Negative pressure wound therapy promoted healing of diabetic foot ulcers more than advanced moist wound therapy

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Negative pressure wound therapy promoted healing of diabetic foot ulcers more than advanced moist wound therapy

QUESTION
Is negative pressure wound therapy (NPWT) using vacuum-assisted closure more effective than advanced moist wound therapy (AMWT) for diabetic foot ulcers?

METHODS
Design: randomised controlled trial.
Allocation: concealed.
Blinding: unblind.
Follow-up period: 16 weeks (efficacy) and 26 weeks (safety).
Setting: 29 diabetic foot and wound clinics in the USA and Canada. Treatment occurred mainly at home (92% of treatment days).

Patients: 341 patients ≥18 years of age (mean age 58 ±, 79% men) with adequately controlled diabetes who had a stage 2 or 3 calcaneal, dorsal, or plantar foot ulcer ≥2 cm² in area after debridement and adequate lower extremity perfusion. Exclusion criteria included active Charcot disease, collagen vascular disease, ulcer malignancy, untreated osteomyelitis, cellulitis, and ulcers resulting from electrical, chemical, or radiation burns.

Intervention: NPWT using vacuum-assisted closure therapy, delivering controlled negative pressure of 50–200 mm Hg, with dressing changes ≥3 times/week (n = 172), or AMWT (mainly hydrogels and alginates) used according to guidelines or institutional protocols (n = 169). Treatment continued until ulcer closure, sufficient granulation tissue formation for healing by primary or secondary intention, or for 16 weeks.

Outcomes: complete ulcer closure, reduction in ulcer surface area, time to ulcer closure (survival analysis), and complications.

Patient follow-up: 98% (intention-to-treat analysis); 70% completed the study.

MAIN RESULTS
NPWT increased the incidence of ulcer closure and reduced time to closure (table). Fewer patients in the NPWT group had amputations (4.1% v 10%, p = 0.04), but groups did not differ for oedema, wound infection, or cellulitis.

CONCLUSION
Negative pressure wound therapy using vacuum-assisted closure was more effective than advanced moist wound therapy for healing of diabetic foot ulcers.

ABSTRACTED FROM

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Clinical impact ratings: General/internal medicine 6/7; Wound care 6/7

Negative pressure wound therapy (NPWT) using vacuum-assisted closure v advanced moist wound therapy (AMWT) for diabetic foot ulcers*

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>NPWT</th>
<th>AMWT</th>
<th>RBI (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete ulcer closure at 16 weeks</td>
<td>43%</td>
<td>29%</td>
<td>49% (12 to 101)</td>
<td>7 (5 to 25)</td>
</tr>
<tr>
<td>Mean decrease in ulcer area at 28 days (cm²)</td>
<td>4.3</td>
<td>2.5</td>
<td>1.8</td>
<td>0.02</td>
</tr>
<tr>
<td>Median days to complete closure (95% CI)</td>
<td>96 (75 to 114)</td>
<td>Not estimable</td>
<td>–</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary. RBI, NNT, and CI calculated from data in article.

The trial by Blume et al is the largest to date comparing NPWT and conventional wound dressings for diabetic foot ulcers and supports the finding of Armstrong et al of improved healing in this patient population.

The well-powered trial by Blume et al clearly described the randomisation method and group demographics, with even distribution of characteristics between groups. Inclusion and exclusion criteria were appropriate and clearly defined, although the restrictions may limit broad application of the evidence to all diabetic foot ulcers. Given the nature of the intervention, it was impossible to blind patients and healthcare providers, but outcome assessors could have been blinded.

Several other issues require mention. First, the authors did not state whether debridement was done before or after randomisation, how it was achieved, or how many patients in each group received it. Debridement is a crucial part of wound bed preparation and had the potential to affect outcomes. Second, stratified randomisation by study centre was not reported, an important design feature when the comparison is usual care. Such stratification would have isolated any centre effects associated with different wound management protocols or staff experience in the 29 study centres. Third, 10% of the AWMT group received saline-soaked gauze dressings, which may have biased the study in favour of NPWT if all such wounds failed to heal. Finally, NPWT therapy was not sufficiently described for replication. Aspects of the regimen, such as pressure level and whether use was intermittent or continuous, were not clearly defined.

The findings of the trial by Blume et al are clinically important, but the cost–benefit ratio for NPWT remains uncertain. Cost-effectiveness needs to be established before NPWT can be considered as a routine management option.

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