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SCIENTIFIC REVIEW

Prophylactic Negative Pressure Wound Therapy in Closed Abdominal Incisions: A Meta-analysis of Randomised Controlled Trials

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Abstract

Introduction Negative pressure wound therapy (NPWT) may prevent subcutaneous fluid accumulation in a closed wound and subsequently reduce surgical site infections (SSI). This meta-analysis aimed to determine the effect of prophylactic NPWT on SSI incidence following abdominal surgery.

Methods A systematic search of MEDLINE and EMBASE databases was performed using PRISMA methodology. All randomised trials reporting the use of NPWT in closed abdominal incisions were included, regardless of the type of operation. The primary outcome measure was the incidence of SSI, stratified by superficial and deep and organ/space infections. Secondary outcomes were wound dehiscence and length of hospital stay.

Results Ten randomised trials met the inclusion criteria (five Caesarean, five midline laparotomy). The use of NPWT reduced overall SSI (11.6% vs. 16.7%, RR 0.67, 95% CI 0.48–0.95, $p = 0.02$). The rate of superficial SSI rate was also reduced (6.3% vs. 11.3%, RR 0.57, 95% CI 0.35–0.94, $p = 0.03$). There was no effect on deep or organ/space SSI (3.2% vs. 4.2%, RR 0.77, 95% CI 0.51–1.18, $p = 0.23$), wound dehiscence (9.7% vs. 10.9%, RR 0.92, 95% CI 0.69–1.21, $p = 0.54$), or length of hospital stay (MD 0.06 days, 95% CI–0.11 to 0.23, $p = 0.51$).

Conclusions Prophylactic use of NPWT may reduce the incidence of superficial SSI in closed abdominal incisions but has no effect on deep or organ space SSI.

Introduction

Surgical site infections (SSIs) are a common complication following intra-abdominal surgery, occurring in 5–15% of patients [1–3]. SSIs are associated with considerable morbidity including prolonged hospital stay, delays in adjuvant chemotherapy in cancer patients, and reduced in quality of life, in addition to increased health care costs [4–6]. SSI and other wound complications represent a significant burden to patients and healthcare systems, despite ongoing efforts directed towards SSI prevention [7, 8].

Negative pressure wound therapy (NPWT) has traditionally been used for the management of open and chronic wounds [9–11]. However, the development of portable, single-use, battery-powered NPWT devices such as the PICO™ (Smith and Nephew Healthcare, Hull, United Kingdom) and Prevena™ (KCI Medical Products, Wiesbaden, Germany) has led to the increasing use of this technique for the prevention of SSI and other wound complications in high-risk closed incisions [12–14]. The use of NPWT in closed surgical incisions may reduce fluid

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accumulation in the avascular dead space, limiting the development of collections and their sequelae [15, 16]. Biomechanical studies have demonstrated NPWT also promotes increased blood flow around closed incisions [17], reduced shear stress at suture lines [18], and increased lymphatic drainage [19], thereby improving wound healing and preventing associated complications.

Prophylactic incisional NPWT is currently recommended by the World Health Organization SSI Guidelines in patients with high-risk surgical wounds, though these guidelines provide no specific comments on its use in specific operations [20]. Previous studies have demonstrated the efficacy of prophylactic NPWT in closed incisions in orthopaedic, thoracic, and vascular surgery [21–23]. However, the benefit of this technique in closed abdominal incisions remains unclear. Several meta-analyses have recently been published; however, these have either included patients undergoing a wide range of operations, or have included observational studies as well as randomised trials [23–27]. Therefore, the aim of this meta-analysis was to determine the effect of prophylactic negative pressure wound therapy on the incidence of SSI and other wound complications in closed abdominal incisions.

Methods

A meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [28]. The MEDLINE and EMBASE databases were systematically searched in December 2018 using a pre-defined strategy. The title, abstract, and keyword fields were searched using the following terms, combined with Boolean OR operators: "negative pressure dressing", "negative pressure therapy", "negative pressure wound therapy", "subatmospheric pressure dressing", "subatmospheric pressure therapy", "suction dressing", "topical negative pressure", "VAC", "vacuum assisted closure", and "vacuum therapy". No date restriction was used, though non-English language and animal articles were excluded.

