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SYSTEMATIC REVIEW

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The impact of pancreatic duct stent placement on the clinically relevant postoperative pancreatic fistula rate for high-risk anastomoses: a systematic review and meta-analysis

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Abstract

Background To evaluate the impact of pancreatic duct stent outcomes on the prognosis of postoperative pancreatic fistula in patients with high-risk anastomoses.

Methods Randomized controlled trials were identified through comprehensive searches in Cochrane Library, Web of Science, Embase, and PubMed databases. Cochrane Collaboration's tool RoB2 was used to evaluate study quality. The presence of non-dilated main pancreatic duct and soft gland texture were used to identify high risk anastomoses. The primary outcome measured was clinically relevant postoperative pancreatic fistula rate. The heterogeneity and sensitivity analyses were performed.

Results Six studies ($n=476$) were included. The pooled data showed no significant difference in the clinically relevant postoperative pancreatic fistula rate between stented and nonstented groups for at least one high-risk factor out of two factors selected ($p=0.234$). Patients with non-dilated main pancreatic duct who received stent placement had a lower clinically relevant postoperative pancreatic fistula rate (RR = 0.582, 95%CI = 0.383–0.883, $p=0.011$). In contrast, patients with soft pancreatic texture showed no significant difference between two groups ($p=0.879$). After removing the study identified by sensitivity analysis as the origin of heterogeneity from general cohorts, the stented group had a lower clinically relevant postoperative pancreatic fistula rate (RR = 0.608, 95%CI = 0.413–0.895, $p=0.012$).

Conclusions There is a lack of robust evidence to support pancreatic duct stent placement for high-risk anastomoses. Nevertheless, stent implantation may be beneficial for patients with non-dilated pancreatic duct or external stent drainage.

Trial registration The protocol was registered in advance with PROSPERO (CRD42023471943).

Keywords Pancreatic fistula, Pancreatectomy, Pancreatic duct stents

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Introduction

Pancreatectomy is widely recognized as an effective treatment for pancreatic tumors. However, despite advancements in surgical techniques and perioperative management, postoperative pancreatic fistula (POPF) is still a significant challenge that impedes the widespread use of pancreatectomy. A universal definition of pancreatic fistula was first established by the International Study Group of Pancreatic Fistula (ISGPF) in 2005 and subsequently revised in 2016 [1, 2]. Clinically relevant postoperative pancreatic fistula (CR-POPF), namely the B + C grade of pancreatic fistula, requires the adjustment of clinical management. Thus, it has become a major concern of interest in the field of pancreatic surgery.

Rather than simply dealing reactively with the obstacles posed by CR-POPF, proactive preventive measures are highly recommended. A substantial and growing body of literature has contributed to predicting the risk of pancreatic fistula. Nowadays, numerous studies have confirmed that non-dilated main pancreatic duct (MPD ≤ 3 mm) and soft pancreatic texture are the most influential risk factors. In addition, much of the current literature has focused on upgrading surgical techniques, and the placement of pancreatic duct stents has attracted great attention.

Existing studies have established a consensus that the anastomosis following pancreatectomy should be stratified based on different risk classifications, necessitating the corresponding application of various surgical techniques. However, based on the current evidence, the efficacy of pancreatic duct stent placement in patients with high-risk anastomoses remains uncertain. This study aims to investigate the impact of pancreatic duct stent placement on the CR-POPF rate in patients with high-risk anastomoses.

Methods

Protocol and registration

This study was performed based on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) 2020 statement for conducting, reporting and updating systematic reviews and meta-analyses (Supplementary Appendix 1) [3]. The AMSTAR (Assessing the methodological quality of systematic reviews) Guidelines was used to aid the methodological quality (Supplementary Appendix 2) [4]. The protocol was registered in advance with PROSPERO. The flow diagram showing the selection of articles is presented in Fig. 1.

Eligibility criteria

The population-intervention-comparison-outcomes-study design (PICOS) model was followed to define eligibility criteria [5]:

Population patients undergoing pancreatectomy and subsequent pancreaticojejunostomy or pancreaticogastrostomy with soft pancreatic texture or MPD ≤ 3 mm.

Intervention pancreatic stent of any diameter placed internally or externally.

Comparison omission of placement of any pancreatic stent.

Outcomes described below in the next section.

