39.0	<25	ERCP (plastic or metallic stent)	NA
Furukawa 2015	Japan	106	67.1	61 (57.5)	39.3/NA	30.8	PEBD (plastic stent)	pancreatic ductal adenocarcinoma
Gavazzi 2016	Italy	180	67.4	108 (60.0)	NA	NA	PBS	malignant carcinoma
Huang 2015	China	270	58.0	184 (68.1)	451.7/NA	489.6	PEBD and PTCD	bile duct cancer
Lee 2017	Korea	849	63.1	500 (58.9)	NA	NA	PEBD and PTCD	pancreatic cancer and bile duct cancer
Liu 2015	China	94	60.0	47 (50.0)	363.2/NA	324.9	ERCP/ENBD/PTCD	malignant carcinoma
Mola 2014	Italy	131	63.8	88 (67.2)	176.1/NA	100.0	ERCP and PTCD	pancreatic cancer
Nakeeb 2016	Egypt	588	NA	352 (59.9)	102.2/61.6	138.5	ERCP	mainly periampullary tumor
Ng 2017	Australia	51	66.0	28 (54.9)	24.5/NA	7.0	PBS	mainly pancreatic cancer and bile duct cancer
Ochoa 2020	Canada	4419	67.0	2427 (54.9)	NA	NA	ERCP	pancreatic ductal adenocarcinoma and periampullary tumor
Okano 2019	Japan	4101	67.8	2489 (60.7)	NA	NA	PBS	mainly pancreatic cancer and bile duct cancer
Ozgun 2021	Turkey	805	59.4	499 (62.0)	114.6/42.8	31.1	ERCP and PTCD	NA
Pamecha 2019	India	177	55.9	131 (74.0)	186.4/70.1	166.3	ERCP and PTCD (plastic stent)	mainly pancreatic ductal adenocarcinoma
Pastena 2018	Italy	1500	63.9	843 (56.2)	107.7/34.2	42.3	ERCP	pancreatic ductal adenocarcinoma and periampullary tumor
Ray 2021	India	404	50.1	254 (62.9)	234.6/NA	115.3	ERCP	pancreatic ductal adenocarcinoma and periampullary tumor
Roberts 2017	England	93	68.3	50 (53.8)	216.6/45.6	297.6	PBS	periampullary tumor
Sahora 2016	America	1000	64.0	510 (51.0)	NA/28.0	14.4	ERCP	mainly pancreatic cancer
Santos 2019	Portugal	82	69.1	47 (57.3)	198.4/NA	61.1	ERCP (plastic stent)	pancreatic ductal adenocarcinoma and periampullary tumor
Shaib 2017	Lebanon	2306	66.5	1327 (57.5)	NA/48.1	107.6	PBS	malignant carcinoma
Shen 2020	China	80	65.6	55 (68.8)	338.0/297.2	303.3	ERCP	malignant carcinoma
Shin 2019	Korea	1568	62.3	957 (61.0)	65.0/NA	22.2	ERCP/ENBD/PTCD	mainly pancreatic cancer and bile duct cancer
Stiff 2011	England	280	64.9	152 (54.3)	130.0/NA	98.0	ERCP and PTCD	mainly pancreatic cancer
Strom 2016	America	193	67.6	98 (50.8)	NA	NA	ERCP and PTCD	malignant carcinoma
Subasi 2022	Turkey	122	63.0	76 (62.3)	NA	NA	PEBD	pancreatic cancer, bile duct cancer and periampullary tumor

Table 1 (continued)

Reference	Country	*n*	Age (year)	Gender (male)	Mean SB of intervention group [BI/AI] (μmol/L)	Mean SB of control group (μmol/L)	Preoperative jaundice reduction	Disease type
Uemura 2015	Japan	932	66.8	494 (53.0)	NA	NA	ERCP and PEBD	pancreatic ductal adenocarcinoma
Wang 2021	China	96	66.2	52 (54.2)	213.7/110.2	139.8	PEBD	pancreatic ductal adenocarcinoma and periampullary tumor
Werba 2021	America	5845	66.9	3194 (54.6)	NA/47.9	92.3	NA	periampullary tumor
Yanagimoto 2014	Japan	185	66.5	115 (62.2)	NA/20.2	32.5	PTCD (plastic or metallic stent)	mainly pancreatic cancer and periampullary tumor
Yang 2019	China	603	59.5	354 (58.7)	NA	NA	ERCP and PTCD	malignant carcinoma
Yu 2024	China	2842	58.1	1738 (61.2)	NA	NA	PTCD and ENBD	mainly pancreatic cancer and periampullary tumor
Zhu 2023	China	148	63.9	97 (65.5)	198.9/NA	100.6	ERCP/ENBD/PTCD	pancreatic ductal adenocarcinoma and periampullary tumor

