Efficacy of modern dressings in the treatment of leg ulcers: a systematic review

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CRD summary
This review compared modern versus conventional dressings for leg ulcers and compared different types of modern dressings. The authors concluded that there was insufficient evidence to determine the most effective type of dressing. Overall, this was a well-conducted review and the authors' conclusion reflects the limited evidence from generally poor-quality studies.

Authors' objectives
To assess the effectiveness of modern and conventional dressings for leg ulcers and to compare the effectiveness of different types of modern dressings.

Searching
MEDLINE (1966 to January 2003), CINAHL (1982 to January 2003), SWEESNET (1999 to 2002) and the Cochrane Controlled Trials Register were searched without language restrictions using the reported search terms. The reference lists of relevant articles were screened. Only published studies were included.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies were eligible if they compared one or more modern dressings (hydrocolloids, polyurethane, alginate, calcium alginate, activated charcoal and collagen) with conventional dressings or other types of modern dressings. Studies of other therapies for leg ulcers were excluded. The included studies used a wide variety of different modern and conventional dressings (full details were reported). In some studies compression was also used. In the included studies, the duration of treatment ranged from 3 weeks to 37 months.

Participants included in the review
Studies of patients with leg ulcers were eligible for inclusion, whereas studies of patients with other types of wound were excluded. The included studies were in patients with venous ulcers and mixed or poorly differentiated ulcers. All but one of the included studies were in ambulatory primary or secondary care patients.

Outcomes assessed in the review
Studies that reported quantitative measures for relevant outcomes were eligible for inclusion. The primary review outcome was the proportion of healed ulcers; it was not clear whether this outcome was determined a priori or selected on the basis that it was the most commonly reported outcome amongst the identified studies. The review also assessed withdrawals and adverse effects.

How were decisions on the relevance of primary studies made?
The authors did not state how the studies were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Validity was assessed and scored using the Jadad scale, which considers the adequacy of randomisation, double-blinding and the handling of withdrawals. The maximum possible score was 5 points. Studies were also assessed for the use of a power calculation and intention-to-treat analysis. Two reviewers independently assessed validity.
Data extraction
Two reviewers independently extracted the data using a specially designed form. The reviewers were not blinded to the authors, institutions, journal or interventions.

Methods of synthesis
How were the studies combined?
The studies were grouped by type of ulcer, intervention and outcomes. Where studies were clinically comparable (intervention, scope, treatment period and outcome) and where there was no evidence of statistically significant heterogeneity, the data were combined using a fixed-effect meta-analysis. Pooled relative risks (RRs) with 95% confidence interval (CIs) were calculated for dichotomous data, while pooled weighted mean differences with 95% CI were calculated for continuous data.

How were differences between studies investigated?
Statistical heterogeneity was assessed using the Q statistic.

Results of the review
Thirty-one RCTs (n=2,079) were included. The authors were unable to obtain one potentially eligible study.

Ten RCTs scored 3 or more points out of 5 on the Jadad scale. Seven studies used intention-to-treat analysis. Two RCTs reported a power calculation. Methodological flaws included small sample sizes and inadequate descriptions of methods, population characteristics, wounds and results.

Leg ulcers of venous origin (26 studies).

Modern versus conventional dressings.
Efficacy: there was no statistically significant difference in the proportion of ulcers healed between hydrocolloid dressings and conventional dressings (RR 0.90, 95% CI: 0.85, 1.15, P=0.9), based on 8 studies (n=782). There was no statistically significant difference in the proportion of ulcers healed between conventional dressings and any of the following modern dressings: polyurethane dressings (3 studies), alginate (2 studies), collagen (1 study), or activated charcoal (1 study).

Withdrawals: there was no statistically significant difference in withdrawal rates between modern and conventional dressings (RR 1.20, 95% CI: 0.76, 1.89, P=0.4), based on 12 studies (n=955).

Modern dressings versus each other.
Efficacy: there was no statistically significant difference in the proportion of ulcers healed between hydrocolloid dressings and other modern dressings (RR 1.13, 95% CI: 0.86, 1.47, P=0.4), based on 6 studies (n=319).

Withdrawals: withdrawal rates varied amongst the studies. There was no statistically significant difference in withdrawal rates between intervention and comparator groups (RR 0.75, 95% CI: 0.41, 1.37, P=0.4), based on 5 studies.

Safety: there was no statistically significant difference in adverse effects between modern and conventional treatments (RR 1.20, 95% CI: 0.75, 1.96, P=0.4). The most common adverse effects for studies comparing modern versus conventional dressings were clinical deterioration of the wound and signs of local infection with or without cellulitis. The reviewers mentioned hypersensitivity and allergic reactions with modern dressings, but gave no further details. For studies comparing different types of modern dressings, there was no statistically significant difference in adverse effects between treatment and comparator groups (RR 0.79, 95% CI: 0.37, 1.67, P=0.5).

Leg ulcers of mixed or undifferentiated origin (5 studies).
Efficacy: there was no statistically significant difference in the rate of healing of mixed ulcers between polyurethane...
versus gauze-saline (1 study), or between hydrocolloid versus either gauze-saline (1 study), alginate (1 study) or occlusive zinc (1 study).

Withdrawals: the number of patients withdrawing was similar for both treatment groups in 3 studies (1 patient in each group for conventional versus modern dressings, 5 with hydrocolloid versus 7 with alginate in the second study, and 6 each for hydrocolloid and zinc dressings in the third study).

Safety: there was one case of erysipelas with moist gauze (1 study), and 6 adverse reactions with hydrocolloid versus 4 with zinc (1 study).

Authors’ conclusions
There was insufficient evidence to determine the most effective type of dressing for leg ulcers.

CRD commentary
The review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched and attempts were made to minimise language bias. Limiting the review to published studies raises the possibility of publication bias. Methods were used to minimise reviewer errors and bias in the validity assessment and data extraction processes, but it was unclear whether similar steps were taken at the study selections stage. Validity was assessed using specified criteria and the results of the assessment were reported.

Adequate information on the individual studies was given. Statistical heterogeneity was assessed and only statistically homogeneous and clinically comparable studies were combined in the meta-analyses. Although effort was made to ensure that only studies using clinically comparable interventions were pooled, it should be noted that these studies used diverse comparators (conventional dressings). The usefulness of pooling studies that used different comparators seems questionable. Overall, this was a well-conducted review and the authors' conclusions are likely to be reliable.

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

Research: The authors stated that well-conducted trials are required to compare modern with conventional dressings for the treatment of venous and mixed leg ulcers, and to determine the most effective type of dressing.

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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.