Study Randomized controlled trials (RCTs). Studies where missing outcome data could not be calculated, imputed or obtained were excluded.

The inclusion criteria were as follows (1) cohorts that included patients undergoing pancreatectomy with and without pancreatic stent placement; (2) cohorts that directly reported CR-POPF rates or provided data that could be used to calculate rates; and (3) RCTs.

The exclusion criteria were as follows (1) cohorts that did not provide sufficient data on high-risk anastomoses, which are defined as having a soft pancreatic texture or MPD ≤ 3 mm; and (2) cohorts that did not report the essential outcomes of each group separately.

Outcome measures

The primary outcome was the CR-POPF rate, defined as the grade B + C fistula following ISGPS. This involves the increase of amylase activity in any drainage fluid on or after postoperative day 3 related to clinically relevant conditions requiring a change in the expected postoperative pathway management, or further leading to organ failure or reoperation. According to the original 2005 ISGPS classification, the POPF severity grade of the included studies was regraded using the 2016 updated ISGPS definition. Biochemical leakage, previously grade A POPF, was excluded. POPF using local definitions was still included if such analysis was possible.

Information sources and search

Four databases, including Cochrane Library, Embase, Web of Science and PubMed, were systematically searched for eligible studies as of October 2023. Search strategies included keywords such as “pancre*”, “fistula*”, “leak*”, “stent*”, “drain*”, etc. The detailed machine search strategy for each database is presented in Supplementary Table 1. The search was conducted without language restriction since data inception. The manual search yielded no works of interest but provided full texts of the identified articles.

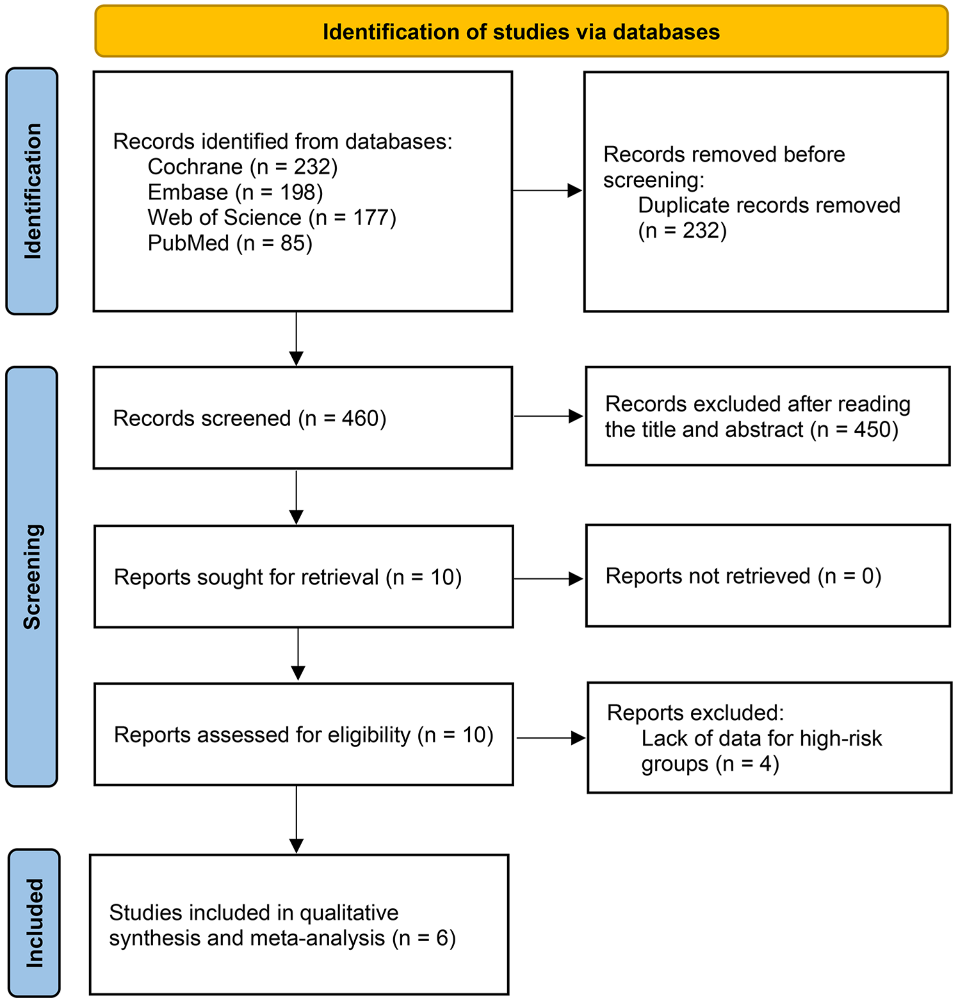

Fig. 1 PRISMA flow diagram of study selection

Study selection
All studies were independently screened by two researchers given the established inclusion and exclusion criteria, referring to the title and abstract, followed by the full text. No other researchers were involved as consensus was reached in all cases.

