Randomized clinical trial and economic analysis of four-layer compression bandaging for venous 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
The use of four-layer compression bandaging (4LB) versus alternative dressings for the treatment of venous ulcers.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients with venous ulcers. A venous ulcer was defined when there was clinical evidence of venous disease, the resting ankle to brachial pressure index was 0.9 or greater, and no other cause was identified.

Setting
The setting was not explicitly stated, but it is likely to have been the community. The economic study was carried out in the large rural and urban region of the Mid-Western Health Board in Ireland.

Dates to which data relate
The patients were recruited between April 1999 and August 2000. However, the time during which the effectiveness and resource use data were gathered was not reported. The price year was not provided.

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

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

Study sample
Power calculations were conducted prior to the beginning of the study. These found that a sample of 200 patients (100 in each group) was required to detect a difference of 20% in healing rates between the two groups at 12 weeks, with 80% power and at a 5% level of significance. Public health nurses, practice nurses and general practitioners (GPs) identified the patients for enrolment in the study. Enrolment stopped when 100 patients in each group were admitted. The mean age was 71.7 (+/- 9.8) years in the 4LB group and 71.4 (+/- 11.5) years in the control group, and there were 35 (4LB group) and 33 (control group) men, respectively. The median duration of leg ulcer was 9 weeks (interquartile
range, IQR: 4 - 27) in the 4LB group versus 11 weeks (IQR: 5 - 28) in the control group.

Study design
This was a prospective, randomised controlled trial that was conducted in the area of the Mid-Western Health Board in Ireland. Randomisation was conducted using a computer-generated sequence of numbers, with the results kept in sealed numbered envelopes and assigned to consecutive patients. The length of follow-up was 12 weeks. Two patients in the intervention group and none in the control group were lost to follow-up. The usual community nurse, who had received formal training in applying the 4LB, dressed all of the patients.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary outcome measures were the healing rates, times to healing, and reduction in ulcer size. Healing was defined as full epithelialisation and no scab present. The study groups were comparable at baseline in terms of their age, gender distribution, size and duration of leg ulcer, and other co-morbidities such as diabetes mellitus and rheumatoid arthritis.

Effectiveness results
The event of having leg ulcers healed after 3 months was 1.8 times (95% confidence interval, CI: 1.2 - 2.9) more likely in the 4LB group than in the control group.

The healing rate at 3 months was 54% in the 4LB group and 34% in the control group, (p<0.001). The difference in healing rate remained significantly different after adjusting for age, baseline ulcer area and duration, and other co-morbidities.

After the fifth week of treatment, time to healing was faster with 4LB than with the control treatments.

The reduction in ulcer size was comparable between the groups.

Clinical conclusions
Healing was more likely in 4LB patients than in control patients and was achieved faster.

Measure of benefits used in the economic analysis
The summary benefit measure used in the economic analysis was the number of healed patients. This was derived directly from the effectiveness study.

Direct costs
Discounting was irrelevant because the costs were incurred during 3 months. The unit costs were not presented, but the quantities of resource use were. The cost categories considered in the analysis were dressing products, nursing time (for dressing, administration and travel), mileage, GPs and hospital services. The cost/resource boundary of the study was that of the health service. The resource use data were estimated from the sample of patients included in the effectiveness study. The unit costs came from local pricing lists for dressings, from average salary rates for nurses (and included allowances), and from the hospital accounting system for hospital costs. The source of the GP costs was not reported. The price year was not reported.

Statistical analysis of costs
Standard statistical tests were carried out to compare the estimated costs in the two groups. The costs were presented as median values and IQRs.
Indirect Costs
The indirect costs were not included.

Currency
Euros (Euro).

Sensitivity analysis
No sensitivity analyses were conducted.

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

Cost results
The estimated median costs per patient were Euro 209.7 (IQR: 137.5 - 269.4) in the 4LB group and Euro 234.6 (IQR: 168.2 - 345.1) in the control group. The total costs did not include GP and hospital services because the use of these was minimal.

Synthesis of costs and benefits
It appears that a cost-effectiveness ratio has been calculated, although the figures were not reported. The authors stated that "the median cost per leg healed was significantly less for the four-layer bandage treatment, (p=0.040)".

Authors' conclusions
Compared with the usual dressings, four-layer bandaging (4LB) represented an effective option for treating patients with leg ulcers in a community setting, without adding extra costs to the health system.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The authors stated that, since a pragmatic trial was conducted, all treatments usually administered to patients with leg ulcers were considered in the control group. Consequently, several dressing approaches were used and all reflected the standard care option. You should decide whether they represent valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a randomised trial, which was appropriate for the study question. The methods of randomisation and sample selection were described. The study sample is likely to have been representative of the study population. Power calculations were performed, thus the sample size was appropriate to detect statistically significant differences in the main outcome measure. Adjusted analyses were also performed to take several potential confounding factors into consideration. The length of, and loss to follow-up were reported. The basis of the analysis was intention to treat. Thus, the internal validity of the analysis was high.

Validity of estimate of measure of benefit
The summary benefit measure was estimated directly from the effectiveness study (see commentary above). However, the number of ulcers healed represented a disease-specific measure, which is difficult to compare with the benefits of other health care interventions.

Validity of estimate of costs
The authors reported the perspective of the study and it appears that all the relevant categories of costs have been included. Statistical tests were conducted on both the resource use and total costs. The source of the data was reported for almost all items. Discounting was not applied, which was appropriate as it was irrelevant. The cost estimates were derived from local prices, but sensitivity analyses were not carried out to consider the variability in data in different settings. Neither the unit cost data nor the price year was reported. The authors stated that there could have been some bias in the cost comparison because more control than intervention patients received home care. However, despite this difference, it is likely that some cost-savings could be realised with 4LB.

Other issues
The authors compared their results with those reported in other studies. They stated that the healing rates observed in their study were different from prior estimations, probably due to the differences in the duration of leg ulcers before enrolment. The issue of the generalisability of the results of the analysis was not addressed. Also, sensitivity analyses were not conducted to ensure the transferability of the conclusions of the analysis. It was not very clear whether a cost-effectiveness ratio was actually calculated, although the authors mentioned the "cost per leg healed".

Implications of the study
The main implication of the study was that 4LB led to faster and more effective healing rates than standard dressing approaches and, despite the high initial acquisition cost, may lead to cost-savings to the health system.

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