Negative pressure wound therapy: a vacuum of evidence?
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CRD summary
This review found some suggestion that negative pressure wound therapy may improve wound healing in comparison with conventional therapy, but further studies are required to prove an additional clinical benefit. These cautious conclusions appear valid and adequately consider the paucity of data, differences between the included studies and their poor quality.

Authors' objectives
To assess the effectiveness and safety of negative pressure wound therapy compared with conventional wound therapy.

Searching
MEDLINE, EMBASE, CINAHL and the Cochrane Library were searched for published and unpublished studies up to 2005. Details of the search strategy were available online (see URL for Additional Data). Trial registers were searched for ongoing studies. The US Food and Drug Administration (FDA), other health agencies, clinical experts, and manufacturers were contacted for further studies. No language restrictions were applied.

Study selection
Randomised controlled trials (RCTs) and non-RCTs that compared negative pressure wound therapy with conventional therapy for the treatment of acute and/or chronic wounds, were eligible for inclusion in the review. Wound healing was the primary outcome of interest.

The types of wounds reported in the included studies were diabetic wounds, pressure wounds, chronic wounds, skin grafts, burns, and open abdominal wounds. Study observation periods ranged from three days to one year. The majority of included studies were single-centre studies. Reported outcomes included the incidence of wound closure, time to wound closure and wound size; outcome definitions within the individual studies varied. Adverse event rates, hospital stay, pain and mortality were reported in a small numbers of studies.

Five authors independently reviewed studies for inclusion.

Assessment of study quality
Two reviewers appeared to assess study quality. The following criteria were used: allocation concealment, blinding of outcome assessors, definition of primary endpoint, sample size calculation, use of intention to treat, withdrawals, validity of statistical analysis, reporting of adverse effects, and industry sponsorship.

Data extraction
Two reviewers independently extracted the study data using a standardised form. Where necessary, the original study authors were contacted for further information. Means and standard deviations were extracted for continuous outcomes.

Methods of synthesis
Studies were grouped according to outcome. Pooled standardised mean differences (SMDs), with 95% confidence intervals (CIs), were calculated using the random-effects model. Statistical heterogeneity was assessed using the $I^2$ statistic.

Publication bias could not be assessed due to the small number of included studies.

Results of the review
Seven RCTs (n=324 patients) and ten non-RCTs (n=278 patients) were included in the review. Sample size ranged from 10 to 162 patients. The overall quality of the studies was described as poor. Only one RCT clearly described using allocation concealment. Outcome assessors were blinded in five studies. Sample size calculation was reported in one
study. Intention-to-treat data were clearly described in three studies and assumed in a further six studies. Three studies did not adequately account for dependence between wounds in the same patient.

Significant differences in favour of negative pressure wound therapy compared with conventional therapy were reported for time to wound closure and incidence of wound closure in two out of five RCTs and two out of four non-RCTs. Pooled data were not calculated due to the presence of significant heterogeneity and differences in outcome measures. However, pooled data suggested a significant reduction in wound size in favour of negative pressure wound therapy (SMD -0.57, 95% CI -0.94 to -0.20 for four RCTs; SMD -1.30, 95% CI -2.07 to -0.54 for two non-RCTs). There was no evidence of statistical heterogeneity.

Adverse events were similar between negative pressure wound therapy and conventional therapy in seven studies. Two studies reported fewer complications with negative pressure wound therapy. Single non-RCTs reported that hospital stay and mortality were reduced for negative pressure wound therapy, but four non-RCTs showed similar hospital stays.

Cost information
One RCT performed an economic analysis and reported similar overall costs for negative pressure wound therapy and conventional therapy.

Authors' conclusions
There was some suggestion that negative pressure wound therapy may improve wound healing in comparison with conventional therapy, but further well-designed studies are required to prove an additional clinical benefit.

CRD commentary
This review assessed a clear research question. Numerous sources were searched for both unpublished and published studies, with no language restrictions, so the risk of publication and language bias appeared low. However, the authors suggested that there was a risk of publication bias due to the large number of ongoing trials, prematurely terminated trials and unpublished trials. The risk of reviewer error and bias also appeared low as multiple reviewers assessed the studies for inclusion and extracted the study data and assessed study validity.

The validity of the included studies was assessed, but the overall quality was poor, so the data included in the review may not be reliable. There appeared to be numerous differences between the included studies, particularly with respect to the definition of outcome measures and patient populations. In some cases this precluded the pooling of study data. These limitations were also acknowledged by the authors.

Despite these limitations, the authors' cautious conclusions appear appropriate and adequately consider the paucity of data, differences between the studies and poor quality of the studies.

Implications of the review for practice and research
Practice: The authors stated that, until better evidence is available, physicians and health policymakers should reconsider the widespread use of negative pressure wound therapy outside the setting of clinical trials.

Research: The authors stated that further well-designed trials of negative pressure wound therapy are needed to confirm clinical effectiveness.

Funding
Institute for Quality and Efficiency in Health Care (IQWiG) (an independent non-profit, non-government scientific institute in Germany).

Bibliographic details
PubMedID
18283145

DOI
10.1001/archsurg.2007.54

Original Paper URL
http://archsurg.ama-assn.org/cgi/content/abstract/143/2/189

Additional Data URL
https://www.iqwig.de/n04-03-negative-pressure-wound-therapy.986.en.html?tid=1198

Indexing Status
Subject indexing assigned by NLM

MeSH
Anti-Infective Agents /therapeutic use; Debridement /methods; Diabetic Foot /diagnosis /therapy; Female; Humans; Male; Negative-Pressure Wound Therapy /methods; Pressure Ulcer /diagnosis /therapy; Randomized Controlled Trials as Topic; Risk Assessment; Sensitivity and Specificity; Severity of Illness Index; Skin Transplantation /methods; Treatment Outcome; Wound Healing /physiology; Wounds and Injuries /diagnosis /therapy

AccessionNumber
12008005789

Date bibliographic record published
03/02/2009

Date abstract record published
01/12/2010

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.