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Prophylactic abdominal drainage does not reduce morbidity and mortality after distal pancreatectomy: A systematic review and meta-analysis of randomized controlled trials

Claudio Ricci, MD, PhD[a,b,*], Laura Alberici, MD[a], Vincenzo D'Ambra, MD[a,b], Carlo Ingaldi, MD, PhD[a], Marco Fichera, MD[a,b], Federico Pisani, MD[a,b], Riccardo Casadei, MD[a,b]

[a] *Division of Pancreatic Surgery, IRCCS Azienda Ospedaliero-Universitaria Di Bologna, Bologna, Italy*
[b] *Department of Internal Medicine and Surgery, Alma Mater Studiorum, University of Bologna, Bologna, Italy*

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ABSTRACT

Background: The study aimed to compare prophylactic drainage with no drain after distal pancreatectomy.
Methods: To identify randomized controlled trials comparing prophylactic drainage versus no drain after distal pancreatectomy, a systematic review was performed through PubMed, the Cochrane Library, and Web of Science. Meta-analysis was performed using a random-effects model. Risk differences and mean differences were calculated. Critical end points were mortality, morbidity, percutaneous redrainage, and relaparotomy. Postoperative pancreatic fistula, postpancreatectomy hemorrhage, delayed gastric emptying, length of stay, and readmission rates were also evaluated.
Results: Three randomized controlled trials were included in the analysis. The 90-day mortality (risk difference −0.01; 95% confidence interval −0.02 to 0.01), major morbidity (risk difference 0.03; 95% confidence interval −0.03 to 0.09), percutaneous drain placement (risk difference 0.02; 95% confidence interval −0.03 to 0.07), and relaparotomy (risk difference 0.02; 95% confidence interval −0.03 to 0.03) risks were similar between the prophylactic drainage and no-drain groups. Postoperative pancreatic fistula rate and length of stay were lower in the no-drain group with a risk difference of 0.09 (95% confidence interval 0.04 to 0.15) and a mean difference of 0.41 (95% confidence interval 0.09 to 0.73). Postpancreatectomy hemorrhage, delayed gastric emptying, and readmission rates were comparable between the 2 groups.
Conclusion: Distal pancreatectomy with or without abdominal drainage has similar mortality, morbidity, and reintervention rates. However, the postoperative pancreatic fistula rate was lower when abdominal drainage was omitted.

Introduction

Intraperitoneal prophylactic drainage after pancreatic resection serves as a security blanket for pancreatic surgeons.[1] It is well established that the postoperative course of pancreatic resections is more complicated than that of other major abdominal surgical procedures, largely due to postoperative pancreatic fistula (POPF).[2] In this context, prophylactic drainage fulfills a dual role: both diagnostic and therapeutic. From a diagnostic standpoint, prophylactic drainage allows for the early identification of POPF and related complications,[3] such as postpancreatectomy hemorrhage (PPH),[4] thus facilitating timely intervention. Therapeutically, it is widely accepted among pancreatic surgeons that prophylactic drainage can alleviate the adverse effects of POPF by enabling the early removal of pancreatic juice and blood from the peritoneal cavity[3] However, the efficacy of prophylactic drainage has not been definitively established, with a recent meta-analysis[5] showing no significant differences in morbidity, mortality, and reintervention rates between the 2 approaches. A key limitation of this meta-analysis was the inclusion of randomized controlled trials (RCTs)

* Corresponding author: Claudio Ricci, MD, PhD, Department of Internal Medicine and Surgery, Alma Mater Studiorum, University of Bologna, Pancreas Unit, Sant'Orsola-Malpighi Hospital, Via Massarenti 9, 40138 Bologna, Italy.
E-mail address: claudio.ricci6@unibo.it (C. Ricci);
Twitter: @claudiochir, @Laualberici

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that involved both pancreaticoduodenectomy (PD) and distal pancreatectomy (DP). In particular, only 1 study[6] for DP was included in the meta-analysis. Indeed, the differences between the 2 procedures are perceived as critical in the pancreatic surgical community,[7,8,] and drain omission seems to be more accepted for DP than for PD. Recently, 2 new randomized studies have been designed to undermine this belief.[9,10] For this reason, a new meta-analysis was planned to clarify the impact of the drain omission policy after DP.

