VenUS 6

Venous Leg Ulcer Study

A multi-centred, pragmatic, parallel group, randomised, controlled, three arm trial to assess the clinical and cost effectiveness of compression therapies for the treatment of venous leg ulcers

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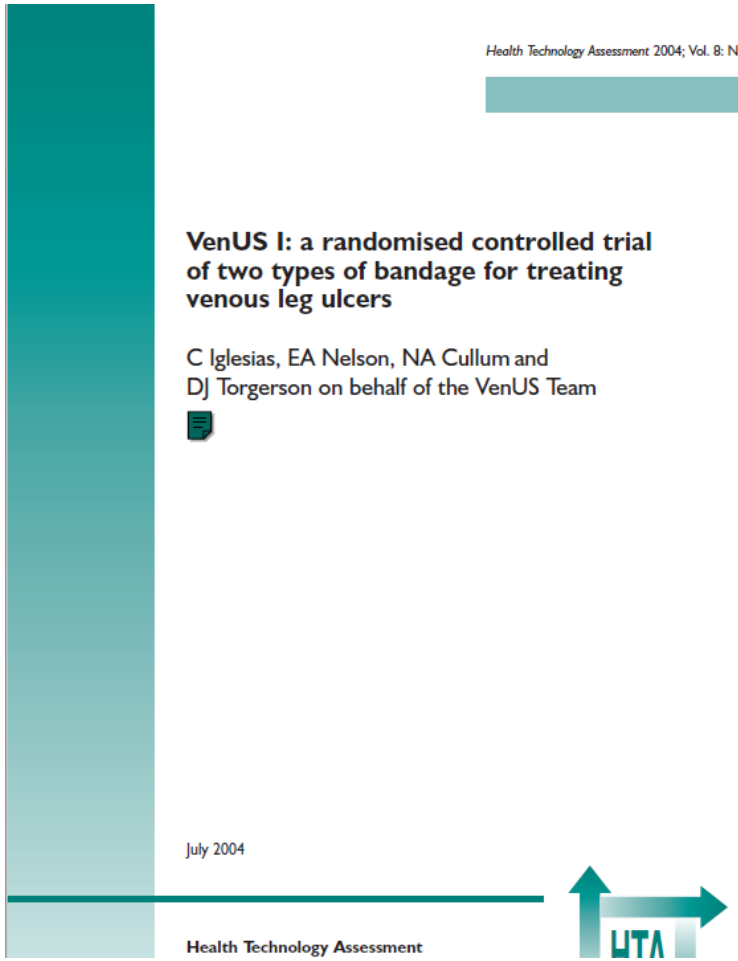
Overview of the session

