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## The effectiveness of topical negative pressure in the treatment of pressure ulcers: a literature review

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### CRD summary

This narrative review of the effectiveness of topical negative pressure in the treatment of pressure ulcers concluded that topical negative pressure was not proven to be more effective than other interventions. The reliability of these conclusions is limited by the small size of included studies and the lack of information on participants, outcomes, study selection and data extraction.

### Authors' objectives

To assess the effectiveness of vacuum-assisted closure (VAC) therapy and in particular topical negative pressure in the treatment of pressure ulcers.

### Searching

MEDLINE, EMBASE and CINAHL were searched from 1992 to 2007. Search terms were reported. There were no language or publication restrictions. References of identified literature were checked. Researchers were contacted to identify unpublished studies.

### Study selection

Eligible studies had to be randomised controlled trials (RCTs) in which topical negative pressure was compared with a control intervention. Participants included patients with pressure ulcers. Wound healing, as volume or surface reduction or increase in granulation tissue, needed to be reported and the control intervention described.

Two of the five included trials included only patients with pressure ulcers. The other three trials included patients with other types of wounds. In all trials, the intervention treatment was topical negative pressure using the VAC technology of KCI Medical Products. In all cases, the vacuum was set at 125mmHg. Dressings were changed every two to seven days. Control treatments were gauzes wetted in saline or Ringer's solution, sodium hypochlorite, acetic acid or nitrofurazone, a papain-urea ointment or a cadexomer-iodine, hydrocolloid, alginate, acetic acid or sodium hypochlorite dressing.

Primary end points were duration of wound healing, decrease in wound volume or wound surface, sufficient granulation tissue for surgical correction or further healing, pain and bacteria growth. Secondary end points were bacterial cleaning, wound care time, cost, comfort and adverse effects.

The first author screened the articles on title and abstract for eligibility based on the inclusion and exclusion criteria.

### Assessment of study quality

All trials were independently assessed for quality by two authors using the Dutch Cochrane quality criteria for randomisation, allocation concealment, blinding of patients, clinicians and assessors, baseline comparability, follow-up, intention-to-treat analysis and intervention bias.

### Data extraction

The authors stated neither how the data were extracted for the review nor how many reviewers performed the data extraction.

### Methods of synthesis

Data was synthesised narratively and p values for each study and each outcome were tabulated.

### Results of the review

Five RCTs were included (n=193). The number of participants ranged from 22 to 65. All participants in two trials had

pressure ulcers; the proportion of participants with pressure ulcers varied in the remaining three trials. The included trials met between three and six of the nine quality criteria. None of the included trials reported adequate allocation concealment. However, all trials were deemed as having adequate follow-up. Four used an intention-to treat analysis.

There were no significant differences in wound healing in the trials where all participants had pressure ulcers. There was a significantly larger decrease in wound volume of 78% in the topical negative pressure group compared to 30% ( $p=0.038$ ) in the control group in one of the three trials that included patients with pressure ulcers.

### **Cost information**

Topical negative pressure was significantly cheaper than the control intervention in one study that included patients with pressure ulcers.

### **Authors' conclusions**

Topical negative pressure had not been proven to be more effective than various control interventions. The authors also concluded that the quality of these studies did not always meet the scientific standard.

### **CRD commentary**

The inclusion criteria were clearly stated and the search strategy appeared adequate. Validity was assessed with appropriate criteria and methods designed to reduce reviewer error and bias. However, such methods were not employed for the selection of studies and were not reported for the extraction of data. The details of included studies were limited; more information on study participants and the reporting of other outcome data in addition to p-values could have strengthened this review. A narrative synthesis of data appeared appropriate due to the heterogeneity in participants and reported outcomes. However, small sample sizes, incomplete reporting of outcome data and possible bias in the selection of studies and extraction of data may limit the reliability of the conclusions.

### **Implications of the review for practice and research**

Practice: The authors did not state any implications for practice.

Research: The authors recommended that follow-up studies randomise patients rather than wounds, use a homogeneous patient population, use a single well-defined and documented control intervention and make a prior calculation of the sample size.

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