n: number; SB: serum bilirubin; BI: before intervention; AI: after intervention; DS: direct surgery; PEBD: preoperative endoscopic biliary drainage; NA: not acceptable; PBS: preoperative biliary stenting; ENBD: endoscopic nasobiliary drainage; PTCD: percutaneous transhepatic cholangial drainage

Data are expressed as mean or mean ± SD or n (%)

begg's test and egger's test, we believe that there is no publication bias in postoperative pancreatic fistula, bile leak, intra-abdominal infection, surgical site infection, sepsis and hospital stay.

The results of sensitivity analysis showed that the conclusions of this meta-analysis were highly robust. Eliminating low-quality studies, using different statistical models, and adjusting heterogeneity thresholds did not significantly change the effect size. The results of the sensitivity analysis are shown in eFigure 24–29 in Supplement 2.

Results of TSA

This study performed TSA analysis on postoperative pancreatic fistula and surgical site infection to evaluate the effectiveness of PBD and non-PBD in reducing the risk of adverse events after PD. The type I error rate α was set to 0.05, the information axis was the sample size, the statistical power was 80%, and the sample size was the required information size (RIS). We chose the random effects model as the primary analysis model to account for heterogeneity among studies (Fig. 5).

According to the analysis results, we observe that the Z-curves of postoperative pancreatic fistula and surgical site infection cross the traditional boundary and the TSA boundary, indicating that the result is statistically significant. In addition, the analysis pointed out that the current sample size has reached RIS and no further experiments are needed to verify the robustness of the conclusions. This indicates that there is clear evidence that non-PBD can reduce the risk of postoperative pancreatic fistula and surgical site infection in patients after PD, with effects of RR = 1.09 and RR = 1.84, respectively.

Discussion

In recent years, numerous studies have investigated whether patients with hepatobiliary and pancreatic cancer should undergo PBD before receiving PD, with varying conclusions. Moole et al. [54]. analyzed data from 3,532 patients with ampullary carcinoma and found that the incidence of postoperative complications was significantly lower in the PBD group compared to the non-PBD group. However, there were no differences in length of hospital stay or mortality. In contrast, a study by Saleh et al. [55]. concluded that PBD had no impact on postoperative mortality or complication rates. Similarly, Scheufele et al. [56]. reported a higher overall incidence of complications and wound infections in the PBD group compared to the non-PBD group, but found no significant effects on mortality, pancreatic leakage, or the incidence of intra-abdominal infections.

Our results suggest that PBD does not lead to improved outcomes for patients; instead, it prolongs postoperative recovery time and increases the risk of complications. However, PBD may help reduce the risk of postoperative bile leak. No significant differences were found between the PBD and non-PBD groups in terms of delayed gastric emptying, pneumonia, post-pancreatectomy hemorrhage, or overall mortality. Although some heterogeneity was observed in our results, the findings are generally acceptable.

To further explore the sources of heterogeneity, we used meta-regression analysis, which indicated that age is a contributing factor for postoperative pancreatic fistula and intra-abdominal infection. Based on this, we conducted a subgroup analysis by age. The results revealed that patients under 65 years old were less likely to undergo PBD before surgery. However, for patients over 65, PBD did not significantly increase the risk of

