

The efficacy of closed incision negative pressure wound therapy to reduce surgical site infections: a systematic review



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Background: Surgical site infection (SSI) is a global concern and a critical threat to surgical outcomes. Despite the incorporation of evidence-based SSI care bundles worldwide, the incidence and associated morbidity and mortality rates of SSIs remain considerable (Strugala and Leaper, 2018). Closed incision Negative Pressure Wound Therapy (ciNPWT) is designed to mitigate against the occurrence of SSI. **Aim:** To assess the prophylactic efficacy of ciNPWT in preventing SSIs in high-risk wounds. **Methods:** CINAHL, MEDLINE, via PubMed and Embase, PubMed Central, Centre for Genomic Regulation, Cochrane Library, and reference lists of recent reviews between January 2010 to April 2019 were systematically searched according to predefined criteria. Randomised controlled trials were included if they compared ciNPWT on clean surgical wounds with conventional dressings. Follow-up periods shorter than 30 days and studies on contaminated wounds were excluded from the review. Risk of bias was assessed with the Cochrane risk of bias tool, while Grading of Recommendations, Assessment, Development and Evaluations were used to qualify evidence. **Results:** From 1,115 records generated by this search, seven randomised intervention trials were included in the qualitative synthesis, which included 863 participants and four types of surgeries associated with a high risk for surgical wound complications. The SSI rate was reduced in the intervention group (overall incidence 5.6%) compared to the standard dressing group (overall incidence 10%). The evidence of the primary outcome was graded as moderate. **Conclusion:** The prophylactic use of ciNPWT significantly reduced the incidence of SSIs compared with conventional dressings. Therefore, ciNPWT should be considered for inclusion in the routine SSI care bundle for high-risk surgical incisions healing by primary intention.

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Disclosure: The author has no conflicts of interest to declare.

The global problem of surgical site infections (SSIs) and their associated morbidity and mortality, is the leading healthcare-associated infection (HCAI) in the general patient population in countries with limited resources (World Health Organization [WHO], 2020). According to the Lancet Commission on Global Surgery, of the 313 million surgical procedures performed worldwide each year, 4.2 million result in patient deaths due to postoperative wound

complications (Nepogodiev et al, 2019). The substantial financial cost of SSI, accumulated in the added length of stay, readmission rates, reoperation rates and complex antimicrobial treatment regimens due to the emergence of antimicrobial-resistant pathogens, is a tremendous burden to the healthcare system (Korol et al, 2013; Willy et al, 2016; WHO, 2020). The actual cost of SSI in terms of suffering, morbidity, financial cost and mortality for patients and their families is also enormous (WHO,

2020). It is estimated that at least 50% of all SSIs are preventable with the implementation of available evidence-based strategies, such as SSI care bundles in the perioperative period (Willy et al, 2016, Berrios-Torres et al, 2017; Strugala and Leaper, 2018).

Traditionally, clean surgical incisions are closed with sutures or staples, or a combination of methods to heal by primary intention. Recently, single-use closed incision Negative Pressure Wound Therapy (ciNPWT) devices, applied over closed incisions, have been used by surgeons from various disciplines with positive outcomes (Willy et al, 2016). Negative pressure, provided by ciNPWT induces wound bed contraction, decreases wound bed surface area by lateral tension and reduces oedema and inflammation by managing wound bed exudates (Newman et al, 2019; Svensson-Björk et al, 2019). Furthermore, the occlusive cover dressing protects the surgical wound from environmental contamination (De Vries et al, 2016).

Problem statement

Surgeons from several surgical specialities use ciNPWT in the management of surgical incisions with positive outcomes. A significant reduction in SSIs have been reported when ciNPWT was used in high-risk wounds. However, the available literature evidence remains of low certainty and does not warrant protocol change (Webster et al, 2019).

Aim

Primary objective

To examine data to determine if ciNPWT reduces the rate of SSI in the high-risk surgical incision compared to conventional dressings.

Secondary objectives

To examine the effect of ciNPWT compared with conventional dressings on dehiscence, readmission/reoperation, length of stay, costs, skin blisters and quality of life.