Inclusion criteria were published randomised controlled trials (RCTs) comparing NPWT with standard wound dressings in closed abdominal incisions, regardless of the device used or operation performed. Exclusion criteria were non-randomised, conference abstracts, use of NPWT in open wounds, and studies including patients undergoing non-abdominal operations. Articles reporting only cost-benefit analyses without any clinical outcomes were also excluded.

Two reviewers (CW and CR) independently screened titles and abstracts of records identified from database searching, with mediation by a third reviewer (SP). Reference lists of relevant identified review articles were also screened for further articles. Identified full-text articles were then also screened by two reviewers (CW and CR), and data were subsequently extracted from included articles. Data points extracted were study authors, year of publication, dates of recruitment, journal, study sponsor, country, number of centres, inclusion/exclusion criteria, NPWT device used, duration of NPWT, number of participants recruited/randomised, and all primary and secondary outcomes. The Cochrane risk of bias tool was used to evaluate the quality of the included studies [29].

Outcome measures

The primary outcome was the occurrence of SSI. All definitions and grading systems were included, regardless of duration of follow-up. Where SSI was further stratified into superficial SSI (sSSI) and deep/organ–space SSI (dSSI), these outcomes were also recorded. Secondary outcomes included surgical site occurrence (SSO), defined as all reported wound complications, wound dehiscence, and collection (defined as seroma or haematoma) diagnosed and evaluated clinically, in addition to length of hospital stay, need for reoperation or readmission to hospital within 30 days. All adverse events related to NPWT reported were also assessed, including allergic reactions, skin blisters, or other adverse reactions. The reported rate of device malfunction was also recorded.

Statistical analysis

The *meta*-package in *R* studio (Version 1.1.463) [30] was employed to perform a random effects meta-analysis utilising the DerSiMangrammonian and Laird method [31]. Subgroup analyses were performed stratifying studies by incision type (Caesarean vs. midline laparotomy), device used (PICO^{TM} vs. Prevena^{TM}), and funding source (industry vs. non-industry). Data were presented using risk ratios (RR) for categorical outcomes and mean difference (MD) for continuous outcomes, with 95% confidence intervals (CI) calculated for all estimates. A p value < 0.05 was considered significant. Heterogeneity was assessed using the I^2 statistic. Publication bias was assessed using visual inspection of funnel plots, and the linear regression test of funnel plot asymmetry as described by Schwarzer [30] and Egger et al. [32].

Results

A total of 1435 records were identified from database searching (Fig. 1), of which ten RCTs met the inclusion criteria (Table 1) [15, 33–41]. Amongst the ten RCTs, five