Table 2 GRADE evidence summary table

No. of studies	Trial design	Quality assessment					No. of patients		Effect		Quality of the evidence
		RoB	Inconsistency	Indirectness	Imprecision	PB	PBD	Non-PBD	Relative (95%CI)	Absolute (95%CI)	
Pancreatic fistula											
35	OS	No	No	No	No	No	2438/16,824 (14.5%)	2083/14,147 (14.7%)	**RR 1.09** (1.03 to 1.15)	**13 more per 1000** (from 4 more to 22 more)	⊕⊕⊕⊝Moderate
Bile leak											
22	OS	No	No	No	No	No	146/5655 (2.6%)	230/6749 (3.4%)	**RR 0.74** (0.6 to 0.91)	**9 fewer per 1000** (from 3 fewer to 14 fewer)	⊕⊕⊕⊕High
Intra-abdominal infection											
26	OS	No	No	No	No	No	1507/13,638 (11.1%)	1091/9077 (12%)	**RR 1.09** (1.01 to 1.17)	**11 more per 1000** (from 1 more to 20 more)	⊕⊕⊕⊝Moderate
Surgical site infection											
32	OS	No	No	No	No	No	2363/17,401 (13.6%)	999/12,432 (8%)	**RR 1.84** (1.71 to 1.98)	**68 more per 1000** (from 57 more to 79 more)	⊕⊕⊕⊕High
Hospital stay											
24	OS	No	Serious[a]	No	No	No	9038	7920	-	SMD **0.14 higher** (0.05 lower to 0.23 higher)	⊕⊕⊝⊝ Low
Sepsis											
17	OS	No	No	No	No	No	1237/14,050 (8.8%)	538/8797 (6.1%)	**RR 1.37** (1.24 to 1.51)	**23 more per 1000** (from 15 more to 31 more)	⊕⊕⊕⊝Moderate

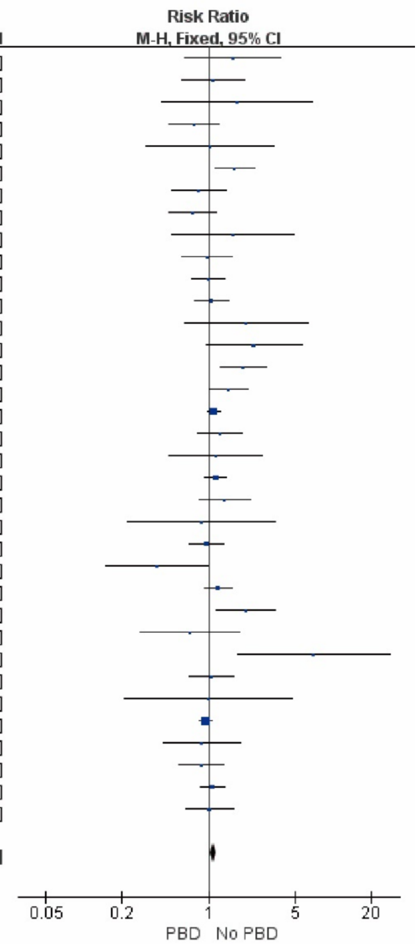
RoB, Risk of bias; PB, Publication bias; PBD, preoperative biliary drainage; OS, Observational studies; SMD, Standardized Mean Difference; RR, Risk Ratio

[a] The included studies may have inconsistencies in this results due to regional and institutional differences

