International Wound Journal

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REVIEW ARTICLE OPEN ACCESS

Effectiveness of Open Incision Negative Pressure Wound Therapy for Surgical Site Infection Prevention for Abdominal Surgery—A Systematic Review and Meta-Analysis

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Received: 23 July 2024 | **Revised:** 31 December 2024 | **Accepted:** 20 January 2025

Funding: The authors received no specific funding for this work.

Keywords: general surgery | negative pressure wound therapy | surgical wound | surgical wound infection

ABSTRACT

Open incision negative pressure wound therapy (NPWT) combines delayed closure with negative pressure to prevent surgical site infection (SSI). Its effectiveness in preventing SSI remains unclear, complicating its risk–benefit assessment. PubMed and Web of Science databases were searched for relevant English studies. Two reviewers independently screened titles and abstracts using the ASReviewer tool. Full-text articles were assessed for eligibility. Eight studies were included in the systematic review and five were pooled in the meta-analysis. Data extraction followed the PRISMA guidelines, and the risk of bias was assessed. A meta-analysis was performed using a random-effects model for SSI occurrence. Eight studies (three RCTs and five cohort studies) with 1655 patients were included. Studies were pooled based on control interventions: primary closure (PC) or delayed primary closure (DPC). Pooled odds ratio (OR) estimates favoured NPWT over PC for SSI reduction (OR, 0.15; 95% CI, 0.02–0.87). No significant SSI risk difference was found between the NPWT and DPC groups (OR, 0.28; 95% CI, 0.06–1.27). Preventive NPWT is associated with a reduced risk of SSI in abdominal surgery compared to PC. Our findings indicate that standardising treatment and reporting protocols could improve future evaluations of NPWT effectiveness.

Trial Registration: PROSPERO identifier: CRD42024401669

1 | Introduction

Surgical site infection (SSI) remains a leading adverse event (AE) in abdominal surgery, with particularly high rates in contaminated surgeries reaching up to 35% [1, 2]. SSI is associated with higher morbidity, decreased quality of life (QoL), and prolonged length of hospital stay (LOS). Consequently, SSI poses a significant financial burden, adding up to 150% of the treatment cost of a patient compared to those without an SSI [3, 4].

CDC categorises wounds into four classes. Class I (clean) includes wounds with no entry into the respiratory, alimentary, or genitourinary tracts. Class II (clean-contaminated) includes controlled entry into these tracts. Class III (contaminated) includes wounds with major sterile technique breaches or spillage from the gastrointestinal tract or non-purluent inflammation. Class IV (dirty-infected) encompasses old wounds with devitalised tissue or pre-existing infections [5, 6].

Various management strategies for contaminated and dirty wounds are used in clinical practice, including subcutaneous drainage, wound irrigation, delayed primary closure (DPC) and negative pressure wound therapy (NPWT) [7–9]. NPWT generates a vacuum to remove the exudate from the wound

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Summary

- This study systematically reviews and analyses the effectiveness of negative pressure wound therapy (NPWT) compared to primary closure and delayed primary closure in surgical site infections (SSI) prevention in abdominal surgery.
- Eight studies with 1655 patients were included, and five studies were pooled for the meta-analysis.
- NPWT significantly reduces the risk of SSI compared to primary closure, while this is not observed when NPWT is compared to delayed primary closure.
- There is a need to standardise treatment and reporting protocols in future research on NPWT.

and promote granulation. Two NPWT methods are used for SSI prevention in surgery: closed-incision NPWT (ciNPWT) and open-incision NPWT (NPWT). Unlike ciNPWT, which is applied over closed incisions, NPWT leaves the incision open initially, allowing continuous removal of exudate from subcutaneous tissue.

High SSI risk in abdominal surgery is caused by subcutaneous tissue contamination with enteric bacteria due to entry into the gastrointestinal tract, gastrointestinal leakage or intra-abdominal infection [10]. Therefore, NPWT seems to target SSI source as vacuum is applied to subcutaneous tissue. However, NPWT is associated with higher costs and requires trained personnel to change the dressing. Moreover, open wounds and pumping systems can cause discomfort to patients.

Currently, there lack of evidence on the effectiveness of NPWT in abdominal wound closure. Several studies attempted to compare NPWT to standard approaches. However, the wide range of reported SSI rates and heterogeneity of these studies lead to unclarity regarding the overall effectiveness of NPWT.

Assessment of NPWT effectiveness involves consideration of multiple outcomes. Consequently, balancing the benefits and harms of preventive NPWT use poses a significant challenge to clinicians. We performed a systematic review to evaluate outcome measures of NPWT effectiveness. We then performed a meta-analysis to address the question of whether NPWT is effective in preventing SSI in abdominal surgery.

