



Prophylactic negative pressure wound therapy for closed laparotomy wounds: a systematic review and meta-analysis of randomised controlled trials

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Abstract

Surgical site infections are a common source of post-operative morbidity and contribute significantly to healthcare costs. Patients undergoing emergency laparotomy and/or bowel surgery are particularly at risk. Prophylactic negative pressure wound therapy (NPWT) has been shown to reduce wound infection. However, to date, there has been a lack of consensus around its use for closed laparotomy wounds. We conducted a systematic review of randomised controlled trials comparing the use of prophylactic negative pressure wound therapy with standard dressings for closed laparotomy incisions. The primary outcome was incidence of incisional surgical site infection (SSI) at 30 days post-operatively. Secondary outcomes included superficial and deep SSI, skin dehiscence, fascial dehiscence and length of stay. A total of 2182 publications were identified, of which, following review of titles, abstracts and full texts, five studies met the criteria for inclusion. Across these studies, 467 patients were randomised to NPWT and 464 to standard dressings. Overall SSI rate was 18.6% ($n = 87/467$) versus 23.9% ($n = 111/464$) in the NPWT and standard dressing groups, respectively (Odds ratio 0.71, 95% CI 0.52–0.99, $p = 0.04^*$). Deep SSI incidence was the same in both groups (2.6%). Both skin dehiscence and fascial dehiscence were slightly higher in the standard dressing group ((4.2%, $n = 11/263$ versus 3.1% ($n = 8/261$) and (0.9% ($n = 3/324$) versus 0.6% ($n = 2/323$)), respectively. This study observed that NPWT reduces the overall SSI for closed laparotomy wounds. It supports data recommending the use of prophylactic NPWT dressings, especially in high-risk patients in both emergency and elective circumstances.

Keywords Laparotomy · Negative pressure wound therapy · Surgical site infection · Wound care

Introduction

Incisional surgical site infection (SSI) causes significant morbidity to patients and expenditure to healthcare providers [1–3]. It can increase hospital stay, promote hernia formation, limit mobilisation and delay commencement of adjuvant chemotherapy and/or interventions [4–8]. In recent years, increased focus and investment have been advocated to reduce SSI rates globally [9], but it remains the most common post-operative morbidity [10, 11]. Recent studies estimate that the incidence of SSI following open abdominal surgery ranges

from 15 to 25%, but this is likely to underestimate the true incidence [12–14]. Patients undergoing emergency abdominal surgery have significantly higher rates of SSI, especially in the setting of sepsis. Other risk factors include obesity, poor nutritional status, a history of smoking, diabetes and surgery specifically on the bowel [11].

Negative pressure wound therapy (NPWT) is increasingly becoming a well-recognised management option for both open and chronic wounds [15–17]. NPWT use in the acute emergency setting following bowel surgery has been proposed to have advantageous benefits in reducing the incidence of SSI. Gomoll et al. first described the successful use of NPWT on closed incisions in a series of orthopaedic trauma cases [18]. Since then, its use has risen exponentially in most surgical specialties [19–22].

Though there have been several retrospective studies suggesting a large reduction in SSI rates following prophylactic NPWT use [23, 24], there remains a lack of consensus on the evidence

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from randomised controlled trials (RCT) [25–28]. Recently, there have been several meta-analyses reporting on NPWT but with considerable inclusion/exclusion limitations.

The aim of this review is to provide the most updated review of current randomised controlled trials producing evidence relating to the prophylactic use of NPWT after laparotomy incisions in general surgical procedures.

Methods

Search strategy

This review was performed according to Cochrane handbook for systematic reviews of interventions [29] and the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement [30]. A comprehensive search was conducted using PubMed, the Cochrane library database and Clinicaltrials.gov in order to identify RCTs comparing prophylactic negative pressure wound therapy (NPWT) to standard dressings in closed laparotomy wounds published between January 2005 and February 2020. The starting point of 2005 was chosen as this was the first recorded use of prophylactic NPWT. The last date of search was 23 February 2020.

English language texts were searched for using the following search headings: “negative pressure wound therapy” or “npwt” or “pico” or “prevena” and “laparotomy” or “abdominal wound” or “abdominal incision”. All titles were initially evaluated, duplicates were removed. Suitable abstracts were extracted for full-text screening. In addition, each of the eligible publication reference list was also screened for further potential articles.

Inclusion criteria

- Randomised controlled trials.
- Comparing NPWT versus standard dressings for closed laparotomy wounds
- Studies must report on surgical site infection rates for general surgical procedures specifically.
- English texts only.