A

Study or Subgroup	PBD Events	PBD Total	No PBD Events	No PBD Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Arkadopoulos 2014	11	76	7	76	0.4%	1.57 [0.64, 3.84]
Bademci 2021	14	48	20	75	0.8%	1.09 [0.61, 1.95]
Bhatti 2020	5	66	3	67	0.2%	1.69 [0.42, 6.80]
Cavell 2013	24	220	41	289	1.8%	0.77 [0.48, 1.23]
Cazauran 2017	4	26	6	40	0.2%	1.03 [0.32, 3.29]
Chen 2021	23	95	189	1270	1.4%	1.63 [1.11, 2.38]
Endo 2019	29	179	22	113	1.4%	0.83 [0.50, 1.37]
Farooqui 2022	35	389	40	333	2.2%	0.75 [0.49, 1.15]
Furukawa 2015	6	46	5	60	0.2%	1.57 [0.51, 4.81]
Gavazzi 2016	25	88	26	90	1.3%	0.98 [0.62, 1.56]
Huang 2015	39	100	66	170	2.5%	1.00 [0.74, 1.37]
Lee 2017	99	569	46	280	3.2%	1.06 [0.77, 1.46]
Liu 2015	8	47	4	47	0.2%	2.00 [0.65, 6.19]
Mola 2014	11	53	7	78	0.3%	2.31 [0.96, 5.58]
Nakeeb 2016	59	314	27	274	1.5%	1.91 [1.25, 2.92]
Ochoa 2020	180	3467	34	952	2.7%	1.45 [1.01, 2.08]
Okano 2019	444	1964	438	2137	21.6%	1.10 [0.98, 1.24]
Ozgun 2021	86	574	28	231	2.1%	1.24 [0.83, 1.84]
Pamecha 2019	8	69	11	108	0.4%	1.14 [0.48, 2.69]
Pastena 2018	159	714	152	786	7.5%	1.15 [0.94, 1.40]
Ray 2021	29	175	28	229	1.2%	1.36 [0.84, 2.19]
Roberts 2017	5	61	3	32	0.2%	0.87 [0.22, 3.43]
Sahora 2016	66	500	68	500	3.5%	0.97 [0.71, 1.33]
Shen 2020	5	40	13	40	0.7%	0.38 [0.15, 0.98]
Shin 2019	124	831	92	737	5.0%	1.20 [0.93, 1.54]
Stiff 2011	26	118	18	162	0.8%	1.98 [1.14, 3.44]
Strom 2016	10	129	7	64	0.5%	0.71 [0.28, 1.78]
Subasi 2022	22	75	2	47	0.1%	6.89 [1.70, 27.98]
Uemura 2015	56	573	33	359	2.1%	1.06 [0.71, 1.60]
Wang 2021	3	48	3	48	0.2%	1.00 [0.21, 4.71]
Werba 2021	643	3900	336	1945	23.1%	0.95 [0.85, 1.08]
Yanagimoto 2014	15	112	11	73	0.7%	0.89 [0.43, 1.83]
Yang 2019	27	183	70	420	2.2%	0.89 [0.59, 1.33]
Yu 2024	100	877	208	1965	6.6%	1.08 [0.86, 1.35]
Zhu 2023	38	98	19	50	1.3%	1.02 [0.66, 1.57]
Total (95% CI)		**16824**		**14147**	**100.0%**	**1.09 [1.03, 1.15]**
Total events	2438		2083			

Heterogeneity: Chi² = 50.93, df = 34 (P = 0.03); I² = 33%
Test for overall effect: Z = 3.01 (P = 0.003)



B

Study or Subgroup	PBD Events	PBD Total	No PBD Events	No PBD Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Arkadopoulos 2014	0	76	1	76	0.7%	0.33 [0.01, 8.06]
Cavell 2013	1	220	6	289	2.5%	0.22 [0.03, 1.81]
Cazauran 2017	0	26	2	40	1.0%	0.30 [0.02, 6.08]
Farooqui 2022	11	389	46	333	23.9%	0.20 [0.11, 0.39]
Gavazzi 2016	3	88	8	90	3.8%	0.38 [0.11, 1.40]
Huang 2015	6	100	8	170	2.9%	1.27 [0.46, 3.57]
Lee 2017	9	569	2	280	1.3%	2.21 [0.48, 10.18]
Liu 2015	2	47	0	47	0.2%	5.00 [0.25, 101.43]
Nakeeb 2016	33	314	16	274	8.2%	1.80 [1.01, 3.20]
Pamecha 2019	2	69	1	108	0.4%	3.13 [0.29, 33.87]
Pastena 2018	29	714	46	786	21.1%	0.69 [0.44, 1.09]
Ray 2021	2	175	9	229	3.8%	0.29 [0.06, 1.33]
Roberts 2017	3	61	1	32	0.6%	1.57 [0.17, 14.52]
Sahora 2016	11	500	11	500	5.3%	1.00 [0.44, 2.29]
Shen 2020	0	40	1	40	0.7%	0.33 [0.01, 7.95]
Shin 2019	3	831	4	737	2.0%	0.67 [0.15, 2.96]
Stiff 2011	4	118	4	162	1.6%	1.37 [0.35, 5.38]
Wang 2021	0	48	1	48	0.7%	0.33 [0.01, 7.98]
Yanagimoto 2014	2	112	1	73	0.6%	1.30 [0.12, 14.12]
Yang 2019	1	183	2	420	0.6%	1.15 [0.10, 12.58]
Yu 2024	22	877	59	1965	17.5%	0.84 [0.52, 1.35]
Zhu 2023	2	98	1	50	0.6%	1.02 [0.09, 10.98]
Total (95% CI)		**5655**		**6749**	**100.0%**	**0.74 [0.60, 0.91]**
Total events	146		230			

