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Negative pressure wound therapy with instillation and dwell time (NPWTi-d): a review of the evidence

✚ Evidence summary

A systematic literature review of publications about use of NPWTi-d was conducted[1] and the results of high-level (Level 1) studies[2–6] and expert opinion publications[7–11] were summarised. Key findings were:

93%
lower-quality studies
(116 of 125 are Levels 3 to 5)[1]

No statistically significant differences in clinical outcomes
(p>0.05) versus NPWT in Level 1 studies[2–5]

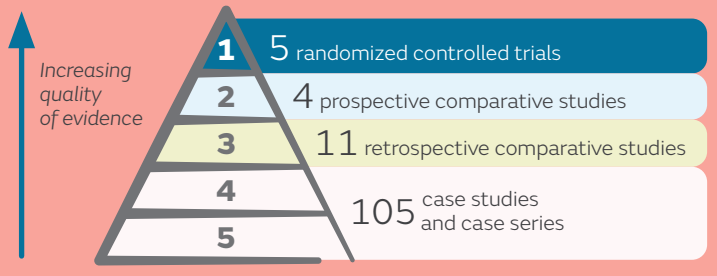
Expert reviews and guidelines
highlight a lack of comparative data and inconsistent use of NPWTi-d[7–11]

Overview and aim

- Instillation NPWT (NPWTi-d) is a modification of traditional NPWT for the treatment of acute and chronic wound infections[12]
  - It involves instillation of saline, an antiseptic or antibiotic into a sealed wound[12]
- A substantial evidence base of high-level studies supports the use of NPWT in a wide range of wound types, whereas less is known about the effects of NPWTi-d[12]
- A systematic review of the literature about use of NPWTi-d was conducted with particular focus on randomized controlled trials (RCTs) comparing NPWTi-d with NPWT[1]
- This report summarizes the results of the highest quality studies (Level 1) that were identified[1] as well as recommendations from consensus groups and health regulators[7–11]

Systematic literature review: results for NPWTi-d

- Of the studies published on NPWTi-d up to July 3, 2020, five Level 1 studies (highest quality; Figure 1) were identified in the systematic literature review[1]
- Another 120 studies were identified, which were all lower-quality evidence (Levels 2 to 5; Figure 1)[1]



4%
of evidence is Level 1
(5 studies)

Figure 1. Overview of evidence supporting the use of NPWTi-d showing number of studies by level of evidence[1]

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Key findings: Level 1 studies

No significant differences in clinical outcomes[2–6]

A brief summary of all five Level 1 studies (RCTs) that were identified as part of the systematic literature review is provided below. In general, there were no significant differences in clinical outcomes in studies comparing NPWTi-d with NPWT.[2–5]

Lavery LA, *et al.* 2020[2]

- This single-center RCT compared healing outcomes in patients with moderate or severe foot infections requiring incision, drainage and intravenous antibiotics
- Patients (n=150) received either NPWT or NPWTi-d with 0.1% polyhexanide-betaine (PHMB) at 30cc/hr (–125mmHg continuous pressure for both) for 16 weeks
- There were **no statistically significant differences in wound healing, time to heal, wound dehiscence, re-infection, leg amputation, or hospital re-admission** between the two treatments (p>0.05; Figure 2)

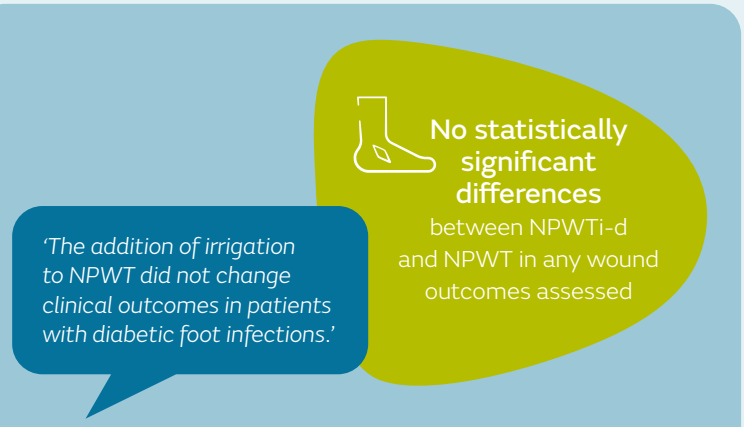

Figure 2. Clinical outcomes with NPWTi-d and NPWT[2]

Kim PJ, *et al.* 2020[3]

- This multicenter RCT compared NPWTi-d (PHMB; 20min dwell time) with NPWT in acute and chronic wounds requiring operative debridement (–125mmHg continuous pressure)
  - >75% of wounds were on the lower extremities
- A total of 181 patients were treated for 56 days from initial debridement or until the wound was deemed ready for closure or coverage, whichever occurred first
- Results showed **no statistically significant difference between the groups in the primary endpoint** of number of required inpatient operating room debridements after initial debridement (p>0.05; Figure 3)
- **Time to readiness for wound closure/coverage, proportion of wounds closed, and incidence of wound complications were all similar**
- Mean decrease in total bacterial count from time of initial surgical debridement to first dressing change was significantly greater with NPWTi-d than NPWT (–0.18 vs 0.60 $\log_{10}$ CFU/g; p=0.02)

