Negative-pressure therapy versus standard wound care: a meta-analysis of randomized trials

Suissa D, Danino A, Nikolis A

CRD summary
The review found that negative pressure therapy seemed to be significantly more effective than standard fare for chronic wounds. In view of limitations in the review, including a suboptimal search, unreliable statistical methods, failure to assess study quality and potential publication bias, these conclusions do not appear reliable.

Authors' objectives
To compare the effectiveness of negative-pressure therapy versus standard wound care for chronic wounds.

Searching
MEDLINE, EMBASE and The Cochrane Library were searched from 1993 to March 2010 for studies in English. Search terms were reported. Reviews and the references lists of all articles were checked.

Study selection
Randomised controlled trials (RCTs) that compared negative-pressure therapy versus standard wound care for chronic wounds were eligible.

Participants in the included studies all had chronic wounds, while 15% of participants in one study had acute wounds. The review authors noted that there were possible differences between participants and wound types across studies (such as wound location and cause, participant co-morbidities). The negative-pressure intervention was -125 millimetres of mercury (where specified), or according to manufacturers' instructions. Controls received standard wound care, which differed across studies (for example in the type of dressing and frequency of application). The review outcomes were wound size (volume or area) and time to healing in days. Duration of follow-up was about 42 days in most studies, but was shorter in three studies (14, 28, 30 days respectively). The authors did not state how the papers were selected for the review or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed quality.

Data extraction
Data were extracted or calculated on change in wound size from baseline to end of follow-up in each study group, and a change ratio was calculated. The ratio of the change ratios between the two groups (relative change ratio) was calculated. The median or mean healing time in days in each group was extracted or estimated from time to healing curves, and ratios of median time to healing were calculated for each study (complete wound closure for most studies, 75% closure for one study); 95% confidence intervals (CIs) and p values were extracted or calculated for each outcome. Where statistical variance was not reported in the primary study it was imputed from similar studies.

The authors did not state how many reviewers performed the data extraction.

Methods of synthesis
Studies were combined using a random-effects DerSimonian and Laird model to calculate pooled relative change ratios and ratios of median time to healing, with 95% confidence intervals. Subgroup analyses were conducted to assess the impact of the measure used for wound size (volume or area) and sensitivity analysis was performed by omitting one outlying study (in which there was high loss to follow-up after 21 days).

Results of the review
Ten RCTs were included in the review (total number of participants not reported, range 10 to 335). Nine were funded by the same manufacturer of negative pressure therapy devices.

When studies were pooled, negative pressure therapy decreased wound size significantly more than standard care (relative change ratio 0.77, 95% CI 0.63 to 0.96; eight RCTs) and shortened time to healing (ratio of median time to healing 0.36, 95% CI 0.23 to 0.55; six RCTs).
healing 0.74, 95% CI 0.70 to 0.78; six RCTs). Subgroup analyses supported the main findings, when the outlying study was excluded.

Authors’ conclusions
Negative pressure therapy seemed to be significantly more effective than standard care for chronic wounds.

CRD commentary
The objectives and inclusion criteria of the review were clear and some relevant sources were searched for studies, but the restriction to studies in English meant that studies in other languages may have been missed. It did not appear that any specific efforts were made to retrieve unpublished studies, despite the likelihood of publication bias in studies of negative-pressure therapy which was pointed out in the review. Although publication bias was not formally assessed, tests were unlikely to be informative with so few studies. It was unclear whether steps were taken to minimise the risk of reviewer bias and error by having more than one reviewer independently select studies and extract the data, and it did not appear that study quality was assessed.

Few details were reported about the clinical and methodological characteristics of the included studies which made it difficult to ascertain whether they were appropriate for pooling; especially as statistical heterogeneity was not formally assessed or reported. This also made it difficult to assess whether the exclusion of an outlier from one analysis was justified by methodological differences. The control interventions were not described. The effect estimate for time to healing appeared unreliable as the pooling of median values for time to event data was not statistically appropriate. Moreover the effect estimates were presented in a form that made it difficult to interpret the clinical significance of the study findings. All these factors made it difficult to assess the reliability or applicability of the review findings.

In view of limitations in the review, including a suboptimal search, unreliable statistical methods, failure to assess study quality and potential publication bias, the authors’ conclusions do not appear reliable.

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

Research: The authors stated that there was a need for large independently funded RCTs of negative pressure therapy for chronic wounds, with protocols registered according to the Consolidated Standards of Reporting Trials guidelines. They also recommended a rigorous cost-benefit analysis.

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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.