- Context and design
- Study activity
- Site experience

Venous leg ulcer studies……

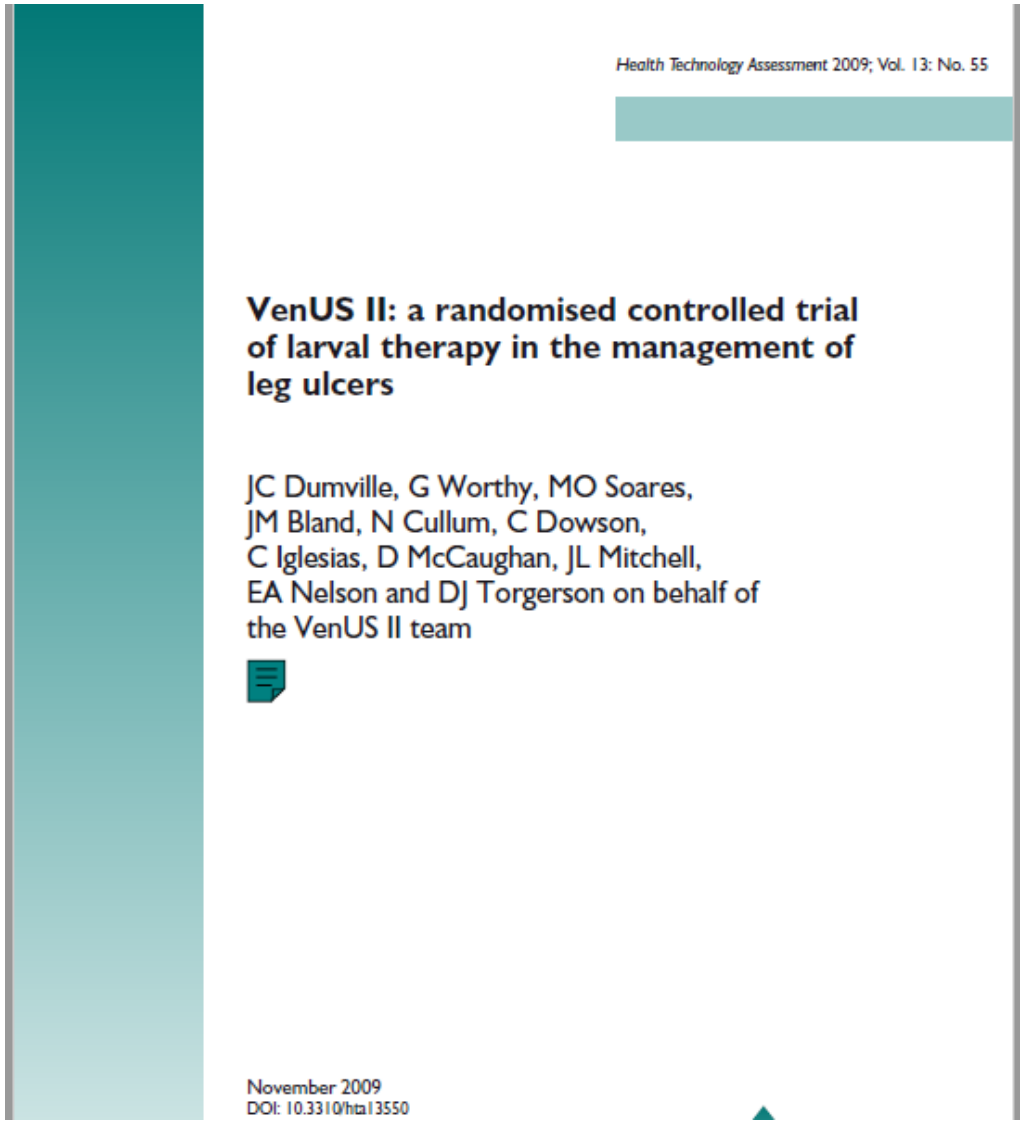


- The four-layer bandage (4LB) compared with the short-stretch bandage.
- 367 participants.
- The 4LB was more clinically and cost-effective than the short stretch bandage.

A Cochrane systematic review identified six trials comparing the 4LB with systems which included SSB.[51] Most of the trials did not identify significant differences between patient groups. One large study (VenUS, n = 387) found no difference between groups at three months but found significantly greater proportion of patients healed at six months with 4LB. This study was conducted in the UK where there is likely to be greater experience with 4LB.[52] There was no difference in generic and disease-specific quality of life between the two groups. Meta-analysis of four trials suggested a higher probability of healing with 4LB but there was significant heterogeneity reducing the certainty of the effect.[51] 1++

A meta-analysis of RCTs with pooling of individual patient data from five trials comparing 4LB with short stretch bandage found that the 4LB was associated with a significantly shorter time to healing.[53] 1++

The VenUS study, found that 4LB was less expensive than non-cohesive SSB which required more re-applications and changes of dressings. However, the SSB could have been reused or replaced by cohesive SSB which can stay in place for up to a week and the cost of nurse training in 4LB was not considered.[52]



- Loose larval therapy and bagged larval therapy compared with hydrogel
- 267 participants
- Larval therapy significantly reduced the time to debridement of sloughy and/or necrotic, chronic venous and mixed venous/arterial leg ulcers, compared with hydrogel; however, larval therapy did not significantly increase the rate of healing of the ulcers.
- Larval therapy was associated with more ulcer-related pain than hydrogel

Larval therapy versus hydrogel

A large randomised controlled trial (n = 267) compared larval therapy and hydrogel for sloughy leg ulcers in patients with at least one venous or mixed venous arterial ulcer with at least 25% coverage of slough. Larval therapy produced significantly faster debridement, median 14 days for loose larva and 28 days for bagged larvae compared with 72 days for hydrogel, but this did not result in faster ulcer healing or improved rates of ulcer healing nor did it reduce bacterial load.[44] 1+

Given the uncertain relationship between debridement and healing no recommendation for larval therapy can be made.