Data extraction
A standardized format was used by two authors to independently extract data that included various factors such as year, country/district, number of centers, age, gender, BMI, stent drainage (internal or external), type of stent, resection technique, anastomosis technique, prophylactic octreotide, biliary drainage, main pancreatic duct diameter, pancreatic texture, sample size, number of cases with CR-POPF and CR-POPF assessment scale. They were all resolved by consensus in case of any discrepancies. When demographic and clinical characteristics were provided in general cohorts instead of high-risk groups, data was still extracted to represent the intended groups.

Assessment of risk of bias
Quality of studies
The Cochrane Collaboration's tool RoB2 was used for quality assessment [6]. A colored risk of bias graph was generated in Supplementary Fig. 1. A rating of "low risk", "high risk" or "some concerns" was assigned to each of the five bias domains: randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. An "overall" risk of bias rating was also created by determining the composite performance of the five domains.

Publication bias
Harbord's test was used without the visual examination of funnel plots to evaluate the potential of publication bias, due to the binary outcome data and small scale of the included studies [7].

Table 1 Demographic characteristics of included studies

Source	Year	Country/ district	No. of centers	Age (years)		Gender (Male/Female)		BMI (Kg/m^2)	
				Stented	Nonstented	Stented	Nonstented	Stented	Nonstented
Winter[a]	2006	USA	1	68 (39–89)	67 (33–88)	32/25	27/29	NS	NS
Poon[*,b]	2007	Hong Kong, China	1	61 ± 12	62 ± 13	31/29	41/19	NS	NS
Kuroki[b]	2011	Japan	1	68.1 ± 11.2	68.2 ± 8.4	13/10	12/10	21.0 ± 2.8	21.9 ± 3.0
Pessaux[b]	2011	France	8	60.8 ± 11.8	60.6 ± 11.8	39/38	47/34	24.6 ± 4	25.2 ± 4.7
Motoi[*,a]	2012	Japan	1	66·0 (33–79)	65·5 (32–80)	26/21	29/17	21·7 (14·3–32·4)	21·5 (16·3–29·3)
Qureshi[*,b]	2018	Pakistan	1	54.25 ± 11.7	51.98 ± 12.5	41/12	31/18	NS	NS

* Data of age, gender and BMI was extracted in the general population as a representation of intended groups

a, a form of median (range) was used; b, a form of mean ± standard deviation was used

NS, not stated

Table 2 Perioperative management details of included studies

Source	Stents drainage	Type of stent	Resection technique	Anastomosis technique	Prophylactic octreotide	Biliary drainage (Yes/No)	
						Stented	Nonstented
Winter	Internal	6 cm of 3.5-8 Fr plastic pediatric feeding tube	12 PD and 101 PPPD	end-to-side PJ	No	NS	NS
Poon[*]	External	3–8 Fr polyvinyl catheter with multiple side-holes	82 PD and 38 PPPD	end-to-side, duct-to-mucosa PJ	No	44/16	34/26
Kuroki	External	5 Fr pancreatic drainage tube with multiple side holes	5 PD, 27 PPPD, and 13 others[a]	end-to-side, duct-to-mucosa PJ	NS	NS	NS
Pessaux	External	3–6 Fr polyvinyl catheter with multiple side-holes	138 PD and 20 PPPD	PJ or PG	Yes	24/53	22/59
Motoi[*]	External	5 Fr polyvinyl catheter with multiple side holes	86 SSPPD and 7 others[b]	ductto-mucosa, two-layer PJ	No	24/23	28/18
Qureshi[*]	External	silastic feeding tube of appropriate size	102 PD	mucosa to mucosa, single-layer PJ	No	NS	NS