Methods

Search strategy and inclusion criteria

The intervention review was conducted according to the Cochrane Handbook for Systematic Reviews (Higgins et al, 2016). General bibliographic databases, MEDLINE, via PubMed and Embase, PubMed Central (PMC), Centre for Genomic Regulation (CRG), Cochrane Library, and reference lists of recent reviews, between January 2010 to April 2019, were systematically searched according to predefined criteria. Cumulative Index to Nursing and Allied Health Literature (CINAHL) was included as a specialised database and accessed through the University of Essex Library, Essex, UK. Expert opinion was sourced through globally recognised

consensus documents on the subject.

Randomised controlled trials (RCTs), single- or multi-centre, of all languages, participants 18 years and older, receiving inpatient surgeries, were included in the review if they compared the prophylactic use of ciNPWT as an intervention in early identified Class I/clean incisional wounds at high-risk of a disruption to normal surgical healing, essentially SSIs. Follow-up periods shorter than 30 days and contaminated wounds (often left open to heal by secondary intention) were excluded from the review. The PICO™ system (Smith & Nephew, Watford, UK) and the Prevena™ Incision Management System (KCI, San Antonio, Texas, USA) were ciNPWT devices included in the study. The comparison interventions were all conventional postoperative wound care dressings.

The measure used for the primary outcome was the Centres for Disease Control and Prevention (CDC) reporting definitions for SSI surveillance: superficial, deep or organ space infections, subject to the range of affected tissues, that occur up to 30 days after surgery, or up to 1 year after surgery in patients receiving implants (Berrios-Torres et al, 2017).

The search strategy of bibliographic databases was constructed according to key concepts from PICO (Patient Population, Intervention, Comparison, Outcome), a specialised framework often used by practitioners of evidence-based practice (Higgins et al, 2016).

MeSH terms used in the literature search

Patient population: "high-risk of surgical wound infections"; "high-risk wounds"; "high-risk of surgical wound infections" OR "high-risk wounds".

Intervention: "topical negative pressure therapy"; "closed surgical incision management"; "closed incision negative therapy"; "topical negative pressure therapy" OR "closed surgical incision management" OR "closed incision negative pressure wound therapy".

Comparison: "traditional dressings"; "surgical dressings"; "traditional dressings" OR "surgical dressings".

Outcome: "surgical wound infections"; "surgical site infections"; "prevention of surgical site infections"; "incidence of surgical site infections"; "prevention of postoperative wound infections"; "prevention of surgical site infections" AND "closed incision" AND "wounds healing by primary intention".

Results

Literature search

The systematic database search resulted in 1,115 articles initially identified. After duplicates were removed, a further 1,024 studies were excluded

based on titles and abstracts. Forty-six full-text articles were assessed for eligibility, of which 39 studies were excluded from the review. Seven RCTs met the inclusion criteria and were included in the review [Figure 1].

Characteristics of included studies

High-risk surgical populations

Cardiothoracic and abdominal surgical patient populations are known for their high risk to surgical complications, and specifically infections. Even so, no study on the cardiothoracic and abdominal surgical populations meeting the inclusion criteria on the subject was identified during the literature search of this systematic review. The seven RCTs represented Caesarean section in obese women (Gunatilake et al, 2017; Ruhstaller et al, 2019); primary/revision total hip and knee arthroplasty (Karlakki et al, 2016; Newman et al, 2018); high-risk groin wounds in lower-extremity revascularisation (Lee et al, 2017; Kwon et al, 2018), and pancreatotomy with midline laparotomy in oncology patients (Kuncewitch et al; 2019). The 863 participants represented 863 incisions, sample sizes of the trials were small, ranging between 73 to 209 people. Four studies were conducted in the USA, one in the UK, and one in Ontario, Canada. One study did not report where it was conducted.

Risk-factors to surgical complications

Risk factors varied across the studies but was

inclusive of BMI ≥ 35 kg/m², poor physical status — American Society of Anaesthesiologists (ASA) grade ≥ 3 , uncontrolled diabetes mellitus, renal dialysis, peripheral vascular disease and current smokers. Furthermore, participants on corticosteroids, a history of cancer, liver disease, depression, organ transplant and human deficiency virus infection, were identified as patients at high risk of surgical complications.