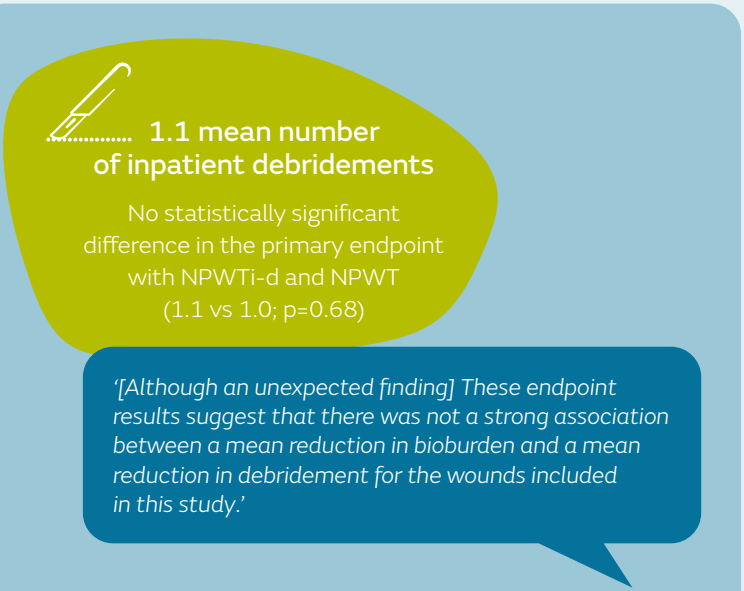

Figure 3. Mean number of inpatient debridements after initial operating room debridement with NPWTi-d and NPWT[3]

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Davis KE, *et al.* 2019[4]

- Another single-center RCT compared NPWTi-d using saline (15mL/hr) with two NPWT systems in patients with moderate and severe infected foot wounds (n=30 per group; –125mmHg continuous pressure)
- There were **no statistically significant differences between the treatments in any of the assessed clinical outcomes** within 12 weeks (p>0.05; Figure 4)
  - Proportion of healed wounds
  - Surgical wound closure rate
  - Number of surgeries
  - Hospital length of stay
  - Time to wound healing

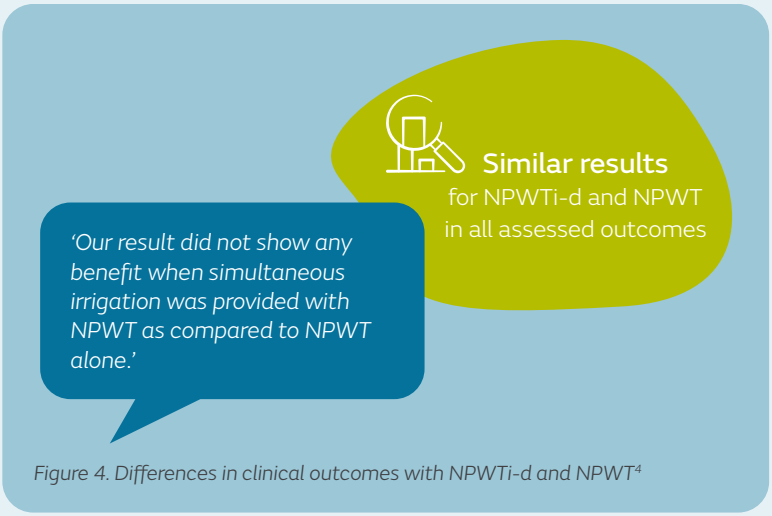

Figure 4. Differences in clinical outcomes with NPWTi-d and NPWT[4]

Yang C, *et al.* 2017[5]

- This RCT compared NPWTi-d (using sodium hypochlorite solution; 10min dwell time) with NPWT (–125 mmHg continuous pressure) in 20 chronic wounds (10 per group) after one week of treatment:
  - Compared with baseline, there was a reduction in biofilm-protected bacteria in the NPWTi-d group (p<0.05) and a slight increase in the NPWT group (p=0.46)
    - However, when the results for each treatment group were compared, the difference was not significant (p=0.11; Figure 5)
  - Use of NPWTi-d did not significantly reduce planktonic bacteria concentrations after initial debridement (p=0.16)
  - Change in wound size was similar with both treatments (Figure 5)

