Comparative cost-effectiveness of four-layer bandaging in the treatment of venous leg ulceration
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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 a four-layer compression bandaging system (Profore) in the treatment of venous leg ulceration versus the traditional Charing Cross bandaging system.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with venous leg ulcers.

Setting
Community, primary care, and hospital. The economic analysis was conducted in York, UK.

Dates to which data relate
Effectiveness and resource data were taken from literature published between 1996 and 1998. The price year was 1997/98.

Source of effectiveness data
Effectiveness data were derived from a review of the literature and assumptions made by the authors.

Modelling
Markov state transition models were built using data from the literature and other sources to estimate the effectiveness and costs associated with each treatment modality. 52 weekly cycles of the model were computed. Individuals could move between two possible states (unhealed and healed) in the base model, and an alternative model also accounted for the possibility of recurrent venous leg ulcers.

Outcomes assessed in the review
Healing rates for venous leg ulceration using Profore bandaging, Charing Cross four-layer compression techniques and standard nursing care provided at community care trusts were derived from a review. Recurrence rates for ulceration were also assessed.
Study designs and other criteria for inclusion in the review
Two randomised controlled trials provided data. One compared Profore with the traditional Charing Cross system over a 24 week period (the study included 232 patients with a mean age of 67.1 years in the Profore group and 67.8 years in the Charing Cross group), whilst the other was a two year study comparing four-layer compression bandaging in community-based specialist clinics with usual nursing care provided in community trusts (the study consisted of 233 patients with a mean age just over 73 years). A third observational study in which all patients were treated with four-layer compression bandaging at 6 community clinics was used to identify recurrence rates.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Summary statistics were reported from each study.

Number of primary studies included
3 studies reported in 5 papers were included in the review.

Methods of combining primary studies
Not combined.

Investigation of differences between primary studies
The review consisted of two sets of comparisons each of which was based mainly on a single randomized controlled trial. The marked differences in the healing rates at 12 and 24 weeks reported in the two randomized trials could be partly explained by the fact that the studies covered populations which differed substantially in patient mobility, ulcer size and duration, and possibly average wound severity.

Results of the review
In the study comparing Profore with Charing Cross, healing rates at 12 weeks were 79% and 65%, respectively, and 84% and 82% at 24 weeks. These differences were not significant. In the second study comparing four-layer compression bandaging with usual care, healing rates at 24 weeks were reported to be 58% and 42% respectively. This difference was significant. Recurrence rates (in the study in which all patients were treated with four-layer compression bandaging at 6 community clinics) were 20% within six months and 33% after one year.

Methods used to derive estimates of effectiveness
Estimates of effectiveness were also based on the authors’ assumptions.

Estimates of effectiveness and key assumptions
Two assumptions were considered in extrapolating trial results from week 24 in comparing Profore to traditional Charing Cross bandaging. These were that no patients were healed between weeks 25 to 52 or that all unhealed patients at week 24 were healed during weeks 25 to 52. It was also assumed that recurrence rates for patients treated in specialist clinics with four-layer compression bandaging were applicable to all patients.
Measure of benefits used in the economic analysis
The benefit measures were the number of ulcers healed and weeks spent in a healed state.

Direct costs
Costs were not discounted given the 52-week time frame of the model. Quantities were reported separately from the costs. Costs of dressings and bandages, dispensing fees, clinic costs, (including staff salaries, transport costs and clinic overheads) and community nursing costs were included in the analysis. Costs for dressings and bandages were obtained from the NHSSA 1997/1998 price list and the March 1998 Drug Tariff. The amount of materials used was calculated using evidence from a 1997 randomised controlled trial examining four-layer compression dressing. Clinic costs were taken from a 1998 publication. Costs were determined from the perspective of the National Health Service (NHS). The number of community nursing visits required was taken from a 1996 study of community leg ulcer clinics and community nurse consultation costs were taken from the 1997 edition of the Personal Social Services Research Unit’s costs for health and social care. The date of the price data was 1997/98.

Indirect Costs
Not included.

Currency
UK pounds sterling (£).