* Data of biliary drainage was extracted in the general population as a representation of intended groups

a, including segmental pancreatectomy, pancreatic head resection with segmental duodenectomy, and duodenum-preserving pancreatic head resection

b, no detailed description in the original article

PD, pancreatoduodenectomy; PPPD, pylorus-preserving pancreaticoduodenectomy; SSPPD, subtotal stomach preserving PD; PJ, pancreaticojejunostomy; PG, pancreaticogastrostomy; NS, not stated

Data synthesis

All statistical analyses were conducted using the STATA software. A random-effect model (Mantel-Haenszel statistical method) was used to determine the pooled outcome measures. The 95% confidence intervals (95% CI) and summary risk ratios (RRs) were estimated. A combination of the L'Abbe plot and Higgins's I-square (I2) statistic was implemented to measure the proportion of variability potentially attributed to heterogeneity [8]. A post-hoc sensitivity analysis was conducted as well.

Results

Study selection and identification

A total of 692 citations were identified in this systematic search. After removing 232 duplicates, the title and abstract of the remaining 460 unique studies were screened, resulting in the exclusion of 450 studies. The remaining ten articles were screened for full text, four of which were rejected due to the lack of data on high-risk anastomoses. Ultimately, six studies met the final eligibility criteria for the systematic review and were used for data extraction [9–14]. The flow diagram is depicted in Fig. 1.

Among them, two studies met the eligibility criteria for cohorts with pancreatic duct diameter less than 3 mm [9, 10], while another two studies were included due to the identification of soft pancreatic texture [11, 12]. One study provided insights for a group of patients with simultaneously non-dilated MPD and soft pancreas [13]. The most recent study reported the circumstances of subgroups with the two risk factors, from which two independent cohorts were identified [14]. To avoid repeatedly including the same patients whose data simultaneously contributed to both cohorts, the pooled effect was calculated using only one cohort of Qureshi's study. Considering that the measurement of MPD size is more objective, the cohort of non-dilated MPD was chosen for the pooled analysis instead of the soft cohort.

Study characteristics

As respectively illustrated in Tables 1, 2 and 3, the six included trials exhibited diversity in demographic

Table 3 Clinically relevant postoperative pancreatic fistula in all included cohorts

Source	MPD diameter	Pancreatic texture	Sample size		No. of CR-POPF		CR-POPF assessment scale
			Stented	Nonstented	Stented	Nonstented	
Winter	NS	Soft	57	56	17	9	ISGPF
Poon	≤ 3 mm	NS	28	32	2	6	Local definition
Kuroki	NS	Soft	23	22	5	6	ISGPF
Pessaux	<3 mm	Soft	77	81	19	29	ISGPF
Motoi	≤ 3 mm	NS	21	20	2	8	ISGPF
Qureshi	≤ 3 mm	ES	24	9	4	3	ISGPF
Qureshi	ES	Soft	34	25	6	3	ISGPF

MPD, main pancreatic duct; CR-POPF, clinically relevant postoperative pancreatic fistula

NS, not stated; ES, else stated

ISGPF, the 2005 version, the presence of amylase-rich fluid (greater than three times the upper limit of normal in the serum) of any measurable volume on or after postoperative day 3

Local definition, >10 mL per day amylase-rich fluid three days after surgery

characteristics, perioperative management, and CR-POPF assessment scale. Five of the trials were published before 2016, while only one was published after 2016 when ISGPS released an update to the definition of pancreatic fistula. Except for one study, which was designed to be a multi-center trial constituting eight centers, the remaining trials were single-center investigations. The mean age of patients ranged from 54.25 to 68.1 years in the stented group and from 51.98 to 68.2 years in the nonstented group. Other basic demographics are presented in Table 1. Most studies conducted conventional or pylorus-preserving pancreaticoduodenectomy (PD or PPPD) with pancreaticojejunostomy (PJ). Concerning the drainage selection, only one study adopted the internal way, while the others preferred the external stents. Details of other perioperative management are shown in Table 2. The included studies had a sample size ranging from 33 to 158, with a total of 476 patients (240 with stents versus 236 without stents) enrolled. Five studies applied the CR-POPF assessment scale according to the 2005 version of the ISGPS definition, while only one study used the local definition requiring more severe conditions. Other specific information about CR-POPF for each cohort is displayed in Table 3.

