

# **VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers**

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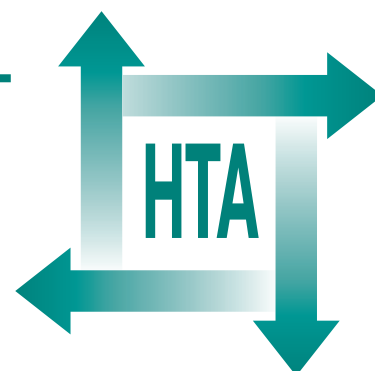
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## ***Executive summary***

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## Executive summary

### Objectives

To compare the clinical and cost-effectiveness of two different compression bandages for the healing of venous leg ulcers.

### Methods

#### Design

A pragmatic, randomised controlled trial (RCT) with an economic evaluation.

#### Setting

Community, district nurse-led services; community leg ulcer clinics; hospital leg ulcer clinics with community outreach. A range of urban and rural settings in England and Scotland.

#### Subjects

Patients were eligible to participate in the trial if they presented with a venous leg ulcer of at least 1-week's duration, at least 1 cm in length or width and an ankle:brachial pressure index of at least 0.8.

#### Interventions

The four-layer bandage (4LB) (which is multilayer elastic compression) compared with the short-stretch bandage (SSB) (multilayer, inelastic compression).

#### Main outcome measures

The primary end-point was complete healing of all the ulcers on the trial leg. Secondary outcomes were the proportion of patients healed at 12 and 24 weeks, rate of recurrence, costs of leg ulcer treatment and quality of life.

### Results

A total of 387 people were recruited to the trial between April 1999 and December 2000; this represents 39% (387/988) of those approached. Patients ranged in age from 23 to 97 years at trial entry, with a mean age of 71 years. Most frequent reasons for exclusion from the trial were patients not suitable for compression, ankle/brachial pressure index lower than 0.8, diabetes mellitus

and maximum ulcer <1 cm. The majority of patients in this trial (82%; 316/387) had a reference ulcer of area  $\leq 10$  cm<sup>2</sup>. To test the difference over time of Kaplan–Meier curves for the two bandage groups, the distribution of the cumulative times to healing of individuals in the two trial groups was compared using the log-rank test. The difference in the distribution of cumulative healing times between the individuals in the two groups was not statistically significant at the 5% level (log rank = 2.46,  $p = 0.12$ ). Adjusting for the effects of variables which may influence healing (centre, baseline ulcer area, duration, episodes, ankle mobility, weight) in a Cox proportional hazards model, a statistically significant treatment effect in favour of the 4LB was identified. At any point in time, the probability of healing for individuals in the SSB treatment arm is significantly lower than that for people treated with the 4LB (hazard ratio 0.72, 95% confidence interval 0.58 to 0.91).

Our base case economic analysis showed that the 4LB is the dominant strategy, that is, it is associated with a greater health benefit and lower costs than the SSB, although the differences are not statistically significant. This result is explained largely by the greater number of community nurse visits required by participants in the short-stretch arm.

### Conclusions

The 4LB, which is currently the UK standard compression bandage for people with venous leg ulcers, was more clinically and cost-effective than the SSB.

#### Implications for healthcare

This trial found a higher healing rate, a reduced median time to healing and lower costs associated with 4LB treatment compared with SSB. The bandage costs were less important than the costs of treatment visits, and patients in SSBs required more treatment overall. Generally, this trial supports the use of the 4LB in preference to the SSB. However, if healing rates are good, and patients and/or their carers are able

to launder and re-apply the bandage, then the treatment is likely to become cost-effective.

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

## Recommendations for future research

- Exploration of the relationship between bandager skill, application technique and ulcer healing, including the potential for patients and/or their carers to apply bandages effectively.
- The relative cost-effectiveness of community leg ulcer clinics should be re-examined using modelling (the only RCT, incorporating

an economic evaluation, comparing home visits with clinic treatment was confounded by major differences in bandage provision).

- Study of nurse decision-making in venous ulcer management to understand better the influences on treatment choice and the frequency of treatment visits (since the latter drives costs in the treatment of venous leg ulceration).

## Publication

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