Exclusion criteria

- Did not compare NPWT to standard dressings
- Non-randomised data
- Did not report data on laparotomy wound outcomes
- Gynaecology-only procedures
- Non-English texts
- Studies which do not describe key features of study design (such as study type, randomisation, blinding, sample size calculation)

Outcomes

The primary outcome was the incidence of incisional surgical site infection. Secondary outcomes included superficial incisional SSI, deep incisional SSI, skin dehiscence, fascial dehiscence and post-operative length of stay.

Data extraction and statistical analysis

The following data were retrieved from the selected publications: journal, author, year published, country, number of patients per arm, specific treatment applied, control used, emergency/elective ratio, mean/median age, gender breakdown, average BMI, diabetes status and SSI rates. Duplicates were erased and the discrepancies clarified.

Statistical analysis was performed using RevMan statistical software (Ver. 5 Copenhagen, Denmark). Binary outcome data were reported as odds ratios (OR) and 95% confidence interval (95% CI) were estimated using the Mantel-Haenszel method. Heterogeneity was assessed by I-squared statistics, with > 50% being considered as considerable heterogeneity. Statistical significance was attributed to *p* value < 0.05.

Assessment of risk of Bias

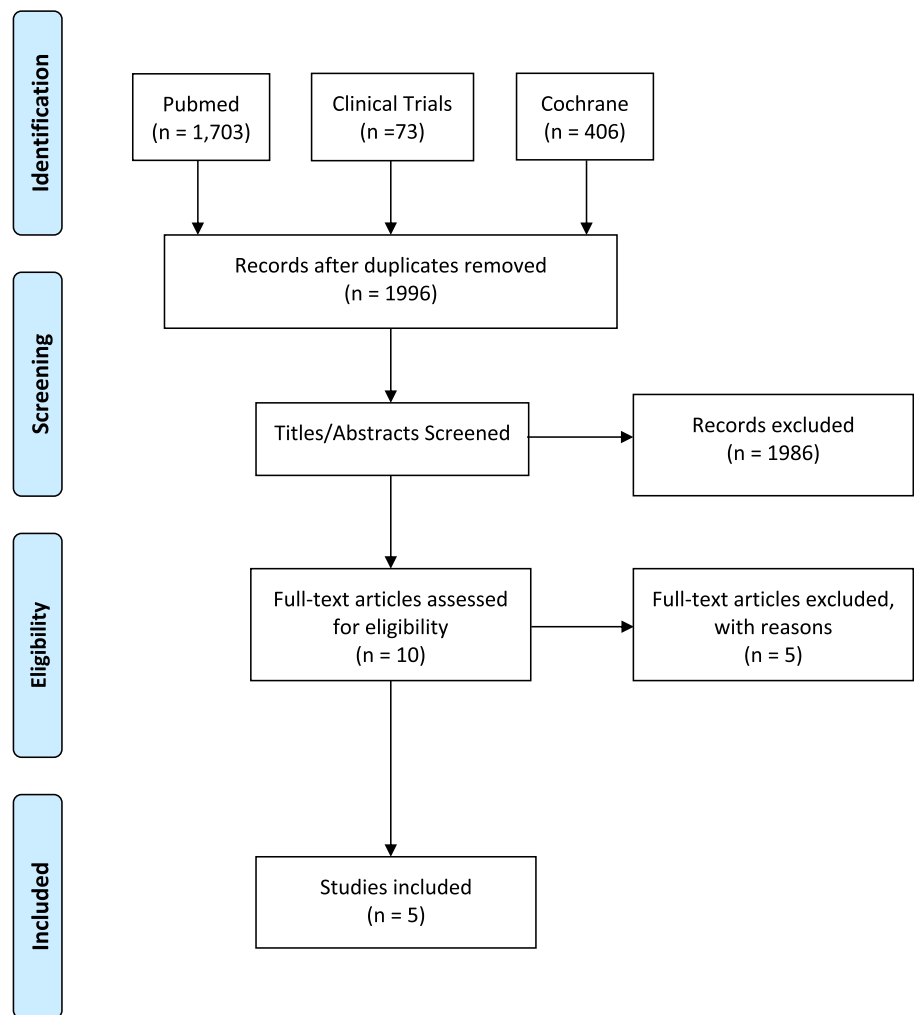
The Cochrane Collaboration’s tool [29] was used to assess risk of bias. Trials were graded as follows: low risk, high risk, and unclear risk. The results of this assessment are depicted in the Appendix Table 4.

