

G65: Is there a role for the use of incisional negative pressure wound therapy (iNPWT) in patients undergoing major orthopaedic surgery?

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Response/Recommendation: Yes. Consider using incisional negative pressure wound therapy (iNPWT) as a measure to prevent surgical site infection (SSI), periprosthetic joint infection (PJI), and fracture related infections. (FRI) in patients undergoing major orthopaedic surgery.

Strength of recommendation: Moderate

Delegate Vote:

Rationale:

Despite existing evidence on the effectiveness of iNPWT for the prevention of SSI, iNPWT is still not standard practice in the field of orthopedics [1]. Therefore, we conducted an up-to date systematic review and meta-analysis to clarify the efficacy of iNPWT over standard of care dressing in reducing SSI/PJI/FRI in major orthopaedic surgery, including spine surgery, fracture surgery and joint arthroplasty, following the provided ICM guidance. We identified all RCTs of any design (eg. randomized controlled trials, and quasi-randomized controlled trials) published until Nov 2024 which assessed the effect of iNPWT on adult patients undergoing clean surgeries including major orthopaedic surgery in reducing SSI. We also included fracture fixation for open fracture if the wound was primarily closed.

We identified 2,875 articles that were subjected to title and abstract screening. We shortlisted 71 articles for full-text screening, added 2 articles following hand search. 59 studies were excluded, and the remaining 14 RCTs (N=4,100) were included in our final analysis [2-15]. We used GRADE (Grading of Recommendations Assessment, Development and Evaluation) to evaluate the certainty of the evidence and created Summary of findings table to describe the results [16].

Evidence was available from various countries including USA, UK, Italy, Australia, North America, Germany and China, on various surgical procedures including primary and revision THA/TKA, and fracture surgeries. There was no study focusing on spinal and upper extremities procedures. All studies were published between 2012 and 2023, with most of the studies reporting outcomes with one month or longer follow-up. Four studies used CDC's criteria for the definition of SSI/PJI [2,3,7,10], whereas 7 studies did not describe their definition of infection[6,8,9,33,52,53,106].

From our analysis focusing on all SSI/PJI/FRI, with moderate certainty of the evidence, iNPWT was significantly effective for preventing all SSI/PJI/FRI in patients undergoing clean wound surgeries with primarily closed surgical incisions compared to standard of care dressings (RR 0.54; 95%CI 0.36-0.79, Figure1). Publication bias was likely as the comparison-adjusted funnel plot seemed to show asymmetry (Egger's test: P=0.039). In the trial sequential analysis (TSA), cumulative number of patients did not exceed the required information size (RIS), and the Z-curves did not cross the trial sequential monitoring or futility boundary, suggesting an inconclusive meta-analysis result (Figure 2). This finding was consistent with our sensitivity analyses including studies with ≥ 30 days follow up (RR 0.55; 95%CI 0.35-0.87), and when

excluding studies with high risk of bias (RR 0.46; 95%CI 0.21-1.00). Similar preventive effects were found among our subgroups focusing clean surgery (RR 0.44; 95%CI 0.27-0.73), high income country (RR 0.55; 95%CI 0.37-0.81), elective surgery (RR 0.43; 95%CI 0.23-0.81), PICO (RR 0.55; 95%CI 0.30-0.98) and PREVENA (RR 0.51; 95%CI 0.32-0.81). There was no significant preventive effect in middle income country and fracture surgeries.

For the secondary outcomes, low certainty evidence showed that iNPWT may reduce the risk of superficial SSI and wound dehiscence. But, very low to low certainty evidence showed that the iNPWT have neither benefit nor harm compared to standard of care for the purpose of preventing deep SSI, skin necrosis, seroma, hematoma, skin blistering, reoperation, adverse events and death.

From our results, iNPWT was significantly effective compared with standard of care dressing for preventing all SSI in adult patients with primarily closed surgical incisions after lower extremity/acetabular fracture surgery and hip/knee joint arthroplasty. Moreover, consistent results were found in the sensitivity analyses, and similar preventive effects were found in various subgroups. But, majority of the trials were industry sponsored (8 RCTS), and there seems to be a chance of publication bias, with an inconclusive TSA result. To note, there is another concern regarding its cost. As these devices are generally costly, there remains some issues regarding cost effectiveness. Unfortunately, the evidence regarding this issue is still limited, therefore further studies are required in this area.