Risk of bias of included studies

Quality assessment

Supplementary Fig. 1 summarizes the quality assessment of individual studies according to the Cochrane Collaboration's tool RoB2. Of all six RCTs, five were judged as having a low risk of bias, while the other one was rated as having some concerns. Due to the lack of double-blinding, the outcome measurement raised concerns in most studies, whereas the randomization process was well done.

Publication bias

No evidence of publication bias was observed when conducting the Harbord's test (Supplementary Fig. 2). The p-values for non-dilated MPD patients, soft texture patients, and patients with at least one high-risk factor were 0.177, 0.556, and 0.433, respectively.

Primary outcomes

By pooling all six studies investigating patients with at least one high-risk factor, no significant difference was found in the CR-POPF rate between the stented and nonstented groups (stented group: 49/230, 21.3% versus nonstented group: 61/220, 27.7%) (RR = 0.716, 95%CI = 0.413–1.241, $p = 0.234$; Fig. 2A), with some heterogeneity (I2 = 49.1%, $p = 0.080$; Supplementary Fig. 3A). Notably, consistent results were observed no matter which high-risk cohort reported by Qureshi et al. was included (including the cohort of soft pancreatic texture: RR = 0.815, 95%CI = 0.467–1.424, $p = 0.473$; I2 = 50.5%, $p = 0.072$; Supplementary Fig. 4A). In addition, when only RCTs with low risk of bias were included, there was still no significant difference in CRPOPF rate (RR = 0.741, 95%CI = 0.395–1.388, $p = 0.349$; I2 = 57.2%, $p = 0.053$; Supplementary Fig. 4B).

Furthermore, four cohorts of patients with MPD less than 3 mm were investigated, finding that the CR-POPF rate was lower in the stented group (27/150, 18%) compared to the nonstented group (46/142, 32.4%) (RR = 0.582, 95%CI = 0.383–0.883, $p = 0.011$; Fig. 2B). Heterogeneity was low (I2 = 0.0%, $p = 0.497$; Supplementary Fig. 3B).

In four cohorts investigating patients with soft pancreas, there was no effect of stent placement on the RR of CR-POPF rate (stented group: 47/191, 24.6% versus nonstented group: 47/184, 25.5%) (RR = 1.044, 95%CI = 0.602–1.811, p = 0.879; Fig. 2C) without significant heterogeneity (I2 = 46.3%, p = 0.134; Supplementary Fig. 3C).

Sensitivity analyses

The stability and reliability were assessed in the sensitivity analysis (Supplementary Fig. 5). It was found that