Results

Literature search and study characteristics

A total of 2182 publications were identified using the aforementioned search criteria. After duplicates were removed, 1996 publications were reviewed. Following the screening of titles and abstracts, ten full texts were assessed for eligibility. Five studies were excluded: one containing a large proportion of gynaecological procedures, one with wounds healed by secondary intention and three which reported on non-randomised data. Five studies were found to meet the predefined inclusion criteria [26–28, 31, 32]. Figure 1 depicts the PRISMA flowchart. There was some variance between studies regarding the type of NPWT dressing used, type of control dressing and total days of dressing application. The characteristics of the included RCTs are summarised in Table 1.

Fig. 1 PRISMA flowchart outlining inclusion/exclusion of studies in the meta-analysis



Patient characteristics

In total, 467 patients were randomised to NPWT and 464 to control dressings. There were 519 male patients and 412 female patients included in this review. There was no significant difference in average BMI or numbers of diabetics in each arm. Most studies examined elective procedures only. Only 4.7% ($n = 44/931$) of the included cases were classified as emergencies. These characteristics are illustrated in Table 2.

Outcomes of interest

Overall SSI was higher in the standard dressing group (odds ratio 0.71 (95% CI 0.52–0.99, $p = 0.04^*$, Fig. 2) at 23.9% ($n = 111/464$) versus 18.6% ($n = 87/467$)) in the NPWT group.

Only three studies reported on rates of superficial and deep SSIs. Superficial SSIs were higher in the standard dressing group (18.5% ($n = 43/232$) versus 9.7% ($n = 22/227$)), but there was no difference in deep SSI rates (2.6% in both groups).

Table 1 Study characteristics of the included RCTs are summarised

Author	Year	NPWT/control	Elective/emergency	Intervention	Control
Flynn [32]	2019	96:92	145:43	PICO (– 80 mmHg × 7 days)	Standard dressing
Javed [28]	2018	62:61	123:0	Prevena (– 125 mmHG × 4 days)	Standard dressing
Murphy [26]	2018	144:140	284:0	Prevena (– 125 mmHg × 5 days)	Standard dressing
Li [31]	2017	33:38	70:1	VAC (– 125 mmHg × 3 days)	Standard dressing
Shen [27]	2017	132:133	265:0	VAC and adaptic (– 125 mmHg × 4 days)	Standard dressing

*EL elective, EM emergency

Table 2 Breakdown on studies with patient demographics

Arm	Flynn [32]		Javed [28]		Murphy [26]		Li [31]		Shen [27]	
	NPWT	Control	NPWT	Control	NPWT	Control	NPWT	Control	NPWT	Control
Patients	96	92	62	61	144	140	33	38	132	133
Age (years)	64.2 (mn)	66.8 (mn)	66.4 (mn)	66.1 (mn)	64 (mn)	64 (mn)	60.8 (mn)	58.7 (mn)	59.5(md)	62 (md)
% Male	54.2%	64.1%	50%	55.7%	51.4%	57.1%	54.5%	65.8%	58.3%	51.9%
BMI (kg/m ²)	30.3 (mn)	30.4 (mn)	26.8 (mn)	25.9 (mn)	27 (mn)	28 (mn)	21.9 (mn)	22.5 (mn)	28.1 (md)	27.6 (md)
Diabetes	22 (22.9%)	27 (29.3%)	16 (25.8%)	19 (31.2%)	25 (17.4%)	25 (17.9%)	2 (5.7%)	3 (7.9%)	35(26.5%)	26(19.5%)

**mn* mean, *md* median

Rates of skin dehiscence and fascial dehiscence were lower in the NPWT group, but not statistically different ((4.2%, $n = 11/263$) versus (3.1% ($n = 8/261$) and 0.9% ($n = 3/324$) versus 0.6% ($n = 2/323$)) for standard and NPWT groups respectively].

Length of stay was only compared in two RCTs. In Murphy et al., the median length of stay was 7 days in both arms, while Flynn et al. observed that the median length of stay in the standard dressing group was 1 day longer (7 versus 8 days). (Table 3 outlines all SSI outcomes).

Discussion

This review of current RCT data observed that the overall SSI rates are significantly reduced with the use of prophylactic NPWT. This supports older meta-analytical data examining the prophylactic NPWT on a variety of closed incisions [33]. However, to date there has been a lack of consensus on the routine use of NPWT following for all laparotomies, not just focusing on emergency cases. A meta-analysis in 2018 noted a decrease in overall SSI rates in NPWT patients [34], but there was considerable heterogeneity in the type of studies included, with one major critique being the inclusion of a RCT which applied NPWT to open rather than closed incisions [35, 36].

