



Title	Randomized Controlled Trial of the use of Three Dressing Preparations in the Management of Chronic Ulceration of the Foot in Diabetes
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Aim

To compare the use of three dressing products in managing chronic foot ulcers.

Conclusions and results

The study included 317 people with diabetes and had five objectives: 1) To test whether a modern dressing product (Aquacel®) is more clinically effective than traditional dressings (Inadine®, N-A®) in treating diabetes-related foot ulcers. 2) To investigate changes in condition and reoccurrence associated with each dressing during the study. 3) To determine the relative cost effectiveness of the three dressings. 4) To assess patients' health-related quality of life (HRQoL), physical and social functioning, and pain associated with each of the dressings. 5) To investigate the self-care contributions by patients and carers.

1) We found no difference in the effectiveness of the three dressing products studied and no difference in the cumulative incidence of adverse or serious adverse events. 2) We confirmed that a greater proportion of smaller ulcers (<1cm²) would heal within the specified time of 24 weeks: 47.7% versus 36.1%. In the 114 for whom data were available, ulcers recurred in 13 (11.4%) within 3 months. At 3-month follow-up, 47% of 232 participants who completed the study had an active ulcer. 3) The only statistically significant difference was in the costs associated with providing dressings. The professional time involved in dressing changes was similar. Further research needs to assess the relationship between unhealed ulcers and the risk of amputation. Given that the effectiveness of dressing types does not differ, the additional cost of Aquacel® does not appear to be justified. 4) We found no difference between dressing groups in terms of HRQoL, although differences were found between those with healed and with unhealed ulcers using the Cardiff Wound Impact Schedule (CWIS). The overall prevalence of pain in unhealed ulcers did not differ between the three groups. 5) We found that 51% of participants had at least one dressing changed by them-

selves or their carer. Almost 70% of all dressing changes were undertaken by nonprofessionals. See Executive Summary link at www.hta.ac.uk/project/1357.asp.

Recommendations

We found no evidence to suggest that any dressing product was more effective, more acceptable, or safer than any other. Further research needs to establish the cost implications of ulcers failing to heal. In the absence of clear evidence of benefit, preference should be given to cheaper, more traditional products in routine clinical practice.

Methods

See Executive Summary link at www.hta.ac.uk/project/1357.asp.

Further research/reviews required

The effectiveness of all dressing products being promoted for chronic foot ulcers in diabetes should be compared with products like those used in this study. The study provides a benchmark for comparisons. The methods used here may be adapted to determine the effectiveness of dressing products for specific types of chronic ulcers. Patients and their carers perform most dressing changes, which has implications in economic evaluations that assume that professionals change all dressings.