Methods

This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[11] The present meta-analysis was conducted de novo, whereas the literature search was updated from a previous review, without imposing any date restrictions (from database inception to November 30, 2024). The search strategy was initially developed for PubMed (Medline) using the PubMed Search Builder, based on 3 main concepts (pancreatic resection, drain, and RCT). This strategy was then adapted for the Cochrane Library and ISI Web of Science using the SR-Accelerator platform to ensure consistency of search terms across databases (https://sr-accelerator.com/#/). The study is registered on PROSPERO (CRD420250651135). The search string was as follows: ('Pancreatectomy' [MeSH] OR 'pancreatic diseases/surgery' [MeSH] OR pancreatectomy [tiab] OR pancreatic resection [tiab] OR pancreas resection [tiab]) AND ('Drainage' [MeSH] OR drain [tiab] OR drains [tiab] OR drain* [tiab] OR suction [tiab]) AND ((randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR clinical trials as topic [mesh: noexp] OR randomly [tiab] OR random [tiab] OR random* [tiab] OR trial [ti]) NOT (animals [mh] NOT humans [mh])).

Eligibility criteria, items, and risk of bias in individual studies

The criteria were based on the patient, intervention, comparison, outcome (PICO) approach[12]: the population was the patients undergoing DP for benign or malignant lesions; the intervention was the commission of the prophylactic drainage; the control was the prophylactic drainage omission (no-drain group). All studies with a randomized design were included. The following information was described for each study: authors, affiliation and country, year of publication, acronyms if present, registration number, sample size, type and the number of drains, type of tumors, and characteristics of pancreatic remnant. The authors evaluated the importance of outcomes using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.[13] Postoperative 90-day mortality, morbidity defined according to the Clavien-Dindo system,[14] need for percutaneous redrainage, and relaparotomy were considered "critical." Clinically relevant POPF,[2] PPH,[4] delayed gastric emptying (DGE),[15] length of stay (LOS), and readmission were judged important but not critical. The qualitative assessment was performed by 2 authors (L.A. and V.D.) and was based on a revised tool for assessing the risk of bias in randomized trials (RoB 2).[16] Any disagreement was resolved after a collegial discussion. All variables were described using frequencies and percentages or mean and standard deviation (SD). If the study reported median and interquartile ranges, a dedicated statistical algorithm was used to obtain mean and SD.[17,18] When continuous data were reported as median and range, mean and SD were estimated using the Hozo method[17]; when interquartile ranges were provided, the Wan method was applied.[18] The converted data were reported in Excel format as a supplementary file for transparency.

Summary measures and synthesis of results

The meta-analysis was carried out in line with recommendations from the Cochrane Collaboration,[19] and the Mantel-Haenszel random-effects model was used to calculate effect sizes.[20] In accordance with the PROSPERO-registered protocol, a random-effects model was chosen a priori to account for potential clinical and methodologic variability across multicenter RCTs; this choice was maintained regardless of the observed heterogeneity, in line with Cochrane guidance.[19] The meta-analysis was carried out to obtain 2 main measures of risk association: risk difference (RD), and mean difference (MD), for dichotomic and continuous values, respectively. RDs and MDs were reported with a 95% confidence interval (CI). We also calculated the number needed to treat (NNT) for dichotomous outcomes. NNT was obtained by solving the following formula, NNT = 1/RD, which indicates how many patients need to avoid drainage to prevent 1 adverse event. When RD assumes a negative value, NNT becomes the number needed to harm, namely, the number of patients treated with drain omission to observe 1 more adverse event.

Risk of bias across studies and meta-regression analysis

The heterogeneity was reported using I^2 and Cochran Q statistics.[21] The effect of confounding covariates was weighted with a meta-regression analysis only in the presence of significant heterogeneity.[22,23] The evaluation of publication bias was carried out using Egger tests,[24] and a P value <.05 indicated a non-negligible small-study effect. The statistical analysis was carried out using dedicated packages for R (R Core Team, 2021).

Grade assessment of evidence quality

The certainty of evidence for each outcome was assessed using the GRADE approach[13] starting with high certainty for RCTs and downgrading according to the risk of bias, inconsistency, indirectness, imprecision, and publication bias. Imprecision was considered present when 95% CI crossed the line of no effect.

Post hoc leave-one-out sensitivity analysis

To assess the robustness of statistically significant results, a post hoc leave-one-out sensitivity analysis was conducted, omitting 1 study at a time to evaluate its influence on the overall pooled effect.