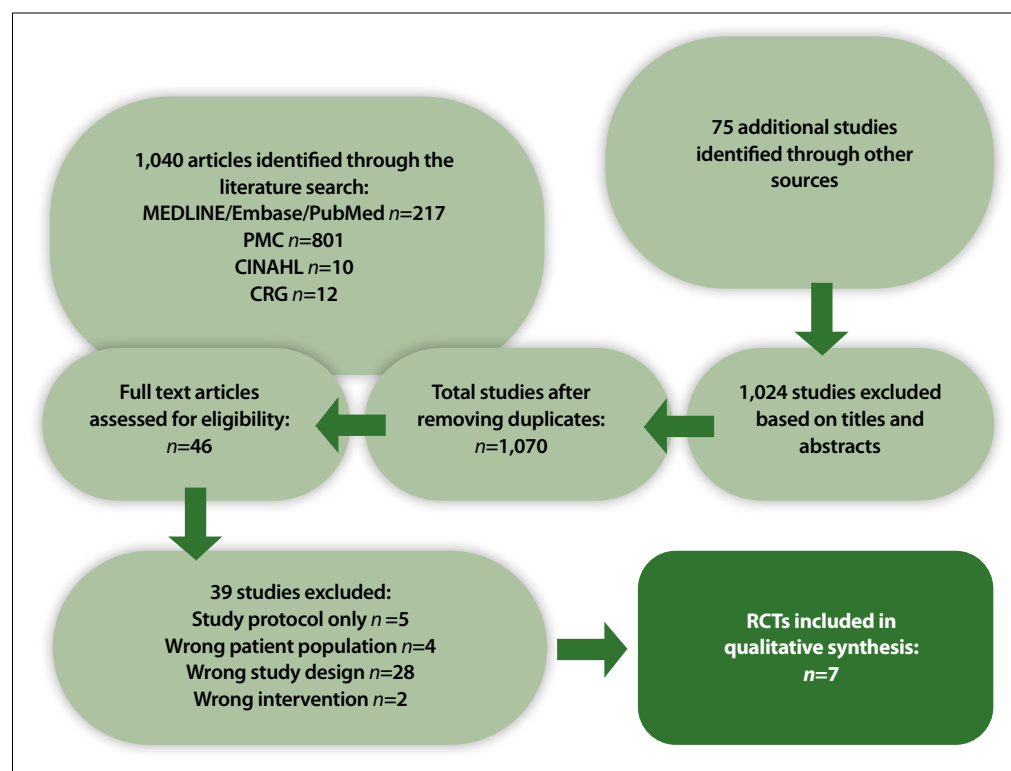
Intervention (ciNPWT)

Gunatilake et al (2017), Kwon et al (2018), Kuncewitch et al (2019), Lee et al (2017), Newman et al (2018) and Ruhstaller et al (2019) used ciNPWT in the form of Prevena Incision Management System set at -125mmHg pressure. Karlakki et al (2016) used the PICO dressing, which delivers continuous negative pressure of -80mmHg.

Duration of ciNPWT

ciNPWT was used for various periods of time. Gunatilake et al (2017) left the ciNPWT in place for 5 to 7 days, Kwon et al (2018) for 5 days, and Lee et al (2017) until either hospital discharge or postoperative day eight, whichever occurred first. Newman et al (2018) left the ciNPWT dressing on for at least 2 days. Ruhstaller et al (2017) left the ciNPWT in place until postoperative day three when study personnel removed it. Kuncewitch et al (2018) chose 4 days of therapy and Karlakki et al (2016) left the ciNPWT in place for a week as the PICO system is programmed to last 7 days.

Figure 1. Flow chart of the systematic review search results.