There are several limitations. First, we did not perform cost analyses. Further well-designed studies are required to address the cost-effectiveness, especially in low-middle income countries, as its efficacy was not clear in this population. Second, although there were 4,100 subjects included in our primary outcome, we have downgraded the evidence level due to the imprecision based on our inconclusive TSA result. Third, although there was no significant difference in adverse events, this may be underestimated as we did not include observational studies. Fourth, we failed to show effectiveness in fracture surgery. The possible explanation for this finding is the additional skin and soft tissue damage after the injury which may not be controlled even with the application of iNPWT. Although the cumulative data showed a trend towards effectiveness, the benefit of iNPWT may be more apparent to those without soft tissue injuries. Fifth, there was no RCT focusing on spinal and upper extremity procedures. Considering the difference among other orthopedic procedures, reproducibility and generalization may not be warranted in these surgeries. Sixth, the number of studies with low risk of bias was very limited, and the definition and follow up period used to assess SSI/PJI varied among studies. These heterogeneities may have affected our results and therefore needs to be interpreted with caution.

Conclusion:

Based on our results, we recommend the use of iNPWT to minimize the risk of SSI in adult patients with primarily closed surgical incisions after lower extremity/acetabular fracture surgery and joint arthroplasty of the hip and knee. This is aligned with the global recommendations including NICE [17], WHO [18] and the ACS/SIS guidelines [19] all of which recommended the use of iNPWT for the purpose of reducing the risk of SSI.

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Figure 1. Meta analysis results – All SSI/PJI/FRI

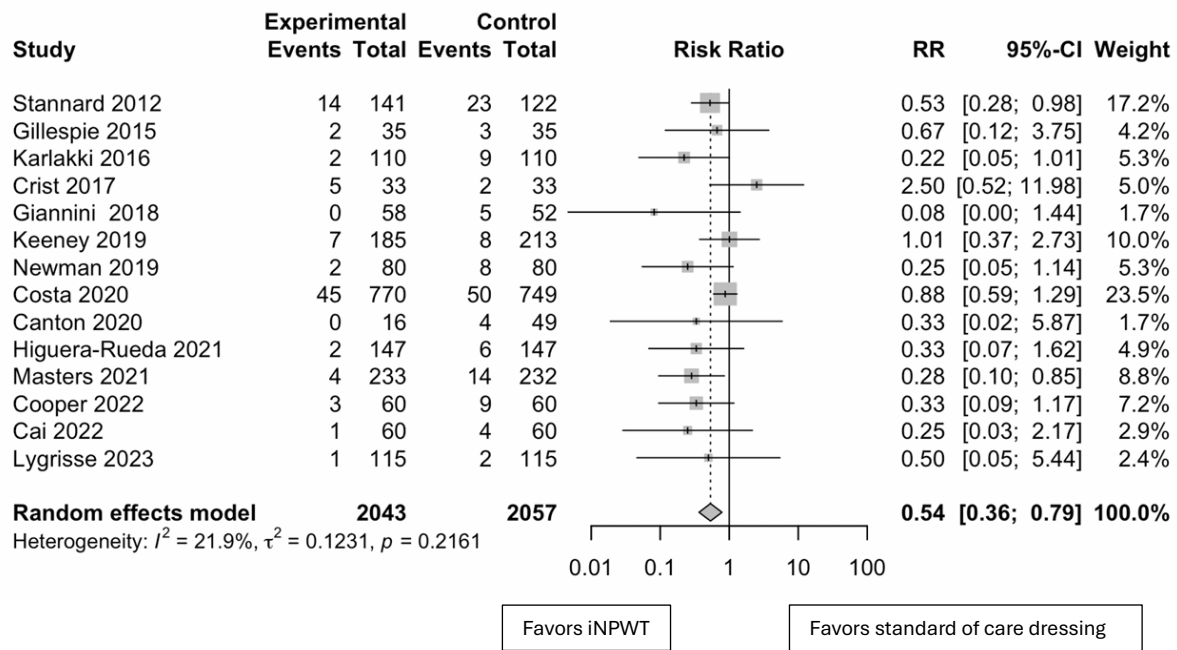


Figure 2. Trial sequential analysis