Results

Studies selection, characteristics, and risk of bias within studies

The updated PRISMA flowchart is reported in Supplementary Figure S1. The RoB 2 evaluation is shown in Supplementary Figure S2. The new systematic search identified 562 potential articles: 202 from the Medline/PubMed database, 273 from the ISI Web of Science, and 87 from the Cochrane database. After removal of duplicates, 482 articles remained. Of these, 146 were excluded because they were not pertinent to the question of the study. Then, 336 articles were reviewed in full-text form, and 334 were excluded. Finally, 2 additional[9,10] trials were used compared with the previous trial,[6] available from the meta-analysis of Hüttner et al.[5] There was 100% agreement between the 2 reviewers. The characteristics of the selected studies are summarized in Table I.

Table I
Characteristics of included studies

Authors, year	Study type/country	Registration number	Sample size	MIDP rate	Drain characteristics			Soft rate	PDAC rate	Wirsung size, mean (mm)	RoB 2
					Closed system	Active suction	Number				
van Buren et al, 2017[6]	Multicenter/USA	NCT01441492	344	44%	Yes	Yes	Discretional	81%	27%	2	Low risk
van Bodegraven et al, 2024[9]	Multicenter/EU	NL9116	282	73%	Discretional	Discretional	Discretional	22%	34%	2	Low risk
Kaiser et al, 2025[10]	Monocentric/ Germany	DRKS00013763	246	32%	Discretional	Discretional	Discretional	49%	32%	NR	Low risk

MIPD, minimally invasive distal pancreatectomy; *NR*, not reported; *PDAC*, pancreatic ductal adenocarcinoma.

Results of individual studies and synthesis of the results

Table II reports both critical and important end points. The mortality risk was similar across the 2 groups (RD −0.01; 95% CI −0.02 to 0.01), with NNH of 100. The risk of major morbidity (Figure 1) was comparable between the 2 groups, yielding RD of 0.03 (95% CI −0.03 to 0.09) and NNT of 33. The risk of percutaneous drain placement was similar between the 2 groups, presenting RD of −0.02 (95% CI −0.03 to 0.07) with NNT of 50. The rate of relaparotomy was similar across the 2 groups (RD 0.02, 95% CI −0.03 to 0.03) and NNT of 50. The prevalence of POPF (Figure 2) was lower in the no-drain group (RD 0.09, 95% CI 0.04 to 0.15). For every 11 patients in whom a drain was omitted, 1 POPF was avoided (NNT 11, 95% CI 25 to 7). LOS was shorter in the no-drain group (MD 0.41, 95% CI 0.09 to 0.73). PPH, DGE, and readmission rate were similar.

Heterogeneity, meta-regression analysis, and publication bias

No significant heterogeneity was observed for any end points, and therefore a meta-regression was not performed. No publication bias was observed.

GRADE certainty of evidence

According to the GRADE assessment, the certainty of evidence was moderate for most critical outcomes, including 90-day mortality, major morbidity, redrainage, and relaparotomy; this was mainly due to imprecision with CIs crossing the null effect. Among noncritical outcomes, the certainty was graded as high for POPF and LOS and as moderate for PPH, DGE, and readmission. Overall, the evidence base can be considered as moderate to high certainty, with the main limitation being imprecision due to small sample size and low event rates.

Post hoc leave-one-out sensitivity analysis

Table III shows the post hoc analysis. The post hoc leave-one-out sensitivity analysis was performed only for POPF and LOS. The reduction in POPF remained consistent across all trials. Exclusion of van Buren et al[6] yielded RD of 0.10 (95% CI 0.01 to 0.20, $P = .023$), exclusion of van Bodegraven et al,[9] resulted in RD of 0.06 (95% CI 0.01 to 0.12, $P = .045$), and exclusion of Kaiser et al[10] resulted in RD of 0.10 (95% CI 0.01 to 0.19, $P = .026$). For LOS, exclusion of van Buren et al[9] (MD 0.60 days, 95% CI 0.08 to 1.13, $P = .024$) and Kaiser et al[10] (MD 0.40 days, 95% CI 0.08 to 0.72, $P = .013$) yielded statistically significant results, whereas omission of van Bodegraven et al[9] rendered the association nonsignificant (MD 0.31 days, 95% CI 0.08 to 0.70, $P = .123$).