Heterogeneity: Chi² = 37.92, df = 21 (P = 0.01); I² = 45%
Test for overall effect: Z = 2.89 (P = 0.004)

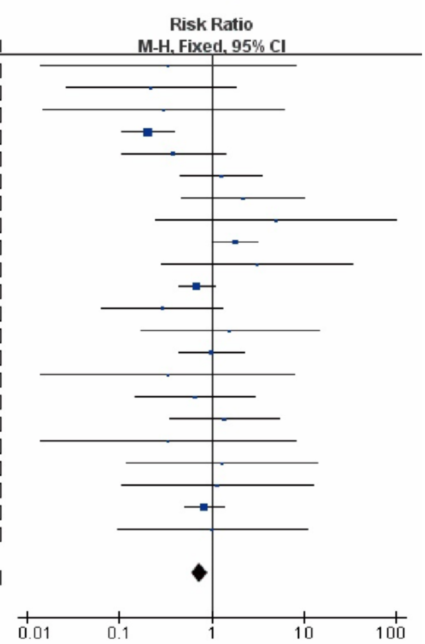


Fig. 2 Forest plot of postoperative (**A**) Pancreatic fistula. (**B**) Bile leak

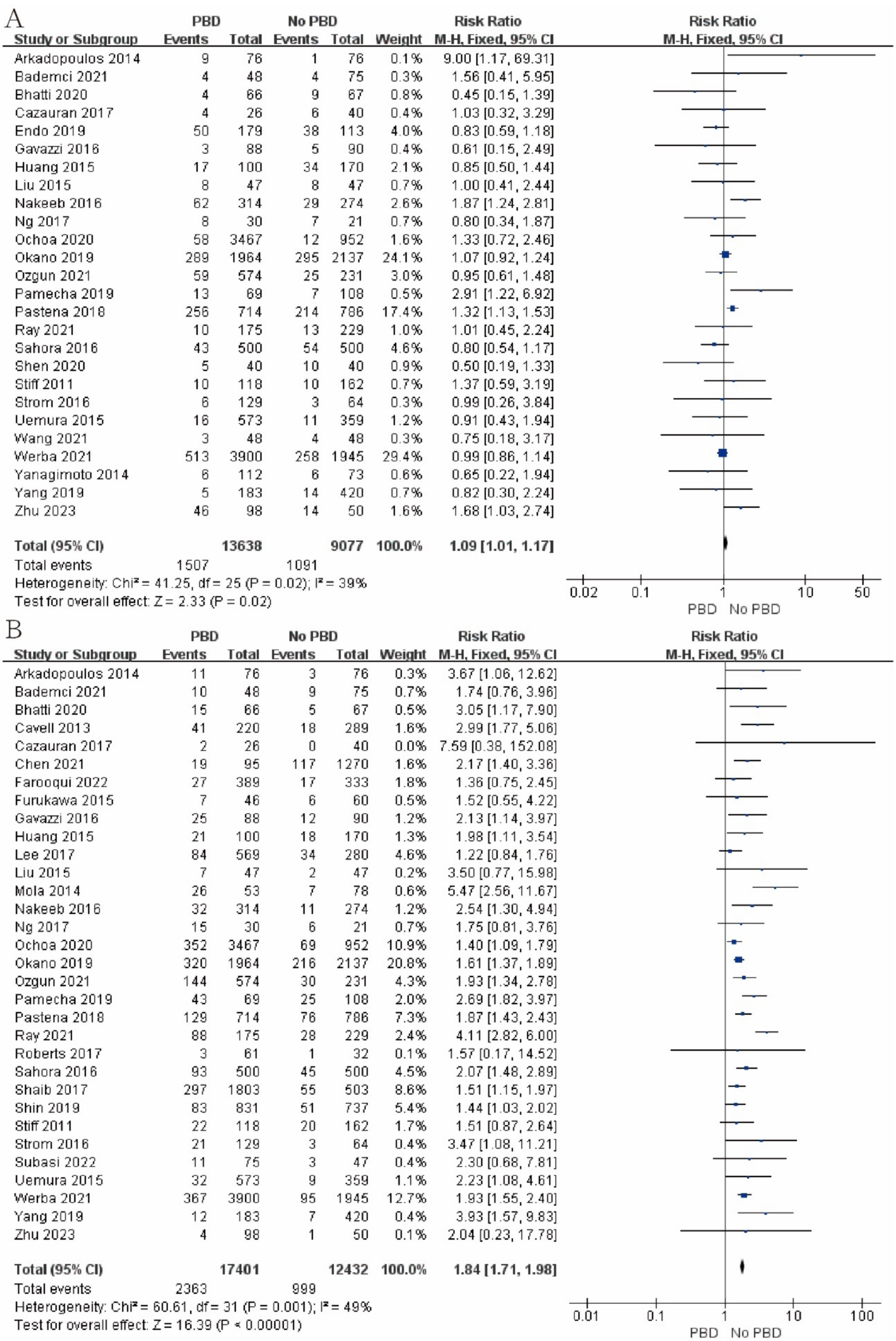


Fig. 3 Forest plot of (**A**) Intra-abdominal infection. (**B**) Surgical site infection