2 | Materials and Methods

2.1 | Search Strategy

The systematic review and meta-analysis were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement based on the patients, interventions, comparisons, outcomes (PICO) format question [11]. A search of the PubMed and Web of Science electronic databases was performed to identify relevant articles without the use of filters. Backward citation chaining of the reference lists of all eligible full-text articles was conducted to identify additional papers. This study was registered with PROSPERO (identifier: CRD42024401669).

2.2 | Evidence Acquisition

Databases were searched on the 20th of November 2023 by two independent researchers (K.P. and P.S.) to identify eligible studies. The search strategy was as follows: (npwt or vac or "negative pressure" or vacuum) and (laparotomy or "abdominal surgery" or [surgery and abdom*]). The initial search yielded 3576 results. The screening protocol is shown in the PRISMA flowchart (Figure 1). Novel AI-powered tools have been used for record selection to improve accuracy. Records were deduplicated with ASySD web application [12], after which 1954 were further processed. To conduct the literature review, we employed the ASReview machine learning tool [13] to prioritise articles based on their textual similarity to previously chosen articles. The selection process was conducted by two researchers (K.P. and P.S.). In case of contrast of individual results, article's eligibility was re-evaluated by means of consensus. Disagreements between the researchers were resolved through discussion and consultation with another author (J.K.). We have adopted a stopping criterion of 150 subsequent irrelevant articles since the last relevant (Van Dijk et al. [14] proposed a criterion of 100 irrelevant articles since the last relevant). The algorithm was initially trained with five relevant and five irrelevant studies; 358 studies (18% of studies imported to ASReview) were manually labelled; of these, 18 studies were identified for full-text screening. The full text was obtained from 18 studies, of which 11 were excluded. One eligible study was identified via a backward citation search. Finally, eight studies were included in the systematic review, of which five were eligible for the meta-analysis.

The following data were retrieved from the included studies: authors, year of publication, enrolment period, journal, centre/country, study design, number of patients, percentage of male patients, age, eligibility criteria, wound class, study protocol, treatment protocol (for intervention and control groups), compliance, follow-up duration, and outcomes.

2.3 | PICO-Based Inclusion and Exclusion Criteria

The PICOTS-based strategy adopted to identify relevant studies is presented in Table 1. Studies in languages other than English were excluded. Studies involving NPWT with instillation were excluded to maintain intervention consistency. Time constraints were not applied.

2.4 | Evidence Synthesis and Risk of Bias Assessment

Cochrane tools ROB 2 [15] and ROBINS—I [16] were used to assess the risk of bias in the studies included in the meta-analysis. Publication bias was assessed using funnel plots.

Two authors (K.P. and P.S.) independently evaluated bias, resolving disagreements through discussion. The risk of bias was visualised using the Metafor R package.