In contrast, Kuper et al. did not observe a reduction in SSI (relative risk 0.56, 95% confidence interval 0.30–1.03) and

suggested the use of prophylactic NPWT in general and colorectal surgery be “tempered” [35]. However, this review included a study which had a high proportion of patients undergoing gynaecology procedures [25]. This makes the applicability of this review to general surgery questionable. The microbiome of the female reproductive system differs significantly from that of the bowel [37], and as previously stated, resectional bowel surgery carries a significantly higher risk of wound contamination and subsequent SSI. It was for these reasons that data pertaining to gynaecology procedures was excluded from analysis in this study.

SSI encompasses a spectrum of wound issues, ranging from simple cellulitis treated with oral antibiotics to chronic wound issues and/or dehiscence which can be a significant burden to both the patient and the healthcare system. The economic costs associated with SSI are significant. In 2008, individual patient costs in NHS hospitals in Britain ranged from £814 to £6626 depending on the severity of wound infection. The financial impact of SSI on the NHS budget is in excess of £90 million per year, largely due to increased length of stay [38]. The cost of single-use NPWT systems ranges from 150 to 330 euros. Cost-analysis performed by the NICE group suggested that the initial additional cost is offset by a reduction in SSI and its impact to healthcare [39]. However, a recent Cochrane review questioned the true cost-effectiveness of NPWT [40]. Surgical site infections do result in the use of avoidable antibiotic therapy, further intervention for wound management, increased length of stay and have

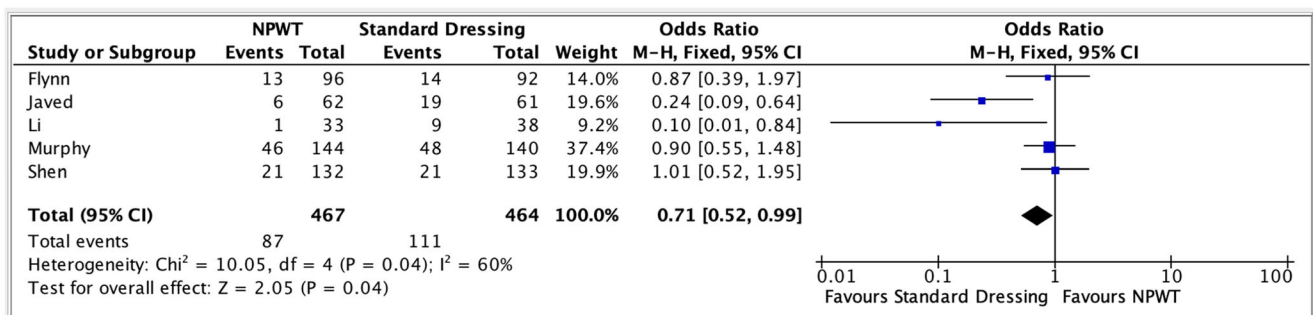


Fig. 2 Forest plot meta-analysis of standard dressing vs. NPWT and its impact on overall incisional surgical site infection

Table 3 Incidence of SSI and skin/fascial dehiscence rates across the included RCTs

Study	Dressing	Overall SSI	Superficial SSI	Deep SSI	Skin dehiscence	Fascial dehiscence	Length of stay (days)
Flynn [32]	NPWT	13.5% (<i>n</i> = 13/96)	NS	NS	6.25% (<i>n</i> = 6/96)	1.0% (<i>n</i> = 1/96)	NS
	Control	15.2% (<i>n</i> = 14/92)	NS	NS	8.7% (<i>n</i> = 8/92)	1.1% (<i>n</i> = 1/92)	NS
Javed [28]	NPWT	9.7% (<i>n</i> = 6/62)	6.5% (<i>n</i> = 4/62)	3.2% (<i>n</i> = 2/62)	NS	0% (<i>n</i> = 0/62)	7 (7–10)
	Control	31.1% (<i>n</i> = 19/61)	27.9% (<i>n</i> = 17/61)	3.3% (<i>n</i> = 2/61)	NS	3.3% (<i>n</i> = 2/61)	8 (7–10)
Murphy [26]	NPWT	31.9% (<i>n</i> = 46/144)	NS	NS	NS	NS	7 (5)
	Control	34.3% (<i>n</i> = 48/140)	NS	NS	NS	NS	7 (5)
Li [31]	NPWT	3.0% (<i>n</i> = 1/33)	3.0% (<i>n</i> = 1/33)	0% (<i>n</i> = 0/33)	0% (<i>n</i> = 0/33)	0% (<i>n</i> = 0/33)	NS
	Control	23.7% (<i>n</i> = 9/38)	23.7% (<i>n</i> = 9/38)	0% (<i>n</i> = 0/38)	0% (<i>n</i> = 0/38)	0% (<i>n</i> = 0/38)	NS
Shen [27]	NPWT	15.9% (<i>n</i> = 21/132)	12.9% (<i>n</i> = 17/132)	3.0% (<i>n</i> = 4/132)	1.5% (<i>n</i> = 2/132)	0.8% (<i>n</i> = 1/132)	NS
	Control	15.9% (<i>n</i> = 21/133)	12.9% (<i>n</i> = 17/133)	3.0% (<i>n</i> = 4/133)	2.3% (<i>n</i> = 3/133)	0% (<i>n</i> = 0/133)	NS
Total	NPWT	18.6% (<i>n</i> = 87/467)	9.7% (<i>n</i> = 22/227)	2.6% (<i>n</i> = 6/227)	3.1% (<i>n</i> = 8/261)	0.6% (<i>n</i> = 2/323)	N/A
	Control	23.9% (<i>n</i> = 111/464)	18.5% (<i>n</i> = 43/232)	2.6% (<i>n</i> = 6/232)	4.2% (<i>n</i> = 11/263)	0.9% (<i>n</i> = 3/324)	N/A

