

Randomised Controlled Trial of Dressings in the Management of Diabetic Foot Ulcers

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There are few data available to govern choice of dressings for chronic diabetic foot ulcers (DFUs), with the majority being promoted without evidence of either efficacy or effectiveness. We therefore undertook a randomised controlled trial of three dressings: a simple knitted viscose primary dressing (N-A®), an antiseptic preparation (Inadine®) and sodium carboxymethylcellulose (Aquacel®). The study was funded by the UK HTA program. 317 patients with DFUs of at least 28 days duration, with area 25-2500 mm², without evidence of marked limb ischaemia (gangrene, or ABPI <0.7) and which were not clinically infected, were randomised 1:1:1 (stratified by centre and by area) to have their wounds dressed two or more times weekly with one of the three dressings for up to 24 weeks, in addition to receiving standard care with regular surveillance, sharp debridement and off-loading. Mean age was 59.6 years; 76% male. There were 88 withdrawals (27.8%) and 229 evaluable patients - sufficient to establish predefined differences between dressings with 80% power, p<0.05. The primary endpoint was epithelialisation maintained for 4 weeks, analysed by intention to treat. 135 (43%) ulcers healed by 24 weeks: 48% with area <1cm² versus 37% >1cm² (p=0.048). There was no difference in the % healed in the three groups (N-A 41%, Inadine 44%, Aquacel 45%, p=0.61), and no difference in mean days to healing (N-A 131, Aquacel 126, Inadine 128, p=0.80). There was a significant difference in the % withdrawn between groups (N-A 35%, Aquacel 29%, Inadine 19%) but no difference in adverse events. There was a significant difference between groups in the incidence of secondary infection as an adverse event (N-A 48, Aquacel 54, Inadine 71, p<0.001), but no difference in incidence of minor (5 total) and major (2 total) amputation, or health related quality of life (SF36, Cardiff Wound Impact Schedule). Almost 70% of all dressing changes were undertaken by non-professionals and the only cost difference between groups was that attributable to the mean total dressings per patient until healing or 24 weeks: N-A £66.56, Inadine £59.74, Aquacel £163.93. We conclude that no difference in effectiveness of the three dressings could be identified, and these data provide a much-needed benchmark for the future studies which are required to provide evidence to underpin clinical choice.