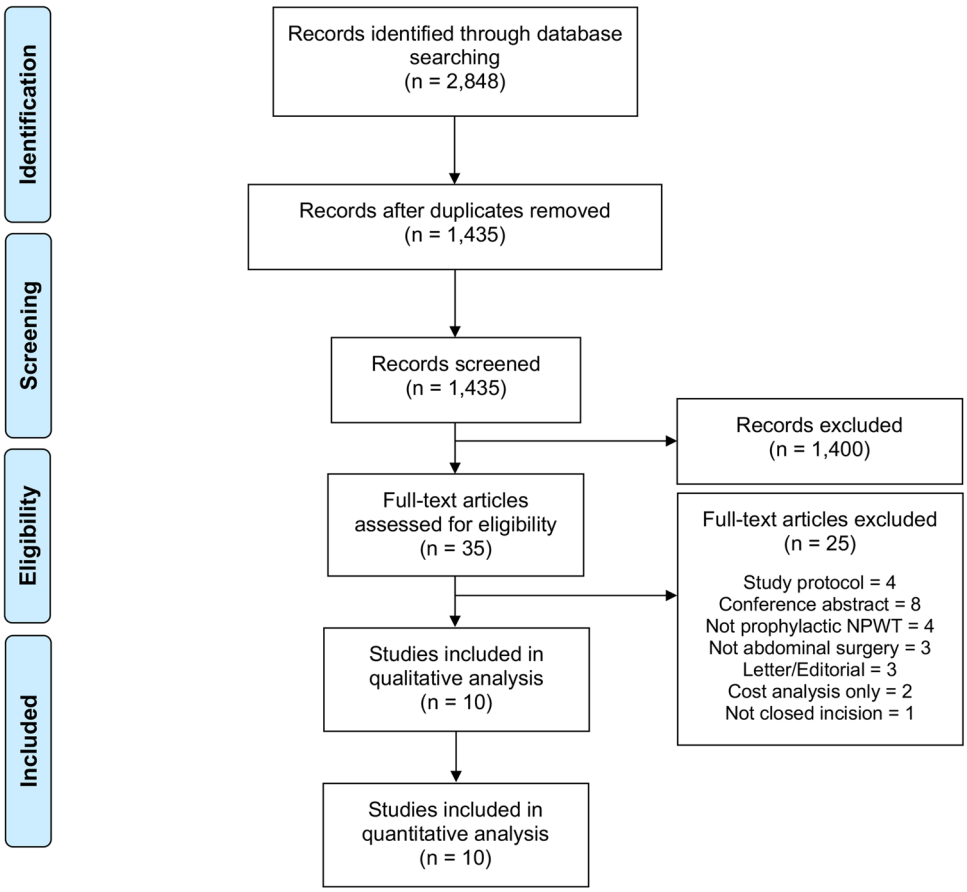

Fig. 1 PRISMA flow diagram of screening process

trials were conducted in patients undergoing Caesarean section, and five in patients undergoing a midline laparotomy. A total of 2117 patients were included (Caesarean = 1325, laparotomy = 792). The type of NPWT device used varied between trials (PICO^{TM} = 3, Prevena^{TM} = 4, not specified = 3). The duration of NPWT dressing ranged from 3 to 7 days post-operatively. All studies used a standard post-operative dressing for comparison, usually dry gauze-based dressings.

The Centres for Disease Control and Prevention (CDC) definition of SSI [42] was used by seven studies [15, 33, 37–41], whereas SSI was defined as by the need for antibiotic therapy in two studies [35, 36]. One study did not provide a definition of SSI [34]. Post-operative follow-up ranged from 28 to 42 days, but was most commonly limited to a 30-day follow-up as advised by the CDC guidelines.

Primary outcome measure

Surgical site infection

Overall SSI (both superficial and deep) was reported as an outcome by nine of ten RCTs, while sSSI and dSSI data were reported by eight and six RCTs, respectively. The incidence of overall SSI was significantly reduced by NPWT compared with standard surgical dressing (11.6% vs. 16.7%, RR 0.65, 95% CI 0.46–0.92, $p = 0.01$, Fig. 2a). Subgroup analysis demonstrated the effect of NPWT on overall SSI rates was consistent across both Caesarean (RR 0.67, 95% CI 0.46–0.96, $p = 0.03$) and laparotomy (RR 0.56, 95% CI 0.30–1.03, $p = 0.06$) cohorts (Supplementary Fig. 1a). There was moderate heterogeneity between studies reporting overall SSI as a primary outcome ($I^2 = 47\%$), and subgroup analysis revealed this was predominantly attributable to laparotomy trials ($I^2 = 67\%$), rather than Caesarean section ($I^2 = 3\%$).

The rate of sSSI was also reduced with NPWT (6.3% vs. 11.3%, RR 0.55, 95% CI 0.32–0.93, $p = 0.03$, Fig. 2b); however, there was no effect on dSSI (3.2% vs. 4.2%, RR 0.80, 95% CI 0.48–1.33, $p = 0.39$, Fig. 2c). Subgroup analysis showed a trend towards reduced sSSI with NPWT in laparotomy (RR 0.38, 95% CI 0.14–1.05, $p = 0.06$), but not Caesarean (RR 0.68, 95% CI 0.33–1.37, $p = 0.29$) (Supplementary Fig. 1b). No effect on dSSI was observed in either cohort (laparotomy $p = 0.51$, Caesarean $p = 0.58$) (Supplementary Fig. 1c).