NS not specified length of stay represented as median (interquartile range)

substantial impact on overall recovery and patient well-being [4, 5].

NPWT acts by several mechanisms to improve wound healing. Firstly, it creates a hypoxic environment, which gives rise to increased levels of circulating interleukins (IL-8 and IL-10) and growth factor expression. This stimulates angiogenesis, granulation and extracellular matrix remodelling [41–43]. Mechanically, by creating a negative pressure environment, it may act to inhibit seroma formation, thereby lowering bacterial bioburden and promoting wound contraction [44–46]. The air-tight seal and suction applied improves wound edge opposition but may also prevent fluids from seeping through the wound onto the patient and the surrounding environment. In light of the COVID-19 pandemic, NPWT may be a valuable tool in reducing spread by forming a cleaner wound area, reducing the number of dressing changes required and potentially reducing length of stay. However, to date, there are no notable studies or recommendations regarding the use of NPWT during the COVID-19 pandemic.

Patients undergoing emergency laparotomy are particularly underrepresented in the RCTs published to date despite having a significantly increased risk of SSI. Forty-three of the 44 emergency cases in this study were included in the study by Flynn et al. However, these patients are described in the study as “sub-acute”. Sub-acute was defined as patients admitted under emergency conditions and requiring surgery on that admission but not immediate surgery [32]. Going forward, it is clear that RCTs must recruit more true emergency cases for analysis, ensuring that study populations are representative of the real world. Patients selected for inclusion should be those that are at increased risk of SSI development. A validated tool to predict SSI risk such that proposed by Ejaz et al. may be beneficial in identifying this cohort of patients [47].

We acknowledge that this study has some limitations. Included patients are from RCT data only, and therefore,

intrinsic selection bias is evident. In addition, there is no data on patient reported outcomes, long-term outcomes such as cosmesis, or cost analysis.

The need for further large, multicentre RCTs examining the use of NPWT in laparotomy has been outlined in recent reviews. Such studies would facilitate sub-group analysis of acute versus elective surgery and cost-benefit assessment while providing clarity on appropriate patient selection, duration of treatment and potential limitations [48].

Conclusion

This study observed a significant reduction of overall SSI rates in closed laparotomy wounds treated with prophylactic NPWT. It supports recommendations that the use of NPWT dressings, especially in high-risk patients, in both emergency and elective settings can have considerable benefit to patient recovery.

Availability of data and material All data previously published and referenced.

Code availability Not applicable.

Compliance with ethical standards

Conflicts of interest All authors declare that they have no conflict of interest.

Ethics approval Review of published data. Not applicable.

Consent to participate Not applicable.

Consent for publication Not applicable.

Appendix

Table 4 Cochrane risk of bias assessment of all included RCTs

Author	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete data outcome	Selective reporting	Other source of bias
Flynn [32]	Low-risk	High-risk	High-risk	Low-risk	Low-risk	Low-risk	Low-risk
Javed [28]	Unclear	Unclear	High-risk	Low-risk	High-risk	Low-risk	Low-risk
Murphy [26]	Low-risk	Low-risk	Low-risk	Low-risk	Low-risk	Low-risk	Low-risk
Li [31]	Low-risk	Low-risk	Low-risk	Low-risk	Low-risk	Low-risk	Low-risk
Shen [27]	Unclear	Unclear	High-risk	Low-risk	High-risk	Low-risk	Low-risk

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