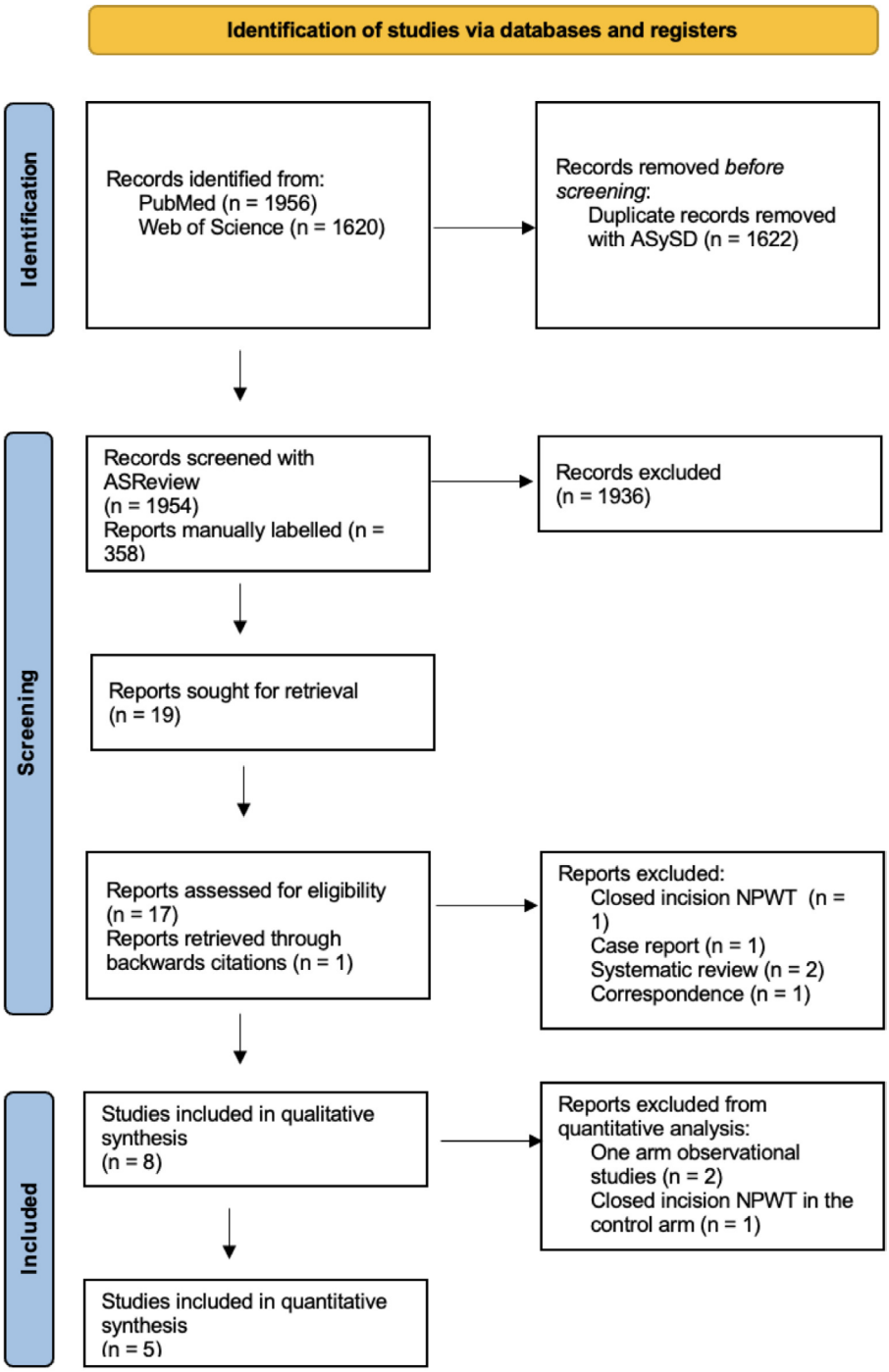


FIGURE 1 | PRISMA screening protocol [11].

2.5 | Statistical Analysis

The odds ratio for developing SSI was used as a summary estimate. Der Simonian and Laird inverse variance random effects were applied to pool the odds ratios of developing SSI due to heterogeneity and dichotomous outcome according to Cochrane guidelines [17]. A forest plot was created to visually interpret the summary estimates. Statistical heterogeneity was assessed using the I^2 coefficient. Analyses were performed using the Metafor R software package.

3 | Results

After screening and full-text assessment (18 articles), 8 articles were included in this review. Of these, two were observational single-arm studies, one was a prospective cohort study with historical controls, two were retrospective cohort studies, and three were randomised controlled trials. One study had three arms with two comparator interventions: DPC and PC. The characteristics of the included studies are summarised in Table 1.

TABLE 1 | PICOTS framework for the systematic review.

Patients	Patients undergoing abdominal surgery
Intervention	NPWT
Comparison	Any wound care not involving NPWT (DPC/PC/closed NPWT were included)
Outcomes	SSI occurrence, LOS
Time	Any
Study design	Original studies with or without control groups

A total of 1655 patients were analysed, of whom 748 received NPWT with DPC and 8849 received standard treatment (DPC, $n = 537$; PC, $n = 374$; ciNPWT, $n = 25$). All studies were performed on patients who underwent surgery for gastrointestinal perforation and/or emergency abdominal surgery. Apart from one study by Rafaqat et al. [18], all included patients had Class III/IV wounds, according to the CDC classification. In the study by Rafaqat et al., the majority of patients had Class III/IV wounds (69.1% of DPC patients and 71.6% of NPWT patients). The median age of the included patients differed between the studies. Two studies by Lozano-Balderas [19] et al. and Singh et al. [20] had significantly lower median age These two studies were conducted in middle-income countries (Mexico and India), whereas the remaining studies were conducted in high-income countries.

3.1 | Intervention—NPWT

The included studies employed commercially available NPWT devices, either V.A.C from KCI or RENASYS from Smith&Nephew (Table 2). One study on large retrospective database does not report device type [18]. Only three studies reported the median duration of NPWT, which ranged from 4 to 7 days. In the study by Singh et al. [20], the closure time was defined by the protocol on the 4th day, and in other studies, the clinician assessed wound readiness for closure. In all studies, except one by Frazee et al. [22], NPWT intervention was terminated with DPC. This study was excluded from the meta-analysis because of substantial differences in wound management between the intervention and control arms.

3.2 | Control Arm

The included studies had two main control intervention types: DPC and PC. We considered the difference between comparator interventions to be significant enough to pool these studies separately. DPC is known to reduce SSI risk compared to PC [22]. Consequently, the studies were grouped by comparator interventions in Tables 2–4, and meta-analyses were conducted separately for each control intervention (DPC and PC).