Sensitivity analysis
Different scenarios were considered by the authors in the analysis. In comparing Profore with components of Charing Cross wound dressing two healing rates were considered. In scenario 1 it was assumed that healing rates were identical whilst in scenario 2 actual healing rates observed in the randomised controlled trial were used. In addition, different versions of the model assumed that either no further patients were healed after 24 weeks, or alternatively, that all unhealed patients at this time were healed during weeks 25 to 52. In the analysis comparing four-layer compression bandaging with usual care four scenarios were considered in which several resource parameters were varied.

Estimated benefits used in the economic analysis
When comparing Profore and Charing Cross systems and assuming identical health rates, 82% of ulcers were healed in each group for scenario 1 and 100% were healed in each group for scenario two. Similarly when using the healing rates observed in the trial, 84% of ulcers were healed using Profore in scenario 1 and 82% using the Charing Cross System. Under scenario 2 both systems produced 100% healing. The median number of weeks required to heal ulceration was 8.5 for Charing Cross patients compared with 6 weeks for Profore patients. In the analysis comparing four-layer compression bandaging with usual care, 11% more ulcers would be healed (excluding recurrent ulcers), 71% compared with 60% for the Profore group compared with usual care. Including recurrent ulcers, 77% of ulcers would be healed in the Profore group compared with 64% in the usual care group. The total number of weeks in a healed state per patient in the Profore and usual care groups, respectively, were 23.28 and 17.85.

Cost results
In the analysis comparing Profore with Charing Cross the average weekly costs for patients in a healed state were 0.76 for both groups and for an unhealed state were 24.72 (Profore) and 24.16 (Charing Cross). The 52 week incremental costs per patient in the Profore group were 8.67 (total cost 412.70) in scenario 1 (no ulcers healed after 24 weeks) and 7.20 (total cost 349.35) in scenario 2 (all ulcers assumed to be healed over the 52 week period). In the analysis comparing Profore treatment in specialist clinics with usual care, the total costs of Profore treatment per patient varied between 631.36 and 759.26 in the 52 week period. These costs were lower than those for usual care, with resource savings in the four scenarios similarly ranging from 473.58 to 772.35. Average weekly costs of care for unhealed patients in the usual care group ranged from 35.75 to 40.76 and for the Profore group ranged from 21.43 to 25.89.
Synthesis of costs and benefits
When comparing Profore with Charing Cross treatment and assuming that healing rates were identical, the Charing cross treatment was dominant. If observed healing rates used in the trial were used, Profore then became the dominant intervention with both lower costs and higher benefits. When comparing Profore treatment to usual care, Profore bandaging was dominant over usual care in all scenarios (the authors calculated average cost per ulcer healed and average cost per week in healed state as the measures of cost-effectiveness analyses).

Authors’ conclusions
Wound care treatments which reduce the mean length of time for patients to heal are likely to be cost-effective compared with current practice. There was no clinically significant difference in healing rates between Profore and traditional Charing Cross treatment and the costs of Profore treatment were higher. However, compared with usual care in different settings, Profore treatment was found to be cost saving due to a reduction in the time required for ulcers to heal.

CRD COMMENTARY - Selection of comparators
A justification was provided for the comparators used in the analysis. Charing Cross wound dressing was reported to be the original treatment in the context in question while usual care represented the current practice in community trusts. Short-stretch or long-stretch bandaging were not used as the comparators in this modelling study since the primary studies comparing these methods with four-layer bandaging were reported to have covered only small numbers of patients with healing rates having been recorded for only a short period of time.

Validity of estimate of measure of benefit
The estimate of the measure of benefit is likely to be internally valid given the use of randomised controlled trials as the main sources of effectiveness data.

Validity of estimate of costs
Quantities were reported separately from the costs and sufficient details were provided by the authors on the sources and quantification of costs used in the model. The cost analysis focussed on direct costs from the perspective of NHS. It would be interesting to consider whether there are also substantial societal costs to specific groups such as patients and informal caregivers.

Other issues
The authors’ conclusions appear to be justified given the randomised designs used in the effectiveness analysis and the sensitivity analyses performed. The issue of generalisability to other settings or countries was not addressed.

Implications of the study
The systematic use of such wound dressing systems in the NHS would lead to a substantial reduction in resources used in the management of venous leg ulcers. For an average health authority serving a population of 500,000, this reduction could represent the equivalent of saving 350,000-1.08 million annually.

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