Table 1 Characteristics of included studies

Study	Country	Recruitment	Cohort	Acute/elective	*n* (NPWT/control)	SSI risk factors	Device	Duration	Incision	Deep tissue closure	Skin closure	Follow-up
Chaboyer [33]	Australia	2012–2014	Caesarean	Elective	87 (44/43)	Obesity	PICO	4 days	NS	NS	Not stated	28 days
Gunatilake et al. [34]	USA	2012–2014	Caesarean	Both	82 (39/43)	Obesity	Prevena	5–7 days	Pfannenstiel	NS	Sutured	42 days
Hyldig et al. [35]	Denmark	2013–2016	Caesarean	Both	876 (432/444)	Obesity	PICO	5 days	Pfannenstiel	"Closure of subcutaneous layers" in 63%"	Sutured/ stapled	30 days
Ruhstaller et al. [36]	USA	2014–2016	Caesarean	Acute	119 (61/58)	Obesity	Prevena	3 days	Pfannenstiel	Subcutaneous layer closed	Stapled	4 weeks
Wihbey et al. [37]	USA	2015–2017	Caesarean	Both	161 (80/81)	Obesity	NS	5–7 days	Pfannenstiel and midline	NS	Sutured/ stapled	30 days
Javed et al. [15]	USA	2017–2018	Whipple	Elective	123 (62/61)	SSI Risk Score [63] ≥1	Prevena	4 days	Midline	Fascia closed and dermis approximated	Sutured	30 days
Li et al. [38]	China	2015	Laparotomy	Both	71 (33/38)	Alcoholism, diabetes, COPD, obesity, colorectal surgery, operative time ≥3 h, blood loss ≥300 mL, hypoalbuminaemia, preoperative hospital stay ≥5d	NS	3 days	Midline	Quill suture to peritoneum, rectus sheath, 3-0 Mersilk to subcutaneous tissues	Sutured	30 days
Murphy et al. [39]	Canada	2015–2017	Colorectal	Elective	284 (144/140)	Converted or open colorectal surgery	Prevena	5 days or until discharge	Midline	NS	Not stated	30 days
O'Leary et al. [40]	Ireland	2013–2016	General abdominal	Both	49 (24/25)	Clean, clean contaminated, or contaminated wounds	PICO	4 days	Midline	1-0 looped PDS to fascia	Stapled	30 days
Shen et al. [41]	USA	2012–2016	GI resection, pancreatectomy, CRS/HIPEC	Elective	265 (132/133)	Clean-contaminated wounds	NS	4 days	Midline or hand-assisted laparoscopy	Looped PDS to fascia, vicryl to subcutaneous tissues	Stapled	30 days