Comparison

The comparison group for the seven RCTs included was conventional wound care dressings. These included occlusive dressings, non-occlusive dressings and silver dressings. Gunatilake et al (2017) used Steri-Strips™ ½ inch (3M Healthcare, St Paul, MN, USA), sterile gauze, and a transparent, non-penetrable film dressing (Tegaderm™, 3M Health Care Ltd, Loughborough, UK) applied to the closed surgical incision for at least 1 day and no longer than 2 days. Kuncewitch et al (2018) used standard dry gauze dressings removed on postoperative day two, followed by daily dry gauze dressings in the study by Lee et al (2017). Ruhstaller et al (2017) used a Telfa™ dressing (H&R Healthcare, Hull, UK) placed over the closed incision overlaid with a 4 cm × 4 cm gauze pad secured with surgical tape. Newman et al (2018) used a silver-impregnated wound dressing (AQUACEL™; ConvaTec, Greensboro, NC) left on for 7 days if a wound complication was not reported. Karlakki et al (2016) used either Mepore® (Mölnlycke Health Care AB, Gothenburg, Sweden) or Tegaderm™ as per the surgeon's preferred practice, which was changed to OPSITE® Post-Op Visible dressing (Smith & Nephew, Watford, UK) on the second postoperative day as per the usual routine practice.

No statistical techniques were used to combine data from the included studies of the review; therefore, heterogeneity was not calculated in this qualitative review. Clinical and methodological heterogeneity were, however, considered. No results were pooled to report an estimate statistical analysis and no sensitivity analysis was performed in this review. A narrative review was conducted on all included studies, as well as a tabled summary of findings for the comparison [Table 1].

Assessment of risk of bias

The Cochrane Collaboration's tool for assessing the risk of bias in randomised trials (Higgins et al, 2011) was used to assess the seven included RCTs. Risk of bias varied across the studies. Unclear selection bias was identified in Kuncewitch et al (2019), not stating how the selection sequence was generated in the study, and Kwon et al (2018), where patients were randomised by coin toss. Other included studies described a clear and adequate process to prevent selection bias. Blinding of participants and personnel was not possible in all studies. As this was unlikely to affect outcomes, the studies were graded low risk of performance bias.

Outcome assessors were aware of group allocation in the Karlakki et al (2016) study and so the article was graded as high risk for detection bias. Kuncewitch et al (2019), Newman et al (2018) and Ruhstaller et al (2017) did not report

on blinding during outcome assessment and, therefore, it was unclear regarding detection bias. The studies were assessed at low risk for reporting bias as all outcomes were analysed and reported.

Assessments of quality of evidence according to GRADE

Although there is a considerable amount of subjectivity in each decision grading (Siemieniuk et al, 2019), the evidence was graded at moderate certainty for the primary outcome, because the true effect is probably close to the estimated effect. The lack of blinding in outcome assessment was evident in all RCTs; however, blinding was unlikely to affect the outcome results. Underpowered studies were downgraded for imprecision.

Effects of the intervention

Primary outcome

The evidence from seven studies (863 wounds; follow-up 30–60 days) comparing ciNPWT with conventional wound care reported that ciNPWT reduced the rate of SSIs in high-risk surgical incisions. The overall SSI rate was reduced in the intervention group 24/425 (5.6%) compared to the conventional dressing group 44/438 (10%) [Table 1]. However, the application of ciNPWT to an elective midline laparotomy wound for patients undergoing major pancreatectomy did not demonstrate a significant difference in SSI rates (Kuncewitch et al, 2019).

Secondary outcomes

Dehiscence

The average incidence of dehiscence was 6/315 (2%) in the intervention group compared to 21/327 (6.4%) in the control group. Gunatilake et al (2017) reported the ciNPWT group had fewer surgical site occurrences (SSOs) than the comparison (7/43 [16.3%] vs 2/39 [5.1%], $P=0.16$).

Skin blisters

Skin blisters were reported in 8.3% of patients in the ciNPWT group; only 1.6% were observed in the comparison. Ruhstaller et al (2017) reported that four times as many patients had a skin blister after removal of the ciNPWT device compared with standard dressings (13.1% vs. 3.6% [$P=0.10$]), although none of the women with skin blistering required additional treatment.

Reoperation and readmission

In the ciNPWT group, 4.8% of participants underwent reoperation, in contrast to 10.9% in the control group. Kwon et al (2018) reported that ciNPWT "significantly reduced major wound complications to 8.5% (including five of six

Table 1. Summary of findings for comparison: closed Incision Negative Pressure Wound Therapy (ciNPWT) compared with postoperative dressings.