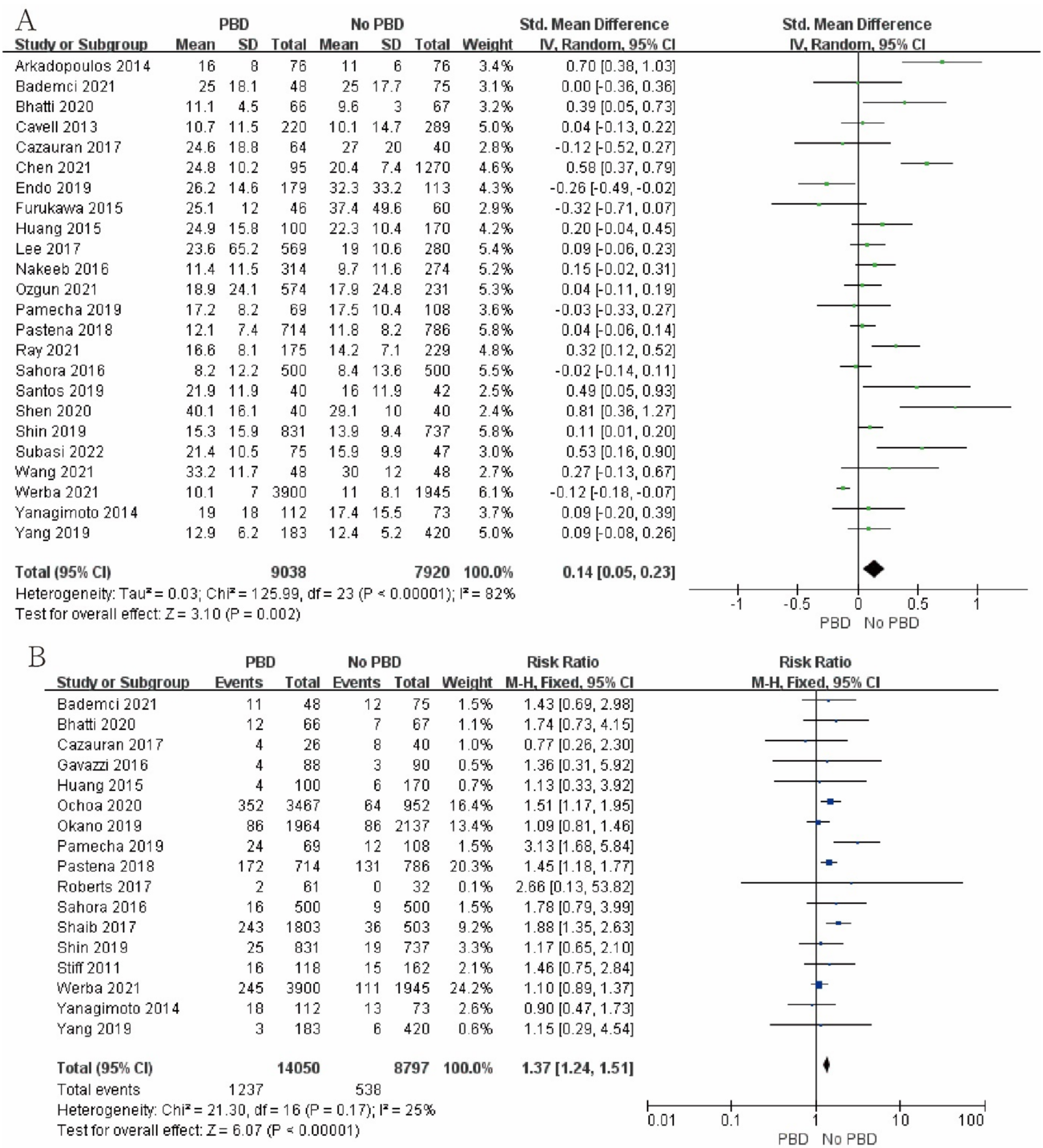


Fig. 4 Forest plot of (**A**) Hospital stay. (**B**) Sepsis

Table 3 Other outcomes and statistical results

Outcomes	Studies	Participants	Risk ratio	95% CI	*p*-value	Corresponding figure
Delayed gastric emptying	26	27,039	0.97	0.90–1.03	0.32	eFigure 1
Pneumonia	14	16,248	1.03	0.87–1.22	0.77	eFigure 2
Post pancreatectomy hemorrhage	24	13,629	1.03	0.90–1.19	0.65	eFigure 3
Overall mortality	28	25,087	1.08	0.91–1.29	0.38	eFigure 4