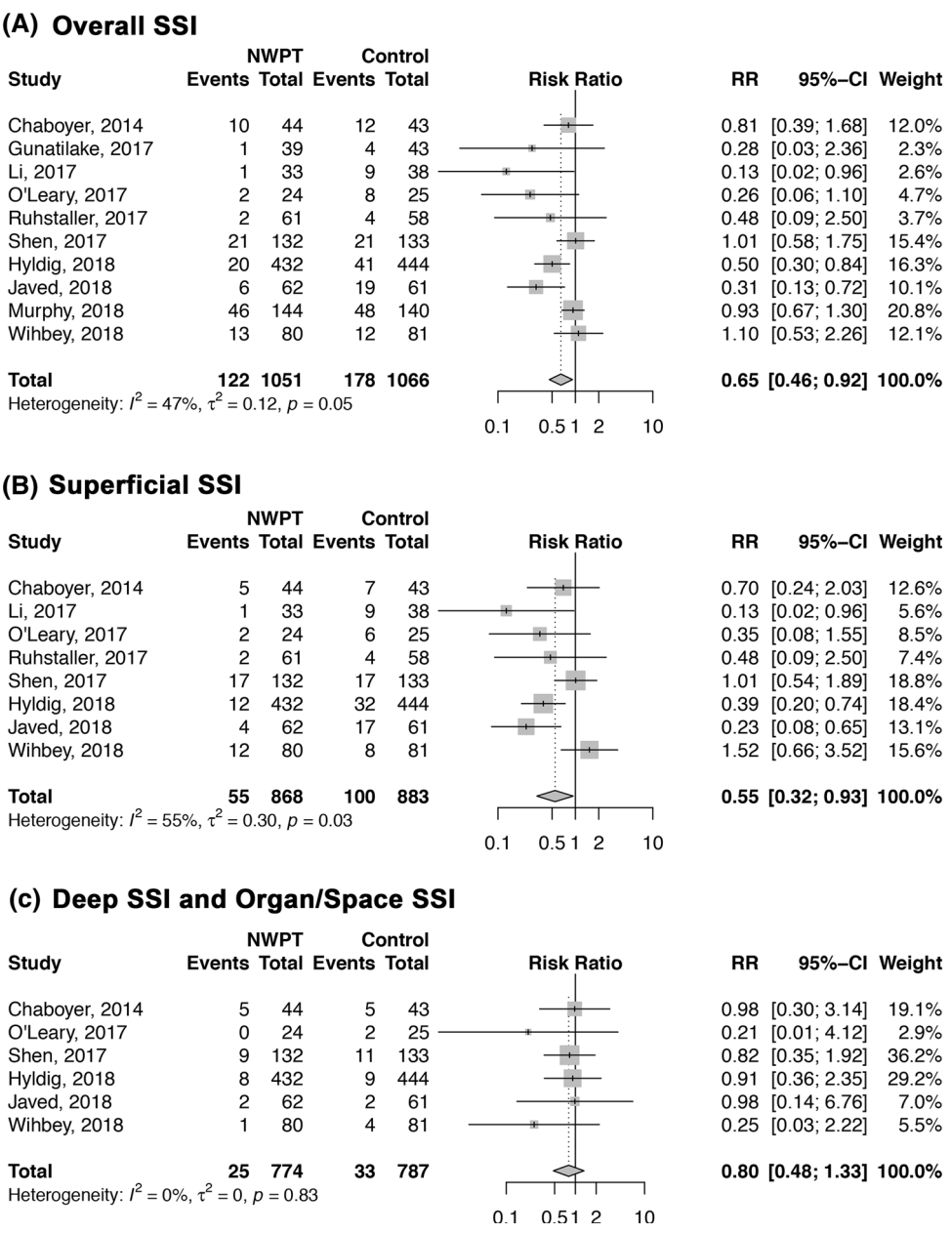

Fig. 2 Forest plots for **a** overall SSI, **b** superficial SSI, and **c** deep and organ/space SSI

Stratification of studies by NPWT device demonstrated a reduction of overall SSI with the use of PICO^{TM} dressings (RR 0.55, 95% CI 0.35–0.87, p = 0.01), and a trend towards reduction with Prevena^{TM} (RR 0.53, 95% CI 0.25–1.15, p = 0.11) (Supplementary Fig. 2a). However, both PICO^{TM} (RR 0.44, 95% CI 0.26–0.74, p = 0.002) and Prevena^{TM} (RR 0.28, 95% CI 0.12–0.68, p = 0.005) demonstrated significant reductions in the incidence of sSSI (Supplementary Fig. 2b).

Secondary outcome measures

NPWT had no significant effect on the rate of SSO (RR 0.89, 95% CI 0.68–1.15, p = 0.36), wound dehiscence (RR 0.92, 95% CI 0.69–1.21, p = 0.54), or wound collection (RR 0.86, 95% CI 0.47–1.58, p = 0.63) (Fig. 3). NPWT had no effect on the length of hospital stay (MD 0.06 days, 95% CI −0.11 to 0.23, p = 0.51), or need for reoperation within 30 days (RR 0.76, 95% CI 0.30–1.92, p = 0.56), but significantly reduced 30 day readmission rates (RR 0.50, 95% CI 0.25–0.97, p = 0.04).