Outcomes	Intervention arm (ciNPWT)	Control arm (postoperative dressing)	Number of incisions	Grading of Recommendations, Assessment, Development and Evaluations (GRADE)
Surgical site infection	Study population: 24/425 (5.6%)	Study population: 44/438 (10%)	863 (seven studies)	Moderate
Dehiscence	Study population: 6/315 (2%)	Study population: 21/327 (6.4%)	642 (five studies)	Low
Re-admission	Study population: 25/262 (9.5%)	Study population: 40/293 (14%)	555 (five studies)	Low
Re-operation	Study population: 9/187 (4.8%)	Study population: 21/193 (10.9%)	380 (three studies)	Low
Length of stay	Study population: 3.8 days 6.4 days 10.6 days 3 days	Study population: 4.7 days 8.9 days 10.6 days 3 days	209 102 119 119	Low
Costs	\$30,492	\$36,537	119 (one study)	Low
Skin barriers	Study population: 20/242 (8.3%)	Study population: 4/245 (1.6%)	487 (three studies)	Low
Quality of life: Pain at rest	Study population: 20/46 (43.5%)	Study population: 39/46 (84.8%)	92 (one study)	Low

infections in 59 incisions; $P < 0.001$), reoperation (8.5%; $P < 0.05$) and readmission (6.8%; $P < 0.04$).¹⁰ On the other hand, Lee et al (2017) found no difference in readmission or reoperation for SSI or mortality between the two groups. Similarly, Newman et al (2019) found no significant difference in terms of readmissions, but the reoperation rate was higher in controls compared to ciNPWT patients (10 [12.5%] vs 2 [2.5%], $P = 0.017$).

Length of stay

Karlakki et al (2016) reported an overall length of stay (LOS) reduction in the ciNPWT group (0.9 days, 95% confidence interval (CI) -0.2 to 2.5), although not statistically significant ($P = 0.07$), there was a significant reduction in patients with extreme values of LOS in the

ciNPWT group (Moses test, $P = 0.003$). Kwon et al (2018) reported no reduction in LOS (10.6 days in both groups), while Lee et al (2017) reported a statistically significant shorter mean duration of LOS in the ciNPWT group (6.4 days) compared with the standard group (8.9 days, $P = 0.01$).

Costs

Estimates of cost savings varied. Some studies reported on the difference between the cost of the device and the usual cost of infection. In the Kwon et al (2018) study the average variable cost in the ciNPWT group was reduced, yielding an average saving of \$6,045 per patient ($P = 0.11$). However, Ruhstaller et al (2017) reported that "at a per-device cost of \$544, prevention of a single infection would cost approximately \$15,000. Thus, the prevention

of one SSI after a Caesarean section would increase post-surgical health care costs, an additional \$10,300 beyond the average cost attributed to the infection itself". Others reported on reduced LOS — Karlakki and colleagues (2016) argued in favour of the cost-effectiveness of ciNPWT by taking the reduced LOS (£275 per day hospital bed), fever dressing changes (nurse time) and potential cost savings for wound care in the community due to reduced wound complications into account in the study group.

Quality of life

Gunatilake et al (2017) reported the ciNPWT group had significantly fewer participants with both pain at rest (39/46 [84.8%] vs. 20/46 [43.5%]; $P < 0.001$), and with incisional pressure (42/46 [91.3%] vs. 25/46 [54.3%]; $P < 0.001$); and a 30% decrease in opioid use (79.1 vs 55.9 mg morphine equivalents, $P = 0.036$).

Discussion

In all included studies, a trend towards the reduced incidence of SSI was reported. Based on reduced wound bed complications, the beneficial role of ciNPWT is advocated by Karlakki et al (2016) in patients undergoing primary hip and knee arthroplasty. Similarly, the findings of Newman et al (2018) supports the use of ciNPWT in patients who are at an increased risk of postoperative complications after revision arthroplasty. In addition, ciNPWT significantly reduces major wound complications, such as reoperation, readmission for patients at high risk of groin wound complications and may lead to a reduction in hospital costs according to Kwon et al (2018). Lee et al (2017) highlighted the significantly shorter mean LOS for high-risk groin wounds in lower-extremity revascularisation due to the ciNPWT intervention. Moreover, Gunatilake et al (2017) observed a reduced trend in surgical site occurrences and a statistically significant reduction on postoperative pain and narcotic use in obese patients undergoing Caesarean delivery by using ciNPWT prophylactically. In contrast, Ruhstaller et al (2017) concluded the routine clinical use of ciNPWT after Caesarean delivery did not result in a significant reduction in wound morbidity over standard care.