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VenUS III: a randomised controlled trial of therapeutic ultrasound in the management of venous leg ulcers

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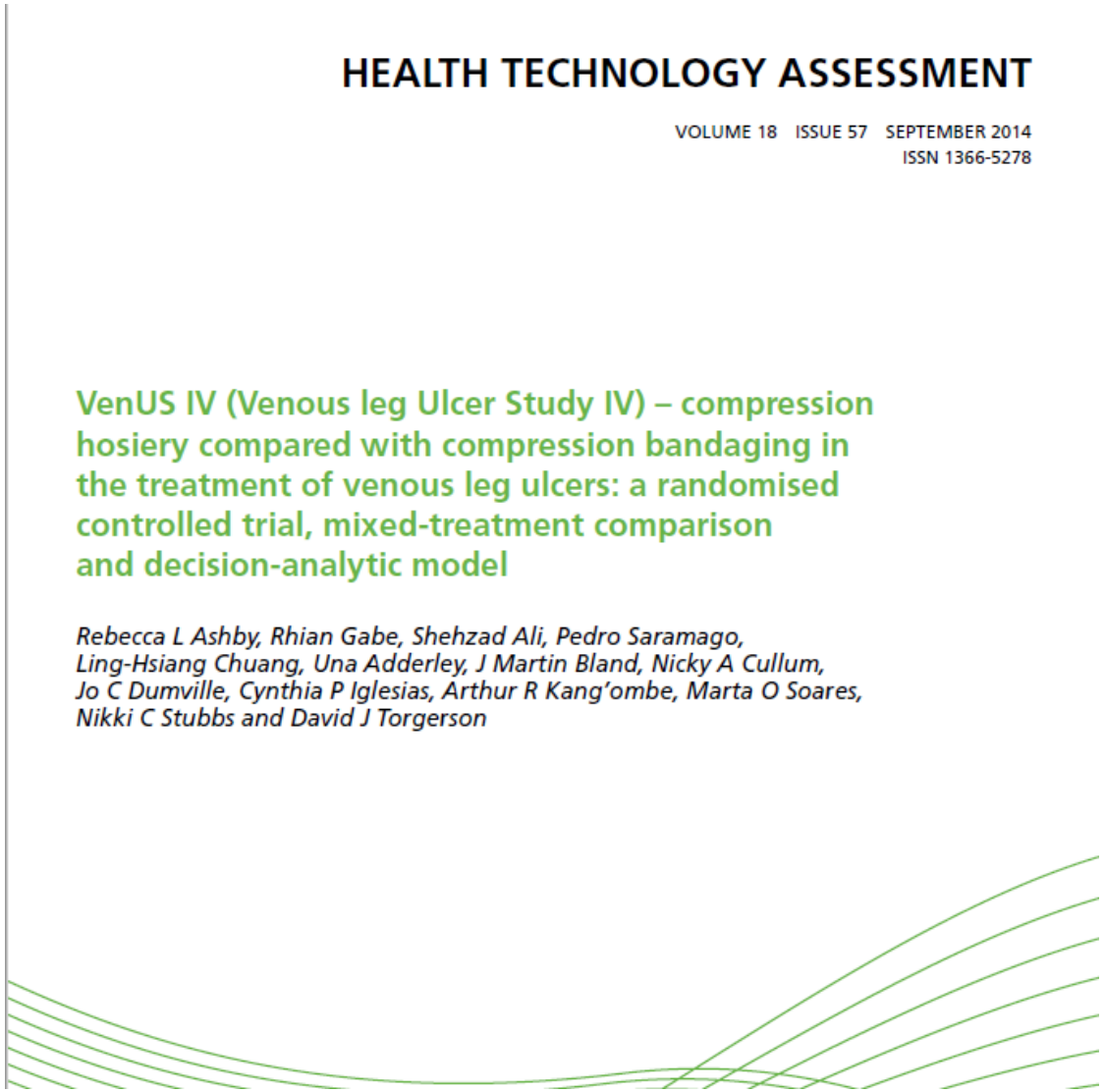
- Low-dose ultrasound alongside standard care compared with standard care alone.
- 337 participants
- Low-dose ultrasound did not increase ulcer healing rates, affect quality of life or reduce recurrence
- Ultrasound was associated with higher costs and more adverse events.



