Economic analysis of VenUS I, a randomized trial of two bandages for treating venous leg ulcers
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two high-compression bandage systems for the treatment of venous leg ulcers were examined. The bandage systems studied were short-stretch bandages (SSB) and four-layer bandages (4LB).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The study population comprised patients with new, existing, or recurrent ulceration of at least 1 week’s duration, at least 1 cm in diameter, and with an ankle: brachial pressure index of at least 0.8. Patients with diabetes were excluded, as were those whose ulcers failed to improve while using one of the study bandages.

Setting
The setting was secondary care. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were derived from a study published in 2004. The price year was 2001.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the clinical study.

Study sample
Limited information on the study sample was provided. A sample of 387 patients was included in the analysis. The mean age was 71 years (range: 23 - 97). There were 192 patients in the SSB group and 195 patients in the 4LB group.

Study design
This was a multi-centre, prospective, randomised clinical trial that was carried out in nine geographical areas in Britain. The length of follow-up was one year. No details on the loss to follow-up were reported.
Analysis of effectiveness
The analysis of the clinical study appears to have been conducted on an intention to treat basis. The outcome measures used in the clinical study were the mean time to healing and quality of life. The mean time to healing was assessed using the Kaplan-Meier approach. Quality of life was estimated using the Euroqol (EQ) 5D questionnaire, which was administered at baseline and every 3 months during the follow-up period.

Effectiveness results
The analysis showed that there was a trend toward increased healing times in the 4LB group, although the difference did not reach statistical significance. A statistical analysis, which was carried out to adjust for the effect of other variables, showed that there was a statistically significant treatment effect in favour of 4LB. The hazard ratio for healing, which was 0.72 (95% confidence interval, CI: 0.57 - 0.91), showed that SSB-treated patients had a significantly lower probability of healing than 4LB-treated patients. The results for quality of life were not reported.

Clinical conclusions
The effectiveness analysis showed a modest advantage of 4LB over SSB in terms of healing times.

Measure of benefits used in the economic analysis
The summary benefit measures used were the healing times and quality-adjusted life-years (QALYs). The QALYs were estimated using quality of life weights.

Direct costs
Discounting was not relevant since the costs were incurred during a 1-year timeframe. The unit costs were presented separately from the quantities of resources used. The health services included in the economic evaluation were nurse visits, doctor visit, outpatient hospital visit and bandage systems. Costs common to both treatment arms, such as wound dressings and skin preparation, were not included. The cost/resource boundary of the NHS was adopted. Resource use was estimated on the basis of prospectively collected patient-level data. The costs came from typical NHS sources. The price year was 2001.

Statistical analysis of costs
Non-parametric statistical tests were used because of the skewed nature of the cost estimates.

Indirect Cost
The indirect costs were not considered in the economic evaluation.

Currency
UK pounds sterling ()

Sensitivity analysis
Sensitivity analyses were used to examine the robustness of the estimated costs. Three alternative scenarios were considered. In the first scenario, for all SSB patients, the history of resources used per month was analysed individually and each time bandages were replaced, the quantity of new bandages reported was replaced with the patient's reported minimum number of bandages used over the interval of treatment. The second scenario considered the possibility of acquiring the 4LB as a kit. Although the 4LB kit was not available on prescription in the UK during the trial, leg ulcer clinics commonly purchase kits and supply them from stocks. In the third scenario, the two options described above were considered simultaneously. A cost-effectiveness acceptability curve was also constructed for each scenario.
Estimated benefits used in the economic analysis
The healing times were 96.7 days (95% CI: 85.3 - 111.6) with 4LB and 107.6 days (95% CI: 95.9 - 122.2) with SSB. The difference was 10.9 days (95% CI: -6.8 - 29.1).

The QALYs were 0.69 (95% CI: 0.66 - 0.74) with 4LB and 0.67 (95% CI: 0.63 - 0.72) with SSB. The difference was -0.02 QALYs (95% CI: -0.08 - 0.04).

Thus, no statistically significant differences were observed between the groups.

Cost results
The 1-year costs were 1,298.41 (95% CI: 1,187.83 - 1,471.90) with 4LB and 1,525.73 (95% CI: 1,373.92 - 1,716.66) with SSB. The difference was 227.32 (95% CI: 16.53 - 448.30).

Synthesis of costs and benefits
Incremental cost-effectiveness and cost-utility ratios were calculated to combine the costs and benefits. The incremental analysis showed that 4LB was the superior strategy. On average, it was associated with a greater health benefit and lower costs than the SSB system.

The sensitivity analysis showed that the cost-difference was smaller than the difference observed in the cost analysis and did not reach statistical significance. The cost-effectiveness acceptability curve confirmed the dominance of 4LB in most scenarios.

Authors' conclusions
Four-layer bandaging (4LB) was more cost-effective than short-stretch bandaging (SSB) for the treatment of venous leg ulcers.

CRD COMMENTARY - Selection of comparators
The authors justified their choice of the comparators on the grounds that they were commonly used across Europe. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The study had been published already and only key aspects of its design and characteristics were reported. The patients were enrolled at several centres and an intention to treat analysis was used to examine the clinical outcomes. Since other features of the trial were not reported, it was not possible to further assess the internal validity of the study.

Validity of estimate of measure of benefit
Two summary benefit measures were used in the economic analysis. The first was disease-specific, while the second (QALYs) was more appropriate as QALYs are comparable with the benefits of other health care interventions. Trial-based quality weights were used to calculate the QALYs.

Validity of estimate of costs
The perspective adopted in the study (i.e. that of the NHS) was explicit. It appears that all the relevant categories of costs have been included. The unit costs, quantities of resources used and the price year were explicitly reported, which helps replicate and reflate the results of the analysis in other settings. A justification was provided for the exclusion of some categories of costs. The source of the data was given. Statistical analyses were carried out to deal with the non-normal distribution of economic data. Alternative scenarios for the resource use data were considered, but the cost estimates were specific to the study setting.
Other issues
The authors did not compare their findings with those from other studies. They also did not explicitly address the issue of the generalisability of the study results to other settings. Limited sensitivity analyses were carried out, which partially enhanced the external validity of the study. The study referred to patients with venous leg ulcers and this was reflected in the authors’ conclusions.

Implications of the study
The study results supported the use of 4LB for the treatment of venous leg ulcers. However, a careful audit of the frequency of district nurse visits was recommended, because too frequent visits could reduce the cost-effectiveness of 4LB. The authors stressed also that SSB remained a valid alternative for patients who preferred or did not tolerate 4LB.

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Other publications of related interest


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