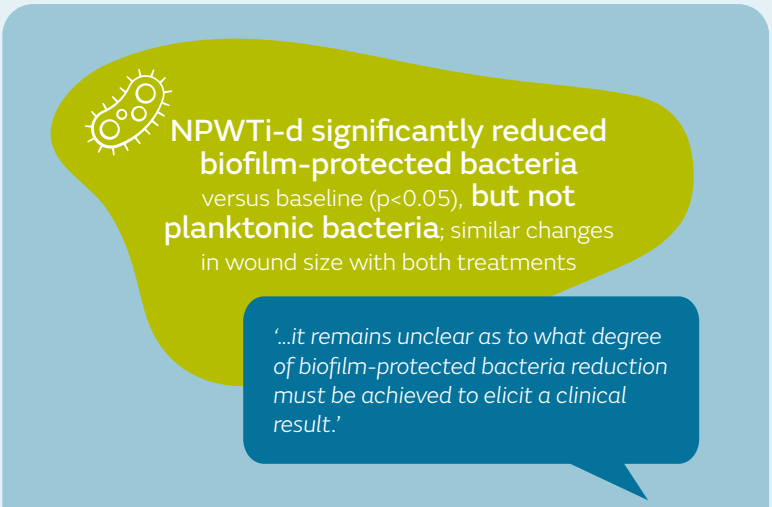

Figure 5. Changes in wound size and reductions in biofilm-protected bacteria with NPWTi-d and NPWT[5]

Kim PJ, *et al.* 2015[6]

- Rather than comparing with NPWT, this RCT evaluated the effects of different NPWTi-d solutions on treatment outcomes in patients (n=100) with wounds that required hospital admission and surgical debridement
  - Most wounds were located on the foot or lower leg (>70%)
- **Use of saline was shown to be as effective as antiseptic** (PHMB; 20min dwell time) but had shorter time to final surgical procedure than antiseptic (p=0.038)
- There were **no statistically significant differences between saline and antiseptic** for number of operating room visits, length of hospital stay, and number of wounds that closed and remained closed at 30-day follow-up (p≥0.05)

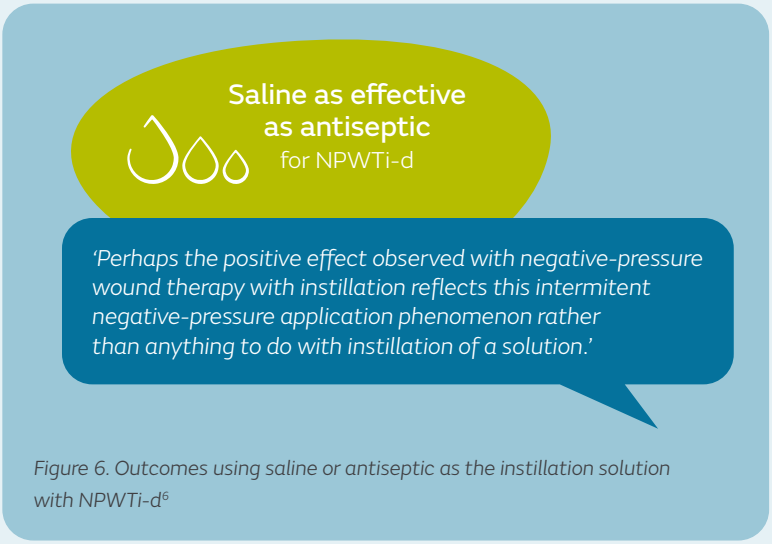

Figure 6. Outcomes using saline or antiseptic as the instillation solution with NPWTi-d[6]

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What experts say

- Several clinical guidelines and expert reviews advocate that large Level 1 RCTs are needed to evaluate the efficacy of NPWTi-d versus NPWT in the clinical setting[7–11]
- The most recent consensus guidelines by Kim PJ and colleagues acknowledge that more comparative data are needed to determine the effectiveness of NPWTi-d[8]
- One health regulator in the UK has produced specific advice on NPWTi-d[9]
  - It states that although NPWTi-d appears more effective than moist wound care and NPWT for acutely infected or chronic non-healing wounds, it is difficult to draw clear conclusions due to inconsistent use and a lack of RCTs[9]

'Randomized controlled studies are needed to compare the safety, efficacy and effectiveness of NPWTi-d to other non-NPWT methods of care.'

McKanna 2016[7]

'While numerous studies regarding successful use of NPWTi-d have been published during the past five years, only a few of the studies provide comparative data. Although expert opinion is low-level evidence, it can provide valuable guidance until further comparative studies are available.'

Kim 2020[8]

'The way the technology is used and the procedures it is compared with are not consistent across the evidence base, making it difficult to draw clear conclusions.'

National Institute for Health and Care Excellence 2019[9]

Summary

- Results of Level 1 studies comparing NPWT show **no significant differences in clinical outcomes** between the two treatments[2-5]
- Most studies evaluating NPWTi-d are **lower-quality evidence** (93% of 125 studies are Levels 3 to 5)[1]
- Clinical guidelines and expert reviews highlight a **lack of comparative trials**[7-11] and **inconsistences with use of NPWTi-d** in clinical practice[9]
- Despite a substantial body of high-level evidence supporting the use of NPWT in a range of wound types,[12] there is **limited high-level (Level 1) evidence** supporting the use of NPWTi-d[1]

For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

References

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