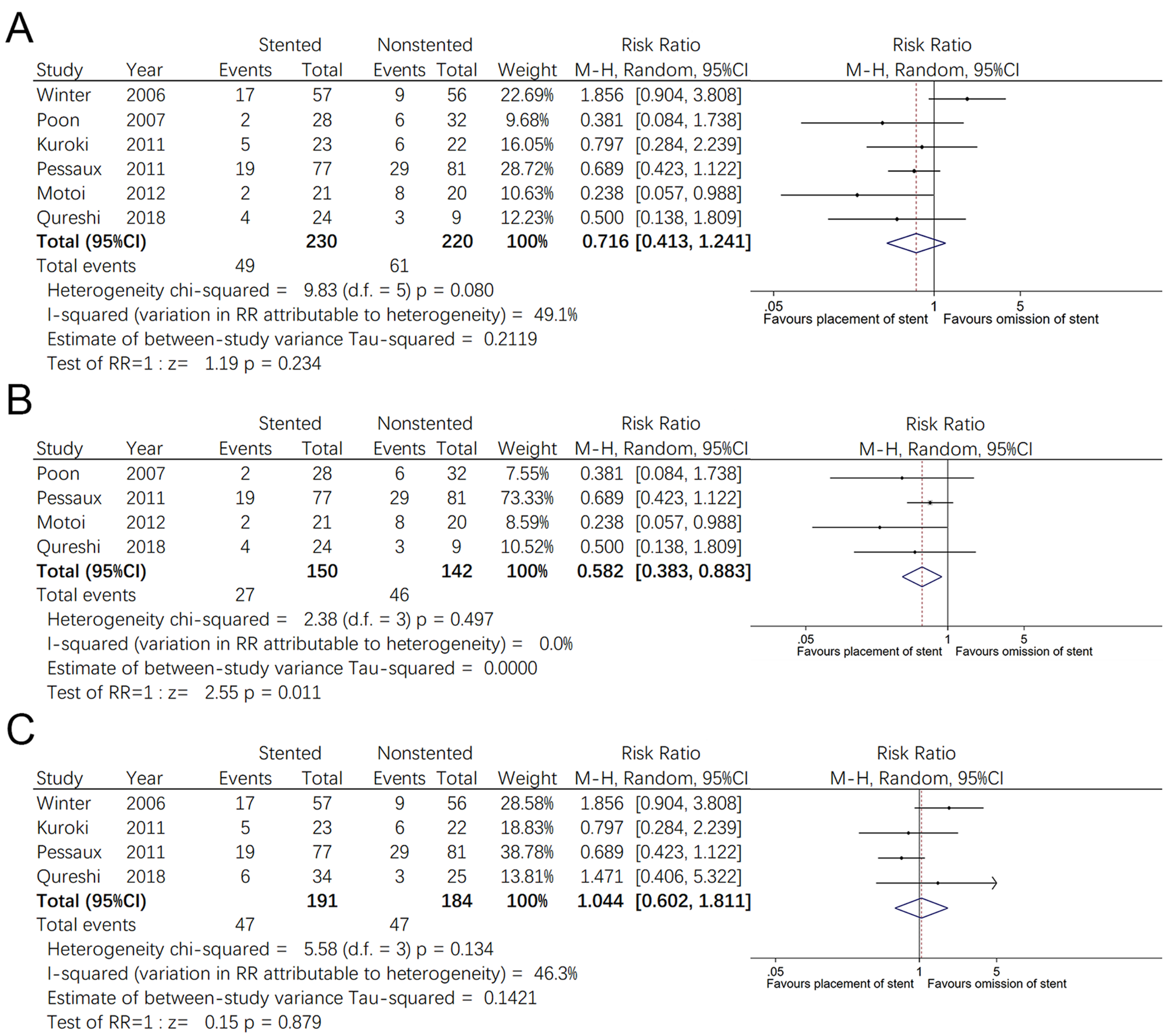

Fig. 2 Forest plots comparing CR-POPF (**A**) in the general high-risk cohort, (**B**) in the cohort with pancreatic duct diameter less than 3 mm, and (**C**) in the cohort with soft pancreatic texture

the removal of any study did not influence the lower CR-POPF rate of stented patients with non-dilated MPD. Similarly, the nonsignificant difference remained consistent for patients with soft texture. Interestingly, when removing Winter's study from cohorts with at least one high-risk factor, the advantage of stent implantation emerged with a pooled RR of 0.608 (95%CI = 0.413–0.895, $p = 0.012$) and with no evidence of statistical heterogeneity (I2 = 0.0%, $p = 0.612$). Subgroup analysis was not performed due to the insufficient number of available studies.

Discussion

This meta-analysis focused on CR-POPF in patients with high-risk anastomoses, with or without stent implantation. Pancreatectomy has long been a traditional treatment for periampullary carcinoma, especially pancreatic head tumors [15, 16]. With the continuous improvement of surgical and perioperative management techniques, the perioperative mortality rate of PD has reduced to ≤ 3% in professional pancreatic surgery centers, compared to 30–50% in the early stages [17]. However, complications still occur in 25–50% of cases, and POPF is the most common and lethal [18, 19]. The clinically relevant postoperative pancreatic fistula proposed by ISGPF, constituting grade B and C fistula, causes changes in clinical strategies. Considering that additional treatment can prolong hospital stays and increase medical expenses for patients and hospitals, CR-POPF is identified as the primary outcome aiming to explore optimal cost-effectiveness management.

Numerous studies have made efforts to stratify anastomoses to identify patients with a high risk of developing CR-POPF. The 10-point Fistula Risk Score (FRS) has been extensively validated and is one of the most preferred risk assessment models [20]. It considers four variables: intraoperative blood loss, pancreatic duct diameter, pathology, and gland texture. The alternative Fistula Risk Score (a-FRS) was developed after external validation of FRS based on three readily available variables: pancreatic texture, duct diameter, and BMI [21]. Minimally invasive pancreatoduodenectomy was further included in the updated alternative Fistula Risk Score (ua-FRS) [22]. Apparently, MPD size and pancreatic texture maintained an unassailable position in the prediction of POPF. Thus, the ISGPS recommends reporting the two most prominent inherent risk factors for better comparability of study findings, clinical decision-making, and auditing [23]. This study adopted these two risk factors to identify patients at high risk of developing POPF.