In two studies, DPC was the control intervention, whereas, in the other two studies, PC was the control intervention. One study included both a DPC and PC arm; therefore, it was included in both meta-analyses [26]. One study used PC with ciNPWT as the control intervention [27]. This study was excluded from the meta-analysis because of the heterogeneity introduced by using ciNPWT in the comparator arm. For DPC groups wound closure time was reported only in two studies; in one closure was attempted on the 4th day [20], in the other after at least 7 days [19, 20]. Detailed control intervention descriptions are rarely available in the original manuscripts. Retrospective studies were conducted in multiple centres adhering to local guidelines that are not defined.

Two studies did not have a comparator arm; therefore, they were excluded from the meta-analysis (Table 4).

3.3 | Outcomes

Seven of the eight studies reported SSI as defined by the CDC criteria [22], one study reported only incisional SSI(iSSI). Frazee et al. provided a definition of SSI that converged with CDC criteria [22]. Six studies reported LOS (Table 5). Only one study reported a significant increase in LOS in the intervention arm [27]. However, this may result from a median NPWT duration of 48 days, which may have influenced the timing of patient discharge. LOS data were not available for all studies and were subjected to local policies regarding patient management and the duration of NPWT. Therefore, we did not include this parameter in the meta-analysis.

Four studies reported adverse effects of NPWT. Due to the lack of standardisation and selective reporting of different adverse effects (Table 3), it was not possible to pool the results.

Only Nakatsutsumi et al. [23] reported care costs. The median healthcare cost was lower in the NPWT group (18.5 [13.9, 29.0] thousand USD) than in the PC group (19.9 [13.2, 30.9] thousand USD); however, this difference was not statistically significant ($p = 0.782$). Two studies reported time to epithelialisation. One study analysed bacterial cultures.

3.4 | NPWT Versus PC Meta-Analysis

Three of the included studies compared NPWT with PC, analysing a total of 509 patients. Pooled analysis demonstrated an additional benefit of NPWT over PC for contaminated wounds (odds ratio 0.15, CI [0.29–0.87]). Heterogeneity of the included studies was considerable ($I^2 = 77\%$).

3.5 | NPWT Versus DPC Meta-Analysis

Three of the included studies compared NPWT to DPC and analysed 1073 patients. The SSI risk difference between NPWT and DPC was not statistically significant (OR, 0.28; 95% CI, 0.06–1.27). Heterogeneity of the included studies was substantial ($I^2 = 76\%$).

3.6 | Risk of Bias

Overall, the included studies had a moderate risk of bias. The most significant bias arises from bias in the measurement of the outcome. Ambiguity in SSI criteria puts into question the current reporting standards (Figures 2 and 3). Detailed bias tables

TABLE 2 | Characteristics of the included studies.

Comparator	First author	Year	Country	Design	Study population	Male %	Age	Surgery type	Wound class CDC	Intervention	NPWT device, manufacturer	NPWT duration	NPWT change interval	NPWT closure	NPWT pressure	Control intervention	Control dressing regimen	Third arm intervention
PC as control intervention	Danno [21]	2018	Japan	Prospective cohort with historical control	28	39%	Median [IQR], NPWT 72.5 (20–90), PC 64 (13–83)	Surgery for LGI perforation	III, IV	NPWT	V.A.C, KCI	NPWT initiated within first 3 days, duration 5–7 days	Every 48–72 h	DPC	Continuous pressure of 100 mm Hg	PC	NA	—
	Frazee [22]	2018	USA	RCT	49	63%	Mean (SD), NPWT 54 (NR), ciNPWT 60 (NR)	Emergency surgery	III, IV	NPWT	V.A.C, KCI	Until epithelialisation (median 48 days)	Every 48–72 h	No DPC	NA	PC + ciNPWT	Prevena (KCI) for 7 days	—
	Nakatsutsumi [23]	2023	Japan	Multicenter retrospective cohort	410	52%	Median [IQR], NPWT 75 (67–81), PC 76 (67–83)	Surgery for colorectal perforation	I–IV	NPWT	V.A.C., KCI, or RENASYS, Smith and Nephew	When good development of granulation tissue was found	Every 48–72 h	DPC	NA	PC	NA	—
DPC as control intervention	Rafaqat [18]	2023	USA	Retrospective cohort (1:1 propensity matching)	954	47%	NPWT 63 (53–73), DPC 63 (53–74)	Emergency laparotomy	I–IV	NPWT	NA	NA	NA	DPC	NA	DPC	NA	—
	Singh [20]	2023	India	RCT	65	52%	Mean (SD), 35 (16)	Surgery for GI perforation	IV	NPWT	V.A.C, KCI	4 days		DPC	Continuous pressure of 120 mm Hg	DPC at Day 4	Sterile gauze dressing changed daily	—
PC + DPC	Lozano-Balderas [19]	2017	Mexico	Three-arm RCT	81	68%	Median [IQR], NPWT 32 (22–46), DPC 39 (22.5–53), PC 30 (20–43)	Laparotomy	III, IV	NPWT	V.A.C, KCI	Until granulation tissue was found, median NA	Every 48–72 h	DPC	NA	DPC after at least 7 days	NA	PC
No control arm	Ota [24]	2020	Japan	Prospective single arm	56	54%	Median [IQR], 68 (31–94)	Surgery for LGI perforation	Hinchey II–IV; CDC not reported	NPWT	V.A.C, KCI	Until granulation is found, median 5 days [3–17]	Every 48–72 h	DPC	Continuous pressure of 75–125 mmHg	—	—	—
	Sato [25]	2022	Japan	Retrospective single arm	22	36%	Median [IQR], 76 (44–92)	Surgery for LGI perforation	III, IV	NPWT	RENASYS, Smith & Nephew	Until granulation was obtained median 7 days [5–11]	Day 3 and day 7	DPC	Continuous pressure of 80 mmHg	—	—	—