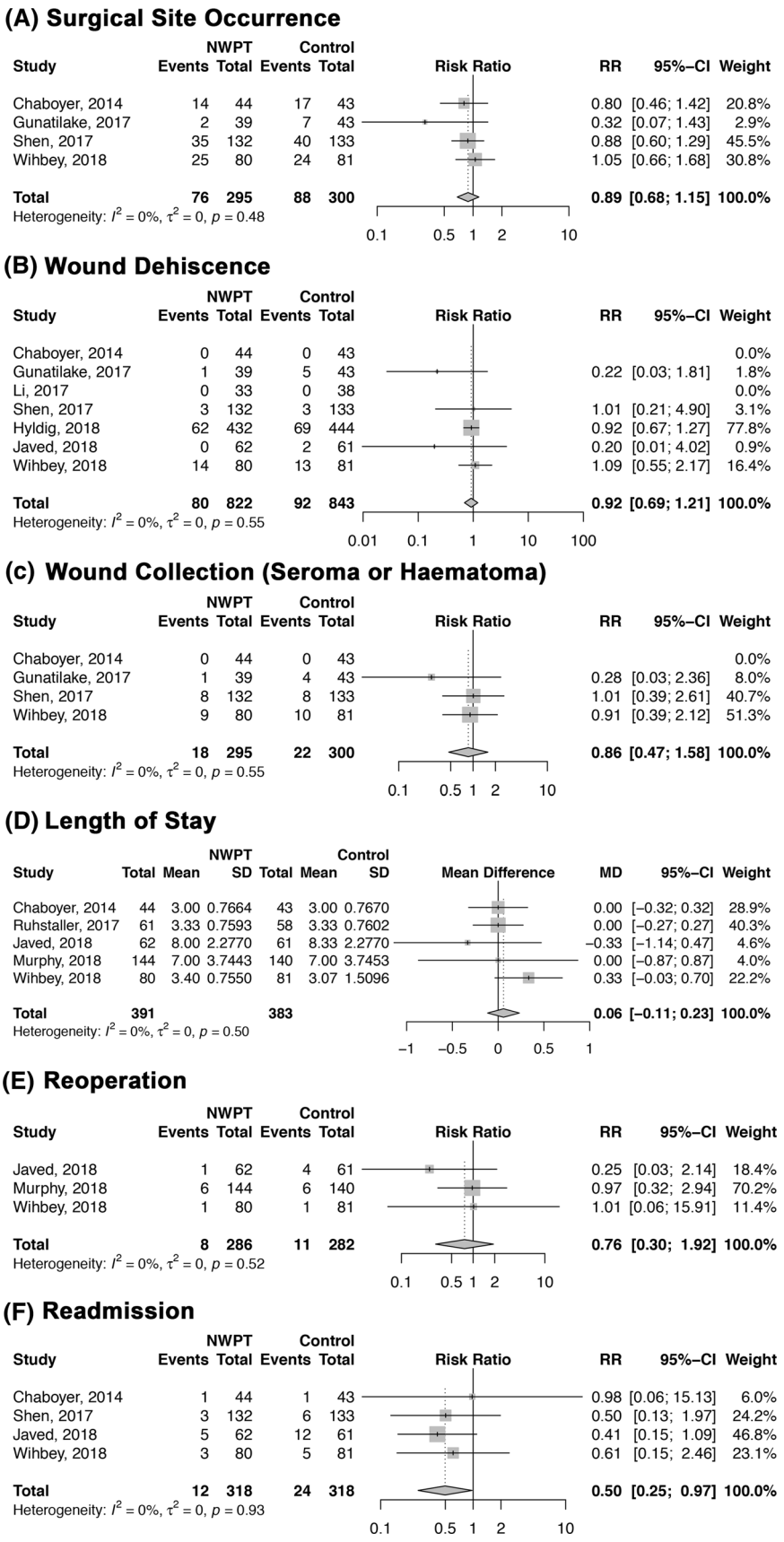

Fig. 3 Forest plots for secondary outcome measures: **a** surgical site occurrence, **b** wound dehiscence, **c** wound collection, **d** length of stay, **e** reoperation, **f** readmission