Agreements and disagreements with other studies and reviews

The results from this systematic review comport with previous reviews measuring the prophylactic role of ciNPWT compared to conventional dressings in preventing SSI in high-risk surgical wounds healing by primary intention. The comprehensive meta-analysis by Strugala and Martin (2018)

showed a clear and significant benefit in favour of the prophylactic use of ciNPWT in reducing SSI, wound dehiscence and LOS from a large database. However, Webster et al (2019), a Cochrane Review, conclude the available evidence on the effect of ciNPWT reducing SSI in incisions healing by primary intention remain of low certainty.

The meta-analysis of Svensson-Björk et al (2019) was the fifth systematic review and meta-analysis published on the subject — its results regarding a reduced SSI incidence in agreement with the previous meta-analysis by Semsarzadeh et al (2015), De Vries et al (2016) and Hyldig et al (2019). The systematic review and meta-analysis of Sandy-Hodgetts and Watts (2015) indicated a statistical-significant difference in favour of ciNPWT compared to standard dressings in the prevention of SSIs. However, no definitive conclusions could be reached given the small size of the studies. Based on the evidence of the review by Willy et al (2016), high-risk incisions, such as sternotomies, are principally recommended for ciNPWT use.

Limitations in study design and implementation

The small study population of included studies (863 incisions) with subsequent large confidence intervals within the individual RCTs made it challenging to estimate the intervention's real effect. Furthermore, heterogeneity within the studies was caused by variables, such as different ciNPWT devices used, the amount of negative pressure used and the duration of ciNPWT treatment (which was often removed before discharge from hospital). Further limitations in data synthesis were caused by variations in conventional dressings used as control and differing SSI measurements.

Potential biases in the review process

One of the included studies used the PICO dressing for the ciNPWT intervention (Karlakki et al, 2016), all the other included studies used the Prevena system — this was discovered during the review process.

Recommendations for research

RCTs identifying the optimal duration and optimal ciNPWT pressure level to a primary incision will fill a research gap (WHO, 2016). Furthermore, conclusive data are needed on the intervention's cost-effectiveness (De Vries et al, 2016; Karlakki et al, 2016; Svensson-Björk et al, 2019). Gunatilake et al (2017) suggested additional benefits of ciNPWT beyond wound complications should be considered in further studies, such as postoperative pain management, narcotic utilisation and patient satisfaction. There is a need for more extensive RCTs to reduce methodological heterogeneity, on

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homogenous study populations and to further reduce clinical heterogeneity between studies. Patient-related and operation-related SSI risk factors are often different for each speciality and operative procedure (Willy et al, 2016). Studies not funded by ciNPWT devices suppliers may increase the credibility of findings and, therefore, evidence quality (Webster et al, 2019).

Recommendations for clinical practice

The available scientific data and multidisciplinary clinical experts support the use of ciNPWT as a prophylactic intervention in the prevention of SSIs. Various algorithms and guidelines are available to assist with clinical decisions in the early identification of patient and procedure-related risk factors for SSI and subsequent prophylactic ciNPWT use (WHO, 2016; World Union of Wound Healing Societies, 2016; Willy et al, 2016; Jeffery et al, 2018; NICE, 2018; Strugala and Leaper, 2018). Given the high financial cost of ciNPWT for SSI prophylaxis, the appropriate use is vital.

Conclusion

According to the findings of this review, moderate certainty of evidence reports that the prophylactic use of ciNPWT on clean high-risk surgical incisions healing by primary intention reduces the incidence of SSI significantly. Therefore, in mitigating the threat of considerable incidence, morbidity, and mortality of SSIs, ciNPWT should warrant inclusion in the routine SSI care bundles for high-risk surgical incisions healing by primary intention. **WINT**

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