TABLE 3 | Outcome measures in the included studies.

Comparator	First author	Year	SSI (CDC)	Postoperative LOS	Time to epithelialisation	Costs	Other AEs	Other outcomes
PC	Danno [21]	2018	X	X	X		Bleeding, pruritus, pain, hematoma	Bacterial cultures
	Frazee [22]	2018	SSI = purulent drainage, localised fever, spreading erythema, and wounds treated with antibiotics or opening/debridement of the wound.	X	X			Death
	Nakatsutsumi [23]	2023	X	X		X	Complications, except for iSSI (not specified)	Death
DPC	Rafaqat [18]	2023	X	X				
	Singh [20]	2023	X	X			Fascial dehiscence	
PC + DPC	Lozano-Balderas [19]	2017	X					
No	Ota [24]	2020	X				Pain	
	Sato [25]	2022	X	X				

TABLE 4 | SSI rates in the included studies by intervention.

Comparator	First author	Year	SSI occurrence in NPWT group %	SSI occurrence in control (DPC) group %	SSI occurrence in control (PC) group %	*p*
PC	Danno [21]	2018	10.7%	—	63.2%	< 0.001
	Frazee [22]	2018	4.2%	—	8%*	1.0
	Nakatsutsumi [23]	2023	22.0%	35.0%	—	< 0.026
DPC	Rafaqat [18]	2023	3.6%	4.4%	—	0.051
	Singh [20]	2023	17.6%	—	61.3%	< 0.01
PC + DPC	Lozano-Balderas [19]	2017	0%	17%	37%	< 0.001
No	Ota [24]	2020	21.4%	—	—	
	Sato [25]	2022	31.8%	—	—	

*In this study, the intervention in the control arm was PC + ciNPWT.

TABLE 5 | LOS in the included studies by intervention.

Comparator	First author	Year	LOS NPWT median (days)	LOS control median (days)	*p*
PC	Danno [21]	2018	22	27	0.45
	Frazee [22]	2018	48	7	< 0.01
	Nakatsutsumi [23]	2023	23	29	0.569
DPC	Rafaqat [18]	2023	10	10	0.91
	Singh [20]	2023	9	10	0.28
PC + DPC	Lozano-Balderas [19]	2017	—	—	—
No	Ota [24]	2020	—		
	Sato [25]	2022	17		

for randomised and non-randomised studies are included in Figures A1 and A2.

4 | Discussion

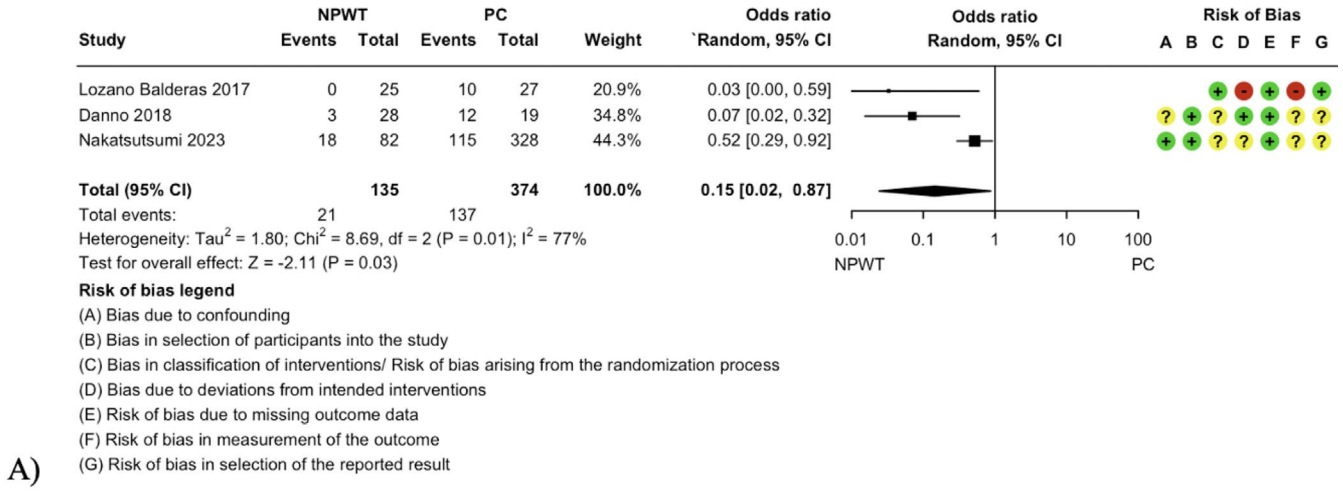
This is the first systematic review and meta-analysis to focus on the effectiveness of preventive NPWT in abdominal surgery. The significance of the effect of NPWT differed depending on the comparator intervention. We demonstrated that the use of NPWT was associated with a lower SSI risk than the use of PC. We did not prove the additional benefit of NPWT over DPC; however, the general direction of the influence of NPWT suggests its potential preventive effects against SSI (Figure 3). This may be attributed to the limited number of studies and small sample sizes. The difference in comparator interventions (i.e., PC and DPC) is paramount as evidence suggests DPC reduces SSI rates in contaminated surgery [22].