Adverse events

Two studies reported events associated with NPWT [15, 39]. Chaboyer et al. [33] reported skin blistering in 4 of 44 patients treated with NPWT (9%), versus 0 of 43 patients (0%) in the control group. Ruhstaller et al. [36] reported 4 of 67 patients (6%) had discomfort with NPWT, with one requesting removal. Wihbey et al. [37] reported early removal of the NPWT device in 5 of 80 patients (6%) for local skin irritation, and a further one patient at the patients' request. One study stated that patients were monitored for adverse events, but this data were not reported [34]. The remaining four studies did not report adverse events from NPWT.

Most studies did not report the rate of NPWT device malfunction post-operatively. Of the four studies that did, this rate ranged from 0 to 7% of patients treated with NPWT [15, 35–37].

Risk of bias

Identified bias in the included studies was predominantly related to lack of blinding of participants, clinicians, and outcome assessors (Supplementary Figs. 3 and 4). Only two studies reported blinding of outcome assessors [38, 39]; in all other studies, assessors were unblinded or further information was not provided. In four studies, randomisation was performed following skin closure [34, 36, 38, 39]. Patients were randomised during skin closure in one study [37], and prior to closure in two [15, 41]. One study did not provide data regarding the timing of randomisation [40].

Seven of the included trials reported industry funding in their disclosures. On sub-analysis, industry-funded trials demonstrated a significant reduction in overall SSI (RR 0.59, 95% CI 0.38–0.92, $p = 0.02$) and a near-significant reduction in sSSI (RR 0.49, 95% CI 0.24–1.01, $p = 0.054$). In contrast, non-industry-funded trials did not demonstrate a significant reduction of SSI (RR 0.74, 95% CI 0.37–1.51, $p = 0.41$) or sSSI (RR 0.65, 95% CI 0.27–1.58, $p = 0.34$) rates; however, the test for subgroup differences was not significant for either SSI ($p = 0.59$) or sSSI ($p = 0.63$).

Publication bias

Visual inspection of funnel plots demonstrated evidence of publication bias in favour of positive results with NPWT (Supplementary Fig. 5). The linear regression test of funnel plot asymmetry was also consistent with this observation ($p = 0.055$).

Discussion

This meta-analysis of RCTs has shown that prophylactic use of NPWT in closed abdominal incisions reduces the incidence of SSI, predominantly due to a reduction in superficial infections. Sensitivity analysis indicated this effect was present in patients undergoing Caesarean section and midline laparotomy. Deep infections, wound collections, and rates of wound dehiscence were not affected by NPWT. Although there was no effect on length of hospital stay, readmissions within 30 days appeared to be reduced by NPWT, presumably secondary to a reduction in SSI. The overall quality of evidence was moderate, although conclusions drawn from the data are limited by heterogeneity, and evidence of publication bias.

Previous studies from orthopaedic, thoracic, and vascular surgery have demonstrated that prophylactic NPWT in closed incisions reduces the incidence of SSI, but has limited effect on other wound complications, in keeping with the findings of this review [21–23]. While incisional NPWT is thought to exert its effect by preventing fluid accumulation in closed wounds, the lack of reduction in deep SSI and wound collections (i.e. haematoma and seroma) implies that this effect may be limited only to superficial layers in a closed incision. One published randomised trial has investigated the use of NPWT in patients undergoing closure of ileostomy [43]; this study was not included in the present meta-analysis as the wounds were not closed completely with an 8 mm wound opening left to allow the wound to drain. Uchino et al. [43] did not show a benefit of NPWT following ileostomy closure; however, further trials are required to confirm this finding.

