Randomized trial of four-layer and two-layer bandage systems in the management of chronic venous ulceration


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
Patients with chronic venous leg ulcers were treated with either four-layer (Profore) or two-layer (Surepress) high-compression elastic bandaging. The patients were monitored for 24 weeks after starting the treatment. The patients visited a specialist clinic once a week, while other bandage changes were carried out by a visiting nurse at home.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients newly presenting for treatment for chronic leg ulcers, who were aged at least 18 years and who were not pregnant were included. The patients had to have been suffering from the ulcers for at least 2 weeks, have signs and symptoms of venous disease, and have an ankle brachial pressure index (ABPI) of at least 0.8. The patients had to have an ankle circumference of more than 18 cm.

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

Dates to which data relate
The effectiveness and resource evidence both related to 1999 to 2000. The price year was 2000.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out on the same sample of patients as that which provided the effectiveness data. However, the costing was carried out retrospectively and used estimated costs rather than the actual costs incurred.

Study sample
Initially, the study was designed to detect a difference in absolute closure rates of 25% with an 80% power and 5% level of significance. This meant that 60 patients were needed in each group. However, as only 109 patients could be recruited in the allocated time, the power was reduced to 74% on the assumption that there would be 54 patients in each group. Of the 109 patients, 57 were in the 4LB group and 52 in the 2LB. Originally, 112 patients began the trial but 3 of
these did not complete the first week of follow-up. There was no sample selection. All the eligible patients were included in the trial.

**Study design**
This was a multi-centred, randomised controlled trial that was carried out in five centres. Randomisation was conducted using sequential numbers on a randomisation list that was stratified for ulcer size. At each centre there were 2 randomisation lists, one for patients with an ulceration area of less than or equal to 10 cm², and one for patients with an ulceration area of more than 10 cm². Separate randomisation lists were used in all centres. Seven of the 57 patients (12%) originally allocated to 4LB and 28 (54%) of the 52 originally allocated to 2LB withdrew from treatment by 24 weeks. When patients withdrew from their allocated treatment, they were switched to an alternative treatment that was not disclosed in the study. The patients were followed up until the ulceration closed or until 24 weeks after the treatment began.

**Analysis of effectiveness**
The basis of the analysis was intention to treat. The authors reported that the patient groups were well matched. They presented detailed information on demographics and health, but they did not report any statistical tests used to demonstrate comparability. The main health outcomes used to assess effectiveness were the mean time taken for the ulcer to close and the percentage of patients in the treatment group achieving closure.

**Effectiveness results**
The median duration of the ulcer was 6 weeks (range: 2 - 104) in the 4LB group and 6 weeks (range: 2 - 104) in the 2LB group.

After 12 weeks, 40 (77%) of the 4LB patients had ulcer closure compared with 30 (58%) of the 2LB group. The odds ratio was 4.23 (95% confidence interval: 1.29 - 13.86; p=0.002).

After 24 weeks, 50 (88%) of the 4LB group and 40(77%) of the 2LB group experienced closure of the ulceration.

The hazard ratio for complete closure was 1.18 (0.69 - 2.02), (p=0.55).

Twenty-six patients experienced 29 adverse incidents, 7 (8 incidents) with 4LB and 19 (21 incidents) with 2LB.

Three of the 4LB patients and 11 of the 2LB patients withdrew from treatment because of an adverse incident. The withdrawal rates were significantly higher for patients on 2LB (56%) than for those on 4LB (14%), (p=0.001).

**Clinical conclusions**
The 4LB offered advantages over 2LB in terms of reduced withdrawal from treatment and fewer adverse events. Closure occurred earlier with the 4LB system.

**Measure of benefits used in the economic analysis**
No summary measure of benefit was calculated since a cost-consequences analysis was carried out.

**Direct costs**
No discounting was carried out since the costs were incurred during less than 2 years. The prices and the quantities were reported separately. The costs of a dressing change at a clinic (clinic costs, dressings cost, other materials) and at home (nurse time, dressings cost, other materials), and the frequency of dressing changes were given. The costs were estimated on the basis of actual dressing changes that occurred, national average health service costs and published data sources on drug prices. The price year was 2000.
Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
No indirect costs were recorded.

Currency
UK pounds sterling (£) and dollars ($) are assumed. It is assumed that the dollars were US$.

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean cost per patient was £876 (US$1,314) in the 4LB group and £916 (US$1,374) in the 2LB group.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors’ conclusions
Four-layer bandaging (4LB) was less expensive than two-layer bandaging (2LB), as it was associated with earlier closure, had fewer withdrawals (more tolerable) and fewer adverse events.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was justified by the fact that they were both widely used in the authors’ setting. You should decide if they are a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were obtained from a single, randomised open-label trial, which was appropriate in addressing the study question. The authors took great pains to ensure that the study sample was randomised between the two treatments, but there was no guarantee that the patients would stay on the treatment throughout the 24 weeks. There was no clear description of the "alternative treatment" to which drop-out patients were allocated. Therefore, the effectiveness results describe the outcomes of patients who were initially allocated to either 2LB or 4LB. The patient groups were described as being comparable at analysis, but statistical tests were not used to show this.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefit. This was, effectively, a cost-consequences analysis. The health benefits are therefore those associated with the effectiveness results.

Validity of estimate of costs
The authors adopted a health system perspective on the costs. Hence the indirect costs were excluded, although they might have been fairly important since patients often need to be taken to the clinic. However, this omission is unlikely
to have affected the authors’ conclusions on the costs, as it will have increased the advantage of 4LB. The resource use quantities were taken from the study only. No analysis of the resource quantities was carried out. The prices were taken from different published sources. No analysis of the costs was carried out. The authors used 2000 prices and converted them into dollars from pounds, but did not give the exchange rate used.

Other issues
The authors compared their results with the findings of other studies, but the issue of generalisability was not addressed. The authors did not present their results selectively and, although they were aware of the weakness of the study, (the heterogeneity within treatment groups) they were unsure as to how fundamental it was.

Implications of the study
The authors concluded that 4LB carried out by trained nurses in the community is probably more effective than 2LB. This is because 4LB results in fewer drop-outs and better results at 12 weeks, even though a difference could not be detected at 24 weeks. 4LB also had a definite cost-advantage over 2LB.

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