Other outcomes, such as cost and patient QoL, should be considered before recommending preventive NPWT for abdominal surgery.

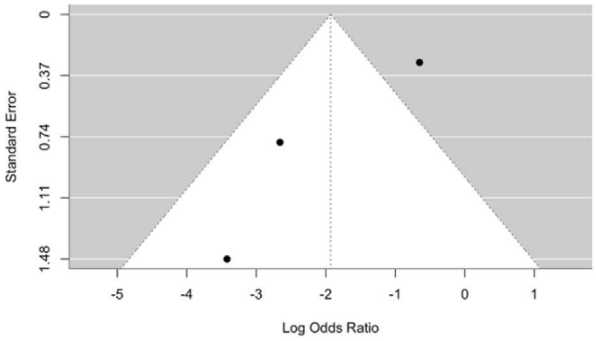
The high degree of heterogeneity between trials, particularly regarding policies on wound and patient management, limits the generalisability of the conclusions of this meta-analysis. Variability is caused by combining studies with different designs (RCTs and non-randomised studies) due to limited evidence.

The heterogeneity of the interventions is also attributable to the variable and seldom reported NPWT duration. In some studies, NPWT was terminated when granulation tissue was found (median 5–7 days) [23, 27, 31]. We believe that this makes the intervention subjective and introduces bias.

Furthermore, populations differ in terms of the median age, with the median age being lower in low-income countries. Other potential sources of heterogeneity include the degree of contamination, location of the perforation, multiple perforations, and comorbidities. Owing to differences in reporting or a lack of reporting, it was not possible to evaluate the influence of these factors. Proper heterogeneity exploration was not possible because of an insufficient number of included studies.



A)



B)

FIGURE 2 | (A) Forest plot of odds ratio of SSI for patients who received NPWT and PC. (B) Funnel plots for assessing publication bias in studies included in NPWT versus PC analysis.

Descriptions of interventions and outcome measures were often ambiguous. The CDC definition of SSI does not adequately address wounds managed with NPWT. This definition lacks the necessary objectivity; for instance, criteria such as wound dehiscence, straightforward in the context of open wounds, are not relevant for wounds under NPWT. Furthermore, a diagnosis made by a physician is sufficient to report SSI according to CDC [5, 6]. These findings highlight the need to develop an objective framework for reporting interventions and their outcomes. Our group has developed a study protocol aimed at systematising and providing quantifiable metrics to assess the effectiveness of NPWT [32]. Below, we present an NPWT effectiveness reporting system (Table 6) that should be considered in future study protocols.

We propose to report effective wound closure by the 30th-day post-op and the time to the end of wound treatment as primary endpoints. Additionally, patient-reported outcomes such as the QoL index are crucial in decision-making processes and therefore should be included in study protocols.

Given the burdensome consequences of SSI, and high costs of preventive NPWT costs and resource use must be analysed in different healthcare systems. Healthcare costs of preventive NPWT and DPC strategy were equivalent in the study by Nakutsumi [31]. Current evidence does not allow to determine whether preventive NPWT is cost-effective.

We further advocate for a standardised and detailed description of NPWT intervention that includes duration, applied pressure, pressure type, device type, manufacturer, and detailed protocol of wound closure (primary and secondary).

A major limitation of this meta-analysis was the small number of studies, and consequently, the low total number of patients included in the analyses. Asymmetric funnel plots (Figures 2 and 3), as evidenced by scatter points outside the 95% confidence interval, may indicate a publication bias. However, in both funnel plots, the number of studies included was very low, rendering the conclusions questionable. Furthermore, the issues of major methodological concerns described above—ambiguity in the interventions' description and outcome reporting–are beyond the scope of the ROB-2 and ROBINS tools. Therefore, the risk of bias analyses should be interpreted with caution, as the actual risk of bias may be more severe.

