Modelling the cost-effectiveness of electric stimulation therapy in non-healing 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.

CRD summary
This study assessed the cost-effectiveness of electric stimulation plus dressing and compression bandaging, compared with dressing and bandaging alone, for chronic venous leg ulcers that had not healed for more than six months. The addition of electric stimulation could be cost-effective, but depended on the device cost, the units per treatment, and the number of nurse visits. The methods were valid, but the clinical analysis was limited and more studies are needed to support the conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
This study assessed the cost-effectiveness of electric stimulation plus dressing and compression bandaging, compared with the dressing and bandaging alone, for the treatment of chronic venous leg ulcers that had not healed for more than six months.

Interventions
Three units of electric stimulation plus bandaging was compared with bandaging alone. Bandaging included interface dressings, secondary dressings, bandages, emollients, creams, and ointments.

Location/setting
UK/out-patient.

Methods
Analytical approach:
The analysis was based on a Markov model, with a five-month time horizon. The authors stated that it was carried out from the perspective of the UK NHS.

Effectiveness data:
The clinical inputs were from a published prospective, single-arm, non-blinded study of 22 patients with venous leg ulcers who received electric stimulation plus bandaging (mean age 69.2 years; 62% female). All patients were assessed for 90 days from the start of therapy; some patients were followed-up for five months. For bandaging without electric stimulation, data for these patients for the six months before stimulation were used, together with data from eight patients who did not receive stimulation during the study period. Other data were assumed by the authors. The primary endpoint was the percentage of ulcers that were healed.

Monetary benefit and utility valuations:
The utility values were from an earlier study by the authors of this study.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure.

Cost data:
The economic analysis included the costs of electric stimulation, nurse visits, bandages, dressings, creams, ointments,
and emollients. The unit costs were reported and were from NHS price lists. The quantities of resources were from case report forms completed during the clinical study. All costs were in UK pounds sterling (£) at 2008 to 2009 prices.

Analysis of uncertainty:
A probabilistic sensitivity analysis was carried out, using Monte Carlo simulation. Beta distributions were assigned to the probabilities and utilities; gamma distributions were assigned to the unit costs; and log-normal distributions were assigned to the resources. A deterministic sensitivity analysis was performed on selected inputs.

Results
Total costs were £748.94 with electric stimulation and £879.90 without it. Electric stimulation led to an improvement of 0.017 QALYs; the QALYs with stimulation were 0.316 and without it they were 0.299. Electric stimulation was dominant, as it was less expensive and more effective.

This result was robust in the sensitivity analyses. Stimulation remained cost-effective in 98% of simulations, at a maximum willingness-to-pay of £20,000 per QALY, assuming a cost per stimulation unit of £40 and three units per treatment.

The most influential inputs were the cost of the therapy, the number of therapy units per treatment, and the number of nurse visits in the improved health states for either group.

For the eligible UK population in a year, electric stimulation could result in a 15% reduction in NHS costs and a 26% reduction in the number of nurse visits, with five months of treatment.

Authors’ conclusions
The authors concluded that adding electric stimulation to bandaging could be cost-effective, but this depended on the cost of the device, the number of units per treatment, and the number of nurse visits.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear as the proposed intervention was compared with the usual treatment. A description of each option was given.

Effectiveness/benefits:
The clinical analysis was based on a study that compared the efficacy before and after the introduction of electric stimulation. The study was limited by a lack of randomisation and a very small sample, as acknowledged by the authors. Most of the patients were followed-up for three months, with only a few supplying data at five months (the model time horizon). An extensive sensitivity analysis was conducted to assess these issues. The authors stated that they were unable to consider the impact of some factors that might affect the results, such as comorbidities and severity and pathology of the underlying disease. QALYs were an appropriate benefit measure given the impact of the ulcers on the patients’ quality of life. The utility values were from members of the general public in the UK; the instrument used to elicit their preferences was not reported.

Costs:
The economic analysis was consistent with the perspective. The unit costs were reported for all items and the impact of variations in these costs was tested in the sensitivity analyses. The resource quantities were mainly from the case report forms which should have ensured that the data were detailed. The price year was clearly stated. The impact of each cost category on the total costs was investigated. In general, the costs were appropriately analysed and transparently reported.

Analysis and results:
The results were clearly reported. An incremental approach was used to compare the costs and benefits of the two strategies, but incremental cost-utility ratios were not required because stimulation dominated usual care. Appropriate methods were used to assess the uncertainty, and the methods and findings were clearly reported, except for the sources for the ranges of values used in the deterministic analysis, which were not reported. The authors acknowledged that the main limitations of their analysis were due to the poor quality of the clinical study that supplied the
effectiveness data, but this was the only source available for electric stimulation. They also stated that their results could not be transferred to the entire UK population, indicating that it would be difficult to transfer them to other settings.

Concluding remarks:
The cost-effectiveness methods were valid, but there were limitations in the clinical analysis. More studies are needed to corroborate the authors’ conclusions.

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