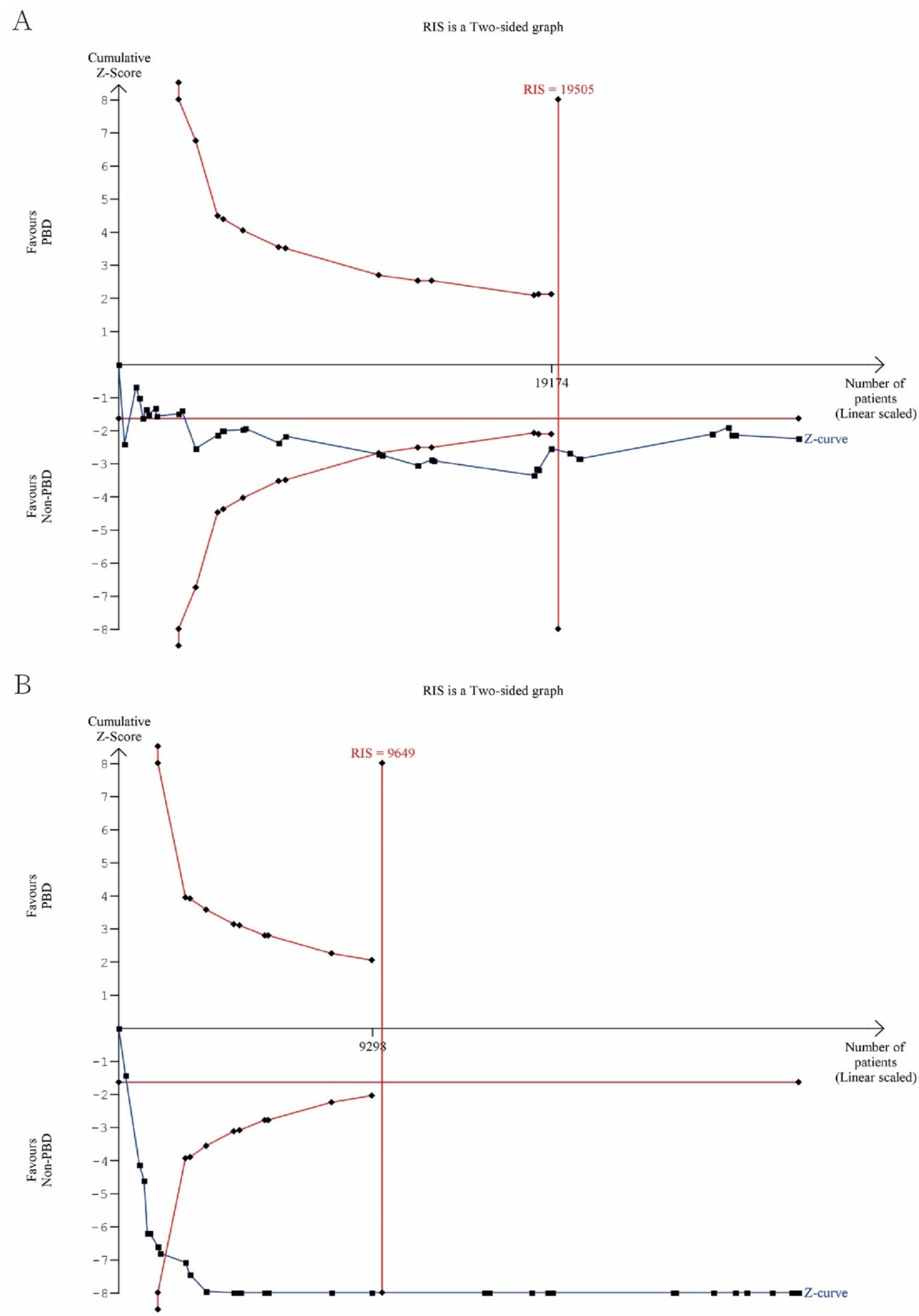


Fig. 5 Trial sequential analysis of postoperative (**A**) pancreatic fistula; (**B**) surgical site infection

pancreatic fistula or intra-abdominal infection. The GRADE evaluation and TSA results indicate that our research provides valuable medical evidence. Additionally, clinical heterogeneity was present, with potential sources of variation stemming from differences in disease types among the patients. Although most participants had pancreatic cancer, a significant number had other types of tumors, such as ampullary cancer and distal bile duct tumors. The pathophysiological mechanisms of obstructive jaundice differ among various tumor types, and the variability in the physical conditions of these patients could contribute to the observed heterogeneity. However, because our study included multiple disease types, an effective subgroup analysis could not be performed.

The primary cause of obstructive jaundice is hyperbilirubinemia, which results from bile duct obstruction and is closely associated with biliary hypertension. In cases of malignant tumors, prolonged biliary obstruction contributes to a chronic inflammatory state and metabolic consumption, further compromising the patient's overall condition. The impact on the body includes a series of functional disorders such as liver and kidney function damage, abnormal coagulation function, intestinal flora shift, and decreased immunity [35]. The traditional empirical medical concept believes that PBD can improve patients' tolerance for anesthesia and surgery, and reduce the occurrence of postoperative complications [2]. However, subsequent studies have shown that PBD increases the risk of complications such as wound infection and sepsis. This may be attributed to the disruption of the sphincter of Oddi's barrier function by most endoscopic drainage procedures, leading to bile contamination. In addition, the invasive operation of PBD itself will also bring new complications such as hemorrhage, infection, pancreatitis, electrolyte imbalance, etc. In severe cases, it will even promote tumor progression and metastasis, resulting in patients losing the opportunity for surgery [36, 57, 58].

Limitations