As the generalisability of our conclusions is limited, large randomised multicenter trials are warranted.

5 | Conclusion

In summary, this systematic review and meta-analysis presents encouraging evidence on the role of NPWT in SSI prevention in abdominal surgery. Our findings suggest NPWT is

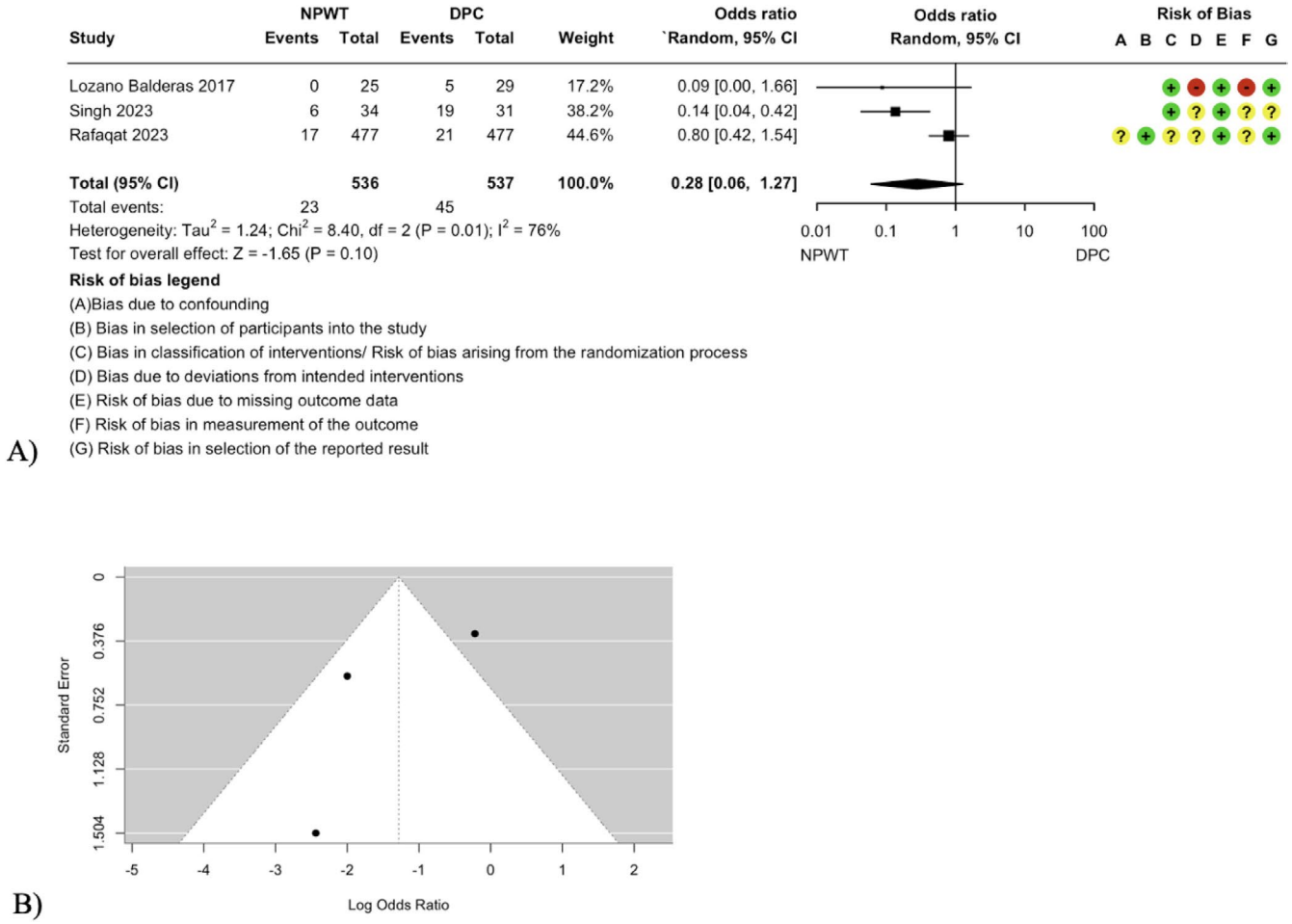


FIGURE 3 | (A) Forest plot of odds ratio of SSI for patients who received NPWT and DPC. (B) Funnel plots for assessing publication bias in studies included in NPWT versus DPC analysis.

TABLE 6 | Proposed NPWT effectiveness reporting system.

