



Title	VenUS1: A Randomised Controlled Trial of Two Types of Bandage for Treating Venous Leg Ulcers
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Aim

To compare the clinical and cost effectiveness of the multilayer, elastic 4-layer bandage (4LB) and multilayer, inelastic short stretch bandage (SSB) in healing venous leg ulcers.

Conclusions and results

Between Apr 1999 and Dec 2000, 387 people were recruited to the trial (39% of those approached). Main reasons for exclusion were: patients unsuitable for compression, ankle/brachial pressure index (ABPI) lower than 0.8, diabetes mellitus, and maximum ulcer length less than 1 cm. Patients were aged 23 to 97 years at trial entry (mean age 71 years). Most patients in the trial (82%; 316/387) had a reference ulcer area ≤ 10 cm². To test the difference over time of Kaplan Meier curves for the 2 bandage groups, the log-rank test was used to compare the distribution of the cumulative times-to-healing of individuals in the 2 trial groups. The difference in distribution was not statistically significant at the 5% level. To explore the effect of several prognostic factors on the distribution of times-to-healing in the 2 bandage groups, a Cox proportional hazards model was fitted to the data. After adjusting healing times for the effects of other variables (center, baseline ulcer area, duration, episodes, ankle mobility, weight) a statistically significant treatment effect favoring the 4LB was identified. The probability of healing for individuals in the SSB treatment arm is significantly lower than that for people treated with the 4LB, indicating that individuals on the SSB are less likely to heal than those on the 4LB. Our base case economic analysis showed that, in comparison to the SSB, the 4LB is a dominant strategy, ie, associated with greater health benefits and lower costs than the SSB. This result is explained by the greater number of community nurse visits required by participants in the SSB arm.

Recommendations

The 4LB, currently the UK standard compression bandage for venous leg ulcers, was more clinically and cost

effective than the SSB. The SSB would be a reasonable alternative for patients who like it and will not tolerate the 4LB.

Methods

A pragmatic, multicenter, open, randomized controlled trial, incorporating economic evaluation was conducted. Patients with venous leg ulcers were randomized to either 4LB or SSB delivered within their usual care arrangements (community based, District Nurse led services; community leg ulcer clinics; hospital leg ulcer clinics with community outreach). Followup continued for 12 months, or until healing, whichever occurred first.

Further research/reviews required

Relationship between bandager skill, application technique, and ulcer healing (including the potential for patients and/or their carers to apply bandages effectively). Relative cost effectiveness of community leg ulcer clinics. Nurse decision making in venous ulcer management (to better understand the influences on treatment choice and the frequency of treatment visits).