Despite the extensive research that has been conducted to develop a universal risk assessment model that can assist in stratifying anastomoses, the strategies of surgical techniques that adapt to the risk classification remain elusive [24]. One of the most controversial strategies is pancreatic duct stenting. Some studies suggested that stents significantly reduce the rate of POPF, while others suggested that stents have no effect and may even increase the rate of POPF [25–28]. Several meta-analyses compared the outcomes of various stent settings after PD, leaving a growing controversy regarding whether or how to use pancreatic duct stents appropriately [29–34]. Therefore, this meta-analysis was designed to explore the potential impact of pancreatic duct stents in high-risk anastomoses.

This study uncovered intriguing insights. In a general high-risk population, a comparable rate of CR-POPF was detected between stented and nonstented groups, although there was some heterogeneity. Because of Winter's unique internal drainage method, it may account for a substantial proportion of heterogeneity. When focusing solely on external drainage, the advantage of stent placement emerges, presenting a nearly vanishing heterogeneity. It is commonly assumed that the longer external stent, compared to the relatively shorter internal stent, isolates pancreatic juice from bile more thoroughly to avoid the activation of pancreatic enzymes, further leading to POPF. In addition, the external stent provides protection for anastomosis throughout the whole healing process, and the chance of stent migration is remarkably reduced, especially in the first few days after operation when the protection of anastomosis is most required.

The situation differed in specific risk factor cohorts. There was evidence of a lower CR-POPF rate for patients with non-dilated MPD who received stent implantation, with no difference in the soft texture cohort. A possible explanation is that stenting directly addresses the primary cause of POPF for patients with non-dilated MPD, namely the narrow and obstructed outflow tract. Conversely, stenting merely plays an auxiliary role in patients with soft pancreas.

Caution is needed when interpreting the results. First, studies included in the meta-analysis failed to uniformly use a standard definition of CR-POPF, making it difficult to compare different populations. In this regard, Poon's study adopted a local definition which requires a drainage volume of more than 10 mL per day collected from peripancreatic drains. Strict conditions inevitably led to a decrease in the occurrence of events. Second, for the cohort with at least one high-risk factor, the statistical analysis revealed some heterogeneity. Although this heterogeneity may be attributed to a single study that employed a unique internal stent drainage method, the interpretation of results still needs caution. Third, the majority of studies provided data on the intended population through subgroup analysis with a relatively weak effective power brought by the small sample size. Finally, due to a limited number of studies included in this analysis, it is unable to conduct further analysis stratified by various perioperative settings.

Conclusions

In conclusion, patients at a high risk of developing postoperative pancreatic fistula may not benefit from the stent placement. However, in case of the pancreatic duct less than 3 mm or external drainage, careful consideration is required. Large and meticulous-designed randomized prospective trials are warranted to illuminate the impact of stent implantation on clinically relevant postoperative pancreatic fistula rate for high-risk anastomoses after pancreatectomy.

Abbreviations

POPF	Postoperative pancreatic fistula
ISGPF	International Study Group of Pancreatic Fistula
CR-POPF	Clinically relevant postoperative pancreatic fistula
MPD	Main pancreatic duct
PICOS	Population-intervention-comparison-outcomes-study
RCTs	Randomized controlled trials
CI	Confidence intervals
RR	Risk ratio
I2	Higgins's I-square
PD	Conventional pancreaticoduodenectomy
PPPD	Pylorus-preserving pancreaticoduodenectomy
PJ	Pancreaticojejunostomy
FRS	Fistula Risk Score

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12876-025-03700-w.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

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Author contributions

J.W. and Y.D. are the guarantors of integrity of the entire study and designed the study concepts; Y.D., X.L. and L.J. participated in the acquisition, analysis, or interpretation of data; Z.L., K.J, Y.M. and J.W participated in the revising of manuscript; Y.D. drafted and edited the manuscript. J.W. approved the final version of the manuscript. All authors contributed to the article and approved the submitted version.

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Data availability

All data generated and analyzed is included in this publication.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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