Endpoint type	Endpoint	Outcome measures
Primary endpoint	Effective wound closure by 30th day post-op	Definitive wound closure, not followed by wound dehiscence by 30th-day post-op
Secondary endpoints	Time to end of surgical treatment of the wound	Time of last out-patient visit ending the process of treating surgical wound
	Length of stay	Postoperative length of hospital stay
	Time of secondary NPWT treatment	Duration of NPWT therapy administered if SSI occurred
	Pain level	Pain measured with Visual Analogue Scale [15]
	Scar quality	Measured with SCAR scale [24]
	Cost	Cost of hospitalisation and outpatient visits
	QoL	PROMIS-29/EQ-5D/SF-36 or other validated questionnaire [28–30]

more optimal for wound management than PC. According to the GRADEpro approach certainty of this evidence is LOW due to the heterogeneity of the studies and the risk of bias [17]. Although we did not find significantly different proportions of SSI odds ratios for NPWT and DPC, we noticed a trend towards lower SSI risk for NPWT. The results of this meta-analysis should be further confirmed by large-scale randomised controlled trials with optimised protocols regarding precisely described interventions and objective outcome reporting.

Ethics Statement

The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The authors have nothing to report.

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Appendix A



FIGURE A1 | Risk of bias assessment for randomised clinical trials (risk-of-bias 2.0).

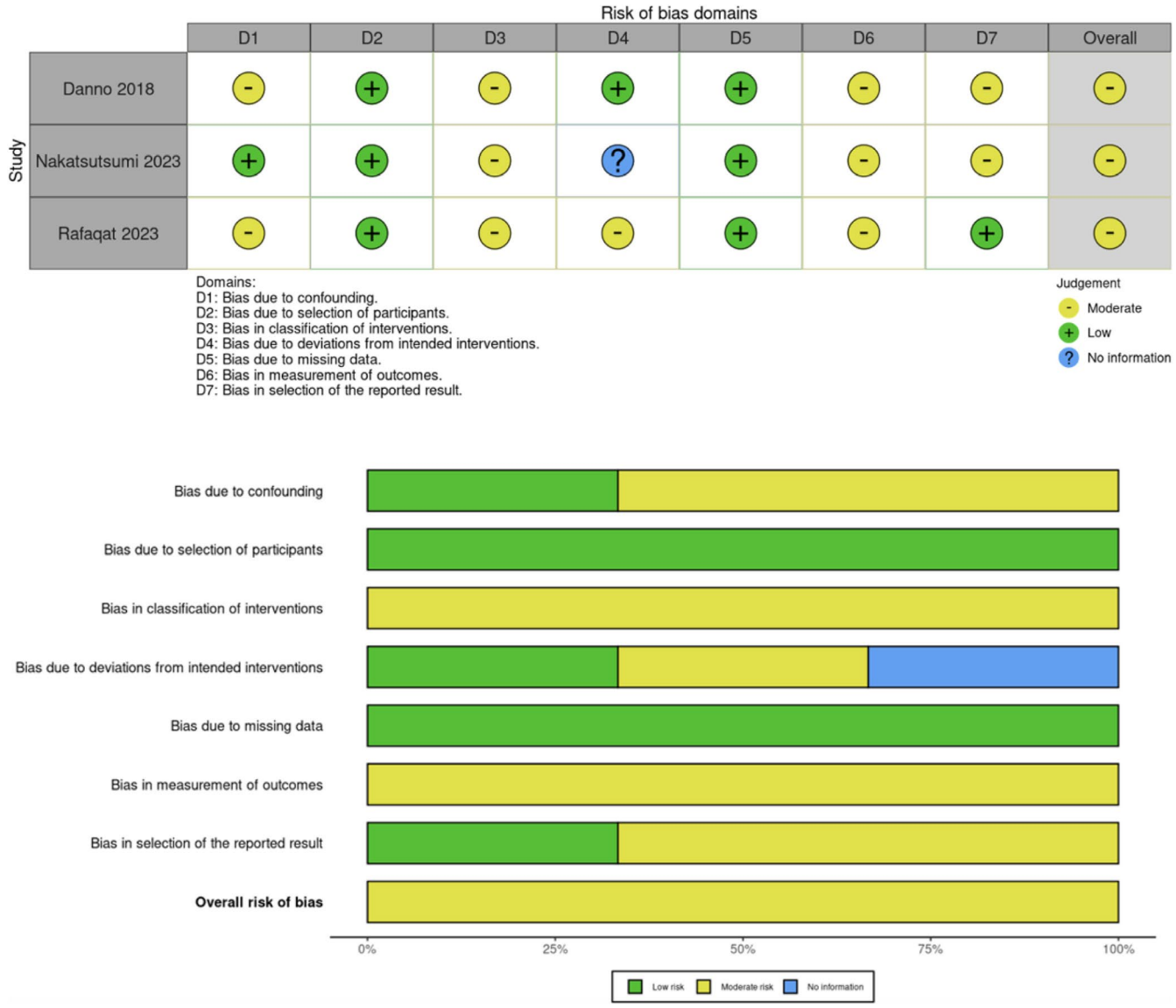


FIGURE A2 | Risk of bias assessment for non-randomised studies and single-arm trials (ROBINS-1).