A systematic review of the effectiveness of negative pressure wound therapy in the management of diabetes foot ulcers

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CRD summary
This review concluded that the included studies had generally positive findings for negative pressure wound therapy in diabetes without any major adverse events, but most studies were small, heterogeneous and methodologically weak. The review was generally well conducted and the authors discussed the limitations of the data. Conclusions were appropriately cautious.

Authors' objectives
To assess the effectiveness of negative pressure wound therapy (NPWT) in the treatment of diabetes-related foot ulcers.

Searching
MEDLINE, EMBASE, CINAHL and Cochrane Central Register of Controlled Trials (CENTRAL) were searched. Search terms were reported. Search dates were not reported. Searching of bibliographies of included studies, citation searching, handsearching of 10 years of four key journals and expert consultation were undertaken to identify additional studies.

Study selection
Randomised controlled trials (RCTs) of NPWT (defined as vacuum-assisted closure with use of negative pressure as a central component of wound management) in patients with type 1 or type 2 diabetes mellitus and foot ulceration (any foot wound, chronic or acute, including postoperative wounds) were eligible for inclusion. The primary outcome of the review was number of patients who achieved complete wound healing (defined as complete re-epitheliation or wound closure). Other outcomes considered were aspects of wound healing (such as time to wound healing, speed of reduction in wound size and tissue repair), adverse events and patient satisfaction and quality of life.

Included studies were described as being conducted in patients with foot wounds, large foot wounds, non-healing foot wounds and partial foot amputations. Control groups were treated with various forms of conventional moist dressing.

Studies were independently screened for inclusion by two reviewers.

Assessment of study quality
The methodological quality of included studies was assessed on criteria of randomisation and concealment of allocation, completeness of follow-up, intention-to-treat analysis and adequacy and blinding of outcome assessment. Studies were graded as low risk of bias if all quality criteria were met, moderate risk of bias if randomisation and concealment were adequate and follow-up was at least 80% and high risk of bias in all other cases.

The authors did not state how many reviewers performed the quality assessment.

Data extraction
Data were extracted on all outcomes (wound healing, adverse events and patient satisfaction) and length of follow-up. Results were based on intention-to-treat analysis. Absolute risk reduction (ARR), odds ratio (OR) and number needed to treat (NNT), with 95% confidence intervals (CIs), were calculated where data were available.

Data were extracted independently by two reviewers who used a standardised data extraction sheet.

Methods of synthesis
Studies were combined in a narrative synthesis.
Results of the review
Four studies (n=206) were included in the review: two single-centre RCTs, one multicentre RCT and one two-centre crossover RCT. Three studies were classified as high risk of bias and one as moderate risk of bias.

The highest quality study of 162 patients with partial foot amputations reported a 20% improvement in wound healing with NPWT (OR 2.0%, 95% CI -1.0% to 4.0%, NNT=6, 95% CI 4 to 64). This study also reported a reduction in the risk of secondary amputation (ARR 7.9%, 95% CI 0.5% to 15.43%) and significantly shorter time to wound closure and improved granulation with NPWT.

Three smaller studies (n=10, n=10 and n=24) also reported improvements in secondary wound healing outcomes.

No serious treatment-related complications were reported in any study.

No data on patient satisfaction or quality of life were reported.

Authors' conclusions
The studies included in this review generally reported positive findings for NPWT without any major adverse events. However, most studies were small, heterogeneous and methodologically weak.

CRD commentary
The review reported a clear set of objectives and well-defined inclusion criteria. A number of sources were searched for relevant studies. No search restrictions were reported. Measures were taken to minimise error and/or bias in study selection and data extraction; it was unclear whether similar measures were applied to quality assessment. The results of quality assessment were reported only as an overall rating. The choice of a narrative synthesis was appropriate given the small number of small and heterogeneous studies included. The authors discussed the limitations of the data set and their conclusions were appropriately cautious.

Implications of the review for practice and research
Practice: The authors did not make any recommendations for practice.

Research: The authors stated that larger trials were needed to assess NPWT therapy in diabetes care with different groups of patients and in relation to different clinical objectives and parameters. They also stated that future studies should assess cost effectiveness and patient experience.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.