Discussion

The present study demonstrates that prophylactic drainage after DP could be safely omitted in low-risk patients. To our knowledge, this meta-analysis is the first to include only RCTs and patients who underwent DP, with an overall sample size of 872 participants: 443 (50.8%) in the prophylactic drainage arm and 429 (49.2%) in the no-drain arm. Considering the critical end points, the 2 competing strategies are equivalent in terms of postoperative mortality, morbidity, need for percutaneous redrainage, and need for relaparotomy. These results should encourage pancreatic surgeons to adopt a modern and popular approach.

Table II
Meta-analysis of critical and noncritical end points*

Outcomes of interest	Event rate (%) or mean (SD)		RD or MD (95% CI)	NNT/NNH (95% CI)	*P* value	Cochran Q, I^2 (%)	Egger *P* value for reporting bias†	GRADE certainty	Reason for downgrading
	Drain	No drain							
Critical end points									
90-day mortality	1/443 (0.2)	5/429 (1.2)	−0.01 (−0.02 to 0.01)	100 (50 to 100)‡	.368	0.214, 0	.760	Moderate	Imprecision
Major morbidity (CDC >2)	151/443 (34.9)	135/429 (31.5)	0.03 (−0.03 to 0.09)	33 (33 to 11)‡	.303	0.860, 0	.407	Moderate	Imprecision
Percutaneous drain placement	73/443 (16.5)	64/429 (14.9)	0.02 (−0.03 to 0.07)	50 (33 to 14)‡	.429	0.340, 7	.872	Moderate	Imprecision
Relaparotomy	22/443 (4.9)	20/429 (4.7)	0.02 (−0.03 to 0.03)	50 (33 to 33)‡	.915	0.581, 0	.918	Moderate	Imprecision
Noncritical end points									
POPF	96/443 (21.7)	54/429 (12.6)	0.09 (0.04 to 0.15)	11 (25 to 7)	.004	0.225, 33	.757	High	—
PPH	10/269 (3.9)	9/259 (3.5)	0.01 (−0.03 to 0.03)	100 (33 to 33)‡	.981	0.503, 0	NA	Moderate	Imprecision
DGE	11/269 (4.1)	5/259 (1.9)	0.02 (−0.01 to 0.05)	50 (100 to 20)‡	.142	0.921, 0	NA	Moderate	Imprecision
	100/443 (22.5)	82/429 (19.1)	0.03 (−0.02 to 0.09)	33 (50 to 11)‡	.218	0.687, 0	.120	Moderate	Imprecision
LOS (days)	7.8 ± 4.9	7.2 ± 4.4	0.41 (0.09 to 0.73)	NA	.011	0.635, 0	.256	High	—

CDC, Clavien-Dindo classification; *CI*, confidence interval; *DGE*, delayed gastric emptying; *GRADE*, Grades of Recommendation, Assessment, Development, and Evaluation; *LOS*, length of stay; *MD*, mean difference; *NA*, not applicable; *NNH*, number needed to harm; *NNT*, number needed to treat; *POPF*, postoperative pancreatic fistula; *PPH*, postpancreatectomy hemorrhage; *RD*, risk difference; *SD*, standard deviation.

* For all end points, all 3 studies were analyzed.

† A reporting bias non-negligible is considered for *P* values < .050.

‡ When RD assumes negative value, NNT becomes NNH.

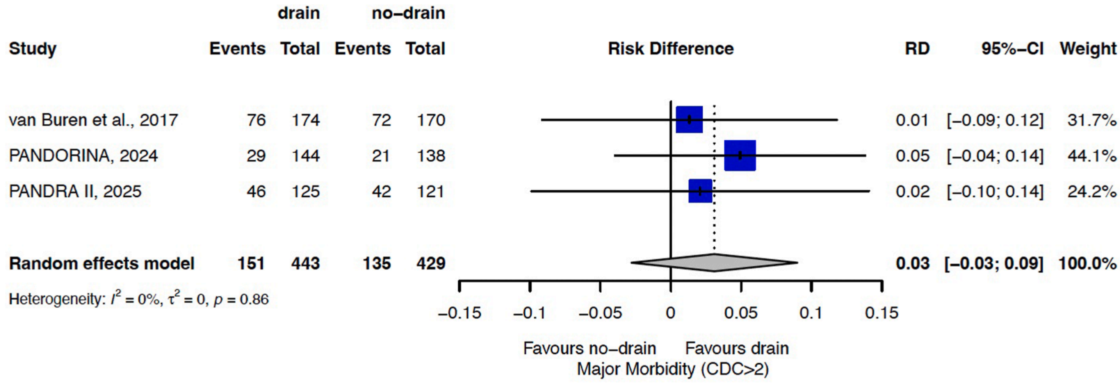

Figure 1. Forest plot comparing major morbidity (Clavien-Dindo >2). Risk difference (*RD*) with 95% confidence interval (*CI*) is shown for each study and the pooled estimate (random-effects model). The results indicate no significant difference in major morbidity between the 2 strategies (RD 0.03, 95% CI −0.03 to 0.09, *P* = .86). *CDC*, Clavien-Dindo classification.