Although this is the largest meta-analysis comparing PBD and non-PBD, incorporating relatively recent literature, all included studies are retrospective cohort studies. This study design inherently carries bias risks, such as selection bias and information bias. In addition, due to the limitation of included literature, this study lacks the evaluation of long-term results. Therefore, we still need a multicenter randomized controlled trial. Finally, although we took multiple approaches to explore the sources of heterogeneity, it is undeniable that there are still confounding factors that cannot be eliminated that affect the results. For example, different regions and institutions have different surgeon experience and different standards of care. Although this does not affect the reliability of our results.

Conclusion

PBD before PD does not provide clear benefits to all patients and is associated with an increased risk of postoperative complications, including pancreatic fistula, intra-abdominal infection, surgical site infection, and sepsis, while only reducing the risk of bile leak. Given these findings, routine PBD should not be recommended, particularly for younger patients (< 65 years) with mild to moderate jaundice and no severe symptoms. However, PBD may be beneficial in select high-risk patients, such as those over 65 years old with severe infections, progressive jaundice, or a high risk of postoperative biliary leakage.

Emerging strategies, such as robotic-assisted PD and extending the interval between PBD and PD, have shown potential benefits in improving physiological recovery and reducing postoperative infectious complications. Future studies should further explore patient selection criteria, optimal PBD duration, and surgical approaches to refine clinical guidelines. Based on our findings and existing literature, an individualized approach to PBD should be emphasized to balance the risks and benefits for each patient.

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

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Not acceptable.

Author contributions
Bo Zhang and Zhengfeng Wang designed the study, Zekun Lang was responsible for the main statistical analysis, Bo Zhang and Kexiang Zhu were responsible for the manuscript writing, Wei Luo, Zhenjie Zhao and Zeliang Zhang were respectively responsible for part of the data extraction and literature screening.

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Data availability
The data used in this study are accessible upon reasonable request to the corresponding author.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Clinical trial number
Not applicable.

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