- Four layer bandage compared with two layer compression hosiery
- 457 participants
- No evidence of a difference in venous ulcer healing between four layer bandage and Two layer hosiery.
- Hosiery may reduce ulcer recurrence rates compared with the four layer bandage and be a cost-effective treatment

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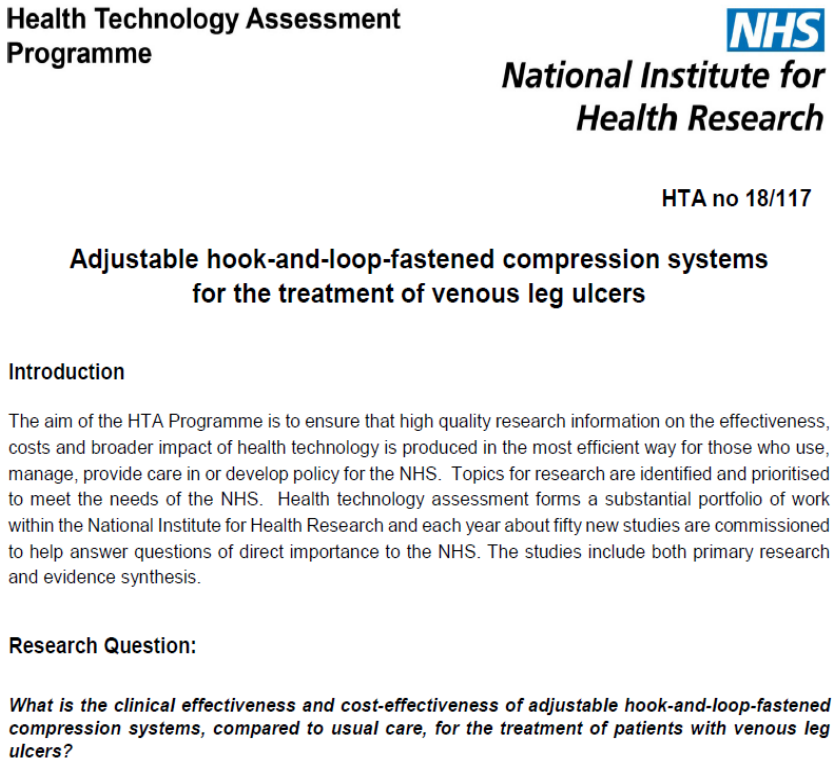
There is evidence that for those willing to wear them, two-layer compression hosiery kits are an effective alternative to four-layer bandaging for healing venous leg ulcers, are more cost effective, may reduce recurrence rates and increase quality of life[29] and are more likely to enable people to self-care. However, two-layer compression hosiery kits are not suitable for all people with venous leg ulcers so multi-component compression bandaging should be offered to patients with significant oedema, exudate, fragile skin and abnormal limb shape.

- 1398 participants over four randomised controlled trials
- Inform national and international Guidelines
- Inform wound care practices in the UK and beyond

VenUS 6



Health Technology Assessment Programme

NHS National Institute for Health Research

HTA no 18/117

Adjustable hook-and-loop-fastened compression systems for the treatment of venous leg ulcers

Introduction

The aim of the HTA Programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technology is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research are identified and prioritised to meet the needs of the NHS. Health technology assessment forms a substantial portfolio of work within the National Institute for Health Research and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

Research Question:

What is the clinical effectiveness and cost-effectiveness of adjustable hook-and-loop-fastened compression systems, compared to usual care, for the treatment of patients with venous leg ulcers?

- Commissioned call
- Two arm study
- Compression wraps compared with usual care

Defining usual care

- Any type of full compression (not wraps)
- Evidence for the two layer bandage inconclusive in a meta-analysis of all relevant RCT data on compression therapy
- Presented a rationale for a three arm study

Evidence based compression (four layer bandage or two layer compression hosiery)	Two layer bandage	Compression wraps