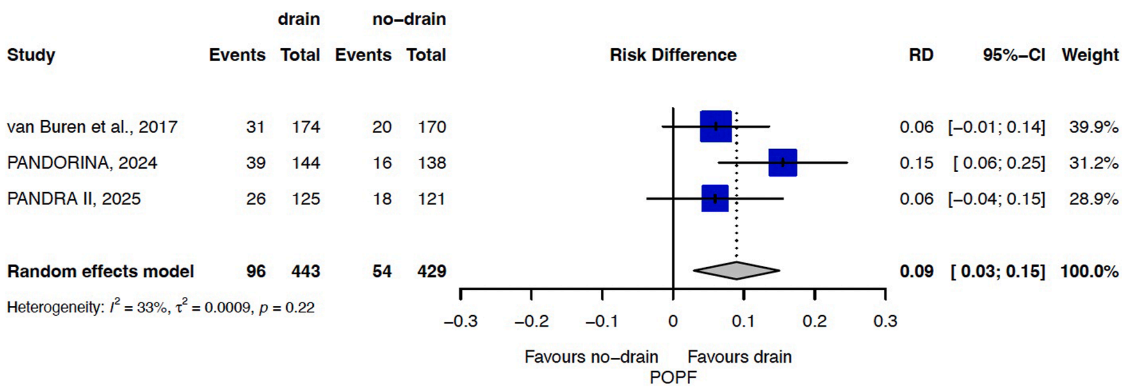

Figure 2. Forest plot comparing clinically relevant postoperative pancreatic fistula (*POPF*) rates. Risk difference (*RD*) with 95% confidence interval (*CI*) is shown for each study and the pooled estimate (random-effects model). The results indicate a significantly higher POPF rate in the drain group (RD 0.09, 95% CI 0.03 to 0.15, *P* = .22).

Table III
Post hoc leave-one-out sensitivity analysis

Outcomes of interest: Noncritical end points	RD or MD (95% CI)	*P* value
POPF		
Omitting van Buren et al, 2017[6]	0.10 (0.01 to 0.02)	.023
Omitting van Bodegraven et al, 2024[9]	0.06 (0.01 to 0.12)	.045
Omitting Kaiser et al, 2025[10]	0.10 (0.01 to 0.19)	.026
LOS (days)		
Omitting van Buren et al, 2017[6]	0.60 (0.08 to 1.13)	.024
Omitting van Bodegraven et al, 2024[9]	0.31 (−0.08 to 0.70)	.123
Omitting Kaiser et al, 2025[10]	0.40 (0.08 to 0.72)	.013

LOS, length of stay; *MD*, mean difference; *POPF*, postoperative pancreatic fistula; *RD*, risk difference; *SD*, standard deviation.
From Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med.* 2009;6(6):e1000097. For more information, visit www.prisma-statement.org.

Recent meta-analyses[25–27] and Enhanced Recovery After Surgery (ERAS) guidelines[28,29] support omitting prophylactic drainage for colorectal, gastric, and liver resections, promoting the drainless approach at least in routine cases. However, in pancreatic surgery, resistance to adopting the drainless approach persists. A recent survey indicated that the omission of drains was not entirely accepted among pancreatic surgeons.[8] This reluctance has various causes, such as the lack of a validated, universally accepted fistula risk score; the availability of radiologic or endoscopic resources for rescue strategies; or the belief that a prophylactic drain could prevent relaparotomy. The current study suggests that these preconceptions lack a rational basis and that omission of drain is a safety strategy, at least in low-risk patients who underwent DP. The current analysis reveals several advantages to the drainless policy.