Recent guidelines for closed incisional NPWT recommend its use in patients with known risk factors for SSI, including: obesity, diabetes mellitus, smoking, other comorbidities, wound contamination, and prolonged surgical time [20, 44]. Although prophylactic incisional NPWT may have limited use in patients with a low SSI risk, moderate–high risk groups may receive a greater benefit [44, 45]. Further research is needed to determine which patients are most likely to benefit from incisional NPWT. Future trials should ensure the underlying risk factors of the included patients are clearly stated and consider stratification of participants (e.g. according to wound contamination) in order to assess which are likely to benefit most from NPWT [46]. Other interventions known to influence SSI rates should also be standardised and clearly reported, including use of sutures versus staples for skin closure [47, 48], use of prophylactic antibiotics and/or bowel preparation [49, 50], and wound edge protection devices [51]. A combined preventative approach through a "SSI bundle" has been shown to significantly reduce SSI

rates [1, 7], so NPWT may form part of a stratified management pathway for high-risk patients [46].

The use of prophylactic NPWT in closed abdominal incisions appears safe, although 5–10% of patients may experience local skin irritation from the device. Adverse events were only reported in a minority of studies, similar to previous meta-analyses on incisional NPWT [23, 26]. Chaboyer et al. [33] reported a higher rate of skin blistering in the NPWT group (9% vs. 0%). This reaction has also been observed in other trials from non-abdominal surgery, particularly orthopaedics [52, 53], and should be reported as a core safety outcome in future trials. Previous reports have expressed concern regarding the development of enteric fistula with NPWT after colorectal surgery [9, 26, 46]; however, this is less likely to occur in the setting of closed incisions and was not reported by any of the studies in this review. Malfunction of the NPWT device was poorly reported, though appears to occur in 0–7% of patients [15, 35–37].

There were several limitations of this meta-analysis primarily related to heterogeneity between the included trials, potential bias related to selective reporting, and industry funding and evidence of publication bias. For the primary outcome of overall SSI, there was moderate heterogeneity between included trials, predominantly attributed to the studies conducted in patients undergoing midline laparotomy. This was expected given the intra- and inter-study variability regarding recruited patients (i.e. colorectal vs. pancreatectomy vs. any laparotomy). Other potential sources of variation include the definitions of SSI, contamination of wounds, and the NPWT device used. However, it was not possible to further stratify the laparotomy studies according to the specific operation performed, or the contamination of wounds (i.e. clean vs. clean contaminated vs. contaminated) due to a lack of individual level patient data and the relatively small number of published studies.

The overall quality of evidence for included studies was moderate; however, the majority of RCTs in this meta-analysis were industry funded. Pooled analysis of the industry-funded trials demonstrated a significant benefit with NPWT, which was not present for the non-industry-funded trials. It is unclear whether this relates to biases in the design and reporting of these studies, the small sample size of the non-industry-funded trials, or publication bias towards studies with positive results [54]. Concerns regarding random sequence generation and allocation concealment in NPWT trials have been expressed [55], although these were not identified in the present meta-analysis.

Further high-quality, adequately powered RCTs are needed to clarify the benefit of prophylactic NPWT in closed abdominal surgery. In order to identify patients in whom NPWT may be most beneficial, studies should clearly describe baseline risk factors, and consider stratification according to wound contamination. Prior work has highlighted inconsistencies in the definitions of SSI used in the literature [56, 57], and it is evident that there is a need for consistent reporting of well-defined outcomes in studies of incisional NPWT. Development of a consensus "core outcome set" may standardise reporting and minimise bias in future trials. Cost-effectiveness assessment was limited to two trials [58, 59], preventing its assessment in this meta-analysis. Therefore, the economic benefit may only be confirmed on quantitative analysis with the addition of future studies. In addition to the CONSORT statement [60], specific guidelines for the reporting of RCTs in wound care are available; these should be followed in future publications [61]. There are multiple ongoing RCTs of prophylactic NPWT in abdominal surgery still to be reported [62–64]; therefore, further meta-analyses are likely to be needed.

Conclusion

Prophylactic use of NPWT may reduce the incidence of superficial SSI in closed abdominal incisions but appears to have no effect on deep or organ space SSI. Further high-quality, appropriately powered randomised trials are needed, with clearly defined cohorts and outcomes measures, in order to confirm their benefits and assess cost-effectiveness.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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