First, it is reasonable to affirm that after DPs, leaks of pancreatic juice and fluid collection are common occurrences. The fluid collection is initially sterile, but the prophylactic drain could facilitate retrograde infection by skin bacteria.[30] The results of this meta-analysis confirmed this hypothesis, as clinically relevant POPF was significantly lower in the no-drain group. However, the reduction of POPF did not alter the cumulative risk of patients experiencing an uneventful postoperative course. Thus, this advantage could be ephemeral and irrelevant from a practical standpoint. Indeed, the only RCT[10] that demonstrated a reduction of overall complications showed a slight decrease in the Comprehensive Complication Index (CCI) score of 10 points, which is nearly irrelevant. On the other hand, 2 of the 3 RCTs[6,9] used significant morbidity as the primary outcome and did not find a significant difference. A second advantage was the reduction in LOS, although the magnitude of effect in this study is limited to half a day. In other words, this advantage, even if statistically significant, appears to be clinically irrelevant. Moreover, this advantage could be achieved by resorting to early drain removal instead of omission. In fact, a recent meta-analysis demonstrated that LOS was significantly lower in patients with early drain removal (MD −2.25, 95% CI −3.23 to −1.28),[31] suggesting that the real competitor of drain omission was early removal, rather than the generic use of drainage. In other words, early removal before the third postoperative day might be an alternative to classic management.[32] However, no data comparing early drain removal with a no drain are available, even though the 2 approaches could be pretty similar, as both aim to avoid retrograde infection. The post hoc leave-one-out sensitivity analysis showed the influence of each single RCT on the pooled results. The overall direction of the effect on POPF remained unchanged across all analyses, although the magnitude and significance of the association varied depending on the study omitted. In particular, the exclusion of either van Buren et al[6] or Kaiser et al[9] yielded estimates similar to those of the main analysis, whereas the omission of the van Bodegraven et al[10] trial attenuated the pooled effect on POPF and rendered the reduction in LOS nonsignificant. These findings suggest that the PANDORINA trial largely drives the statistical significance of the observed benefit. However, the consistency of the effect direction across trials indicates that drain omission may still be associated with a reduction in POPF. Nevertheless, the dependency of significance on a single study highlights the need for cautious interpretation and for further confirmatory evidence.

This study has strengths and limitations. The extension of DP may influence the POPF rate, the severity of complications, and the feasibility of rescue strategies, such as percutaneous drainage.[33] However, no data are available on this topic in the 3 RCTs. Moreover, additional risk factors can influence the results, such as the type of approach (minimally invasive versus open), the type of tumor resected (pancreatic ductal adenocarcinoma versus other types), and patient (comorbidity, age) and pancreas-related (Wirsung duct size and thickness) factors. Additionally, the number and type of drainages could introduce another source of variability. Nonetheless, the heterogeneity of the end points remained very low and nonsignificant, suggesting that the randomization process was well executed in all 3 studies. In other words, these limitations represent, at the same time, a strength because the cumulative data seem to provide information about a real-life population, thereby increasing the external validity of the results in all settings. Finally, the absolute safety of the drainless approach should be acknowledged with caution. The mortality rate was nearly 6 times higher in the no-drain group (1.2% vs 0.2%), and the readmission rate remained higher (19.1%). Although these differences did not reach statistical significance, they highlight potential safety concerns that the present analysis, owing to limited sample size (only 3 RCTs are included) and low event rates, may be underpowered to detect.

In conclusion, the findings of this study indicate that the drainless approach could be a safe alternative for patients who have undergone DP. However, at the same time, the aggregated data suggested the absence of significant advantages in the postoperative course for the drainless approach. Although a statistically significant reduction in POPF was observed with drain omission, this finding did not translate into a clinically meaningful reduction of overall complications. Moreover, the only statistically significant advantage of drain omission was the reduction of LOS, even if this gain is minimal with limited clinical relevance. Finally, the question of safety should be further investigated by increasing the sample size. Future studies should concentrate on risk stratification or comparison with early removal, which should be investigated to implement the ERAS principle in pancreatic surgery.

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Conflict of Interest/Disclosure

All authors declared the absence of conflict of interest.

CRediT authorship contribution statement

Claudio Ricci: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Laura Alberici:** Methodology, Data curation, Conceptualization. **Vincenzo D'Ambra:** Software, Resources. **Carlo Ingaldi:** Visualization, Validation. **Marco Fichera:** Writing – original draft, Visualization, Conceptualization. **Federico Pisani:** Data curation. **Riccardo Casadei:** Writing – review & editing.

Supplementary Materials

Supplementary material associated with this article can be found, in the online version, at [https://doi.org/10.1016/j.surg.2025.109815].

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