Economic evaluation of a randomized controlled trial of ultrasound therapy for hard-to-heal venous leg ulcers


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 examined the cost-effectiveness of low-dose ultrasound therapy, along with standard care, for the treatment of hard-to-heal leg ulcers. The authors concluded that ultrasound did not heal venous leg ulcers more quickly than standard care alone and was not likely to be cost-effective for the NHS. The cost-effectiveness framework was robust and the uncertainty was considered, which enhances the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study examined the cost-effectiveness of low-dose ultrasound therapy, along with standard care, for the treatment of hard-to-heal leg ulcers, using individual patient data from a clinical trial.

Interventions
Low-dose ultrasound therapy was administered weekly for 12 weeks in addition to standard care and this was compared with standard care alone.

Location/setting
UK/primary care.

Methods
Analytical approach:
This economic evaluation was carried out alongside one study (a clinical trial), with a 12-month time horizon. The authors stated that the perspective of the UK NHS and Personal Social Services was adopted.

Effectiveness data:
The clinical data were from a published, pragmatic, multicentre, randomised controlled trial; Venous Ulcer Studies (VenUS) III trial (Watson, et al. 2011, see ‘Other Publications of Related Interest’ below for bibliographic details). The time horizon was one year. There were 337 participants, with 168 in the ultrasound group and 169 in the standard care group. Full data for 18 participants were missing (eight in the ultrasound group and 10 in the standard care group). The intention-to-treat principle was used for missing data. The time until healing of the reference ulcer was the main endpoint.

Monetary benefit and utility valuations:
The utility values were collected from the patients enrolled in the trial, using the European Quality of life (EQ-5D) instrument. This was completed at three, six, nine, and 12 months from the beginning of the trial.

Measure of benefit:
Ulcer-free days and quality-adjusted life-years (QALYs) were the summary benefit measures.

Cost data:
The economic analysis included three main components, which were the ultrasound machine, compression therapy, and health care consultations with doctors, nurses, and as hospital out-patients. The resource quantities were from the
clinical trial and were collected prospectively by nurses and patients. The calculation of the cost of the ultrasound machine took into account depreciation of the equipment and the opportunity cost to provide an equivalent annual equipment cost. The unit costs were official UK rates. All costs were in UK pounds sterling (£) and the price year was 2007.

Analysis of uncertainty:
Bias-corrected, non-parametric bootstrapping was applied to create confidence intervals around the differences in costs and benefits. Cost-effectiveness acceptability curves were generated. A one-way sensitivity analysis investigated reductions in the cost of the ultrasound machine, which could be used for other purposes.

Results
The one-year costs were £1,583.39 with ultrasound and £1,385.51 with standard care. The QALYs were 0.515 and the time to healing was 259.7 days with ultrasound and the QALYs were 0.525 and the time to healing was 245.0 with standard care. None of these bias-corrected differences was statistically significant.

The cost difference was £197.88 (95% CI -35.19 to 420.32) and the QALY difference was -0.009 (95% CI -0.042 to 0.024), indicating that standard care dominated ultrasound, as ultrasound was less effective and more expensive. This conclusion was highly uncertain, as shown by the wide confidence intervals around the estimates.

Bootstrapping showed that the likelihood of ultrasound being cost-effective at a threshold of £30,000 per QALY was less than 20%. Reductions in the cost of the ultrasound machine did not alter the base case conclusion.

Authors' conclusions
The authors concluded that ultrasound treatment did not heal venous leg ulcers more quickly than standard care alone and was not likely to be cost-effective for the NHS.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear as ultrasound treatment was added to usual care, which was the background comparator. Usual care included compression therapy, but was not fully described.

Effectiveness/benefits:
The clinical data were from a trial, and its design should have ensured their validity. Statistical analyses were appropriately carried out to deal with missing data, imbalances between groups, and any centre effect. The trial was published elsewhere and its details were not reported in this publication. Two benefit measures were used. Time to healing was a common and direct endpoint of treatment, while QALYs captured the impact of the disease on the patients' health and will allow cross-disease comparisons to be made. The utility values were elicited, using a validated instrument, from the patients in the clinical trial.

Costs:
The costs reflected the perspective of the NHS, as stated by the authors. The resource use was accurately collected by questionnaires completed prospectively both by nurses and by patients. The pragmatic design made the trial suitable for the economic analysis. The cost of the ultrasound equipment was a key contributor to the total costs and was assumed to be equal in all locations. This cost was varied in the sensitivity analysis. The authors stated that ulcer dressings and skin preparation were assumed to be similar between groups and were not considered. Statistical analyses were used to assess the cost difference between groups. Details, such as the price year and sources for the unit costs, were provided.

Analysis and results:
The results were clearly presented. An incremental approach was used to combine the costs and benefits for the two interventions. Specific sensitivity analyses were used to assess uncertainty. The use of individual patient data allowed bootstrapping analysis to simulate the variability in patients' characteristics. The authors acknowledged that a limitation of their analysis was the use of one clinical trial and they stated that it might have been interesting to have evaluated the two treatments for leg ulcers at the same time. The transferability of the results was not discussed and the findings should be considered to be specific to the authors’ setting.
Concluding remarks:
The cost-effectiveness framework was robust and the uncertainty was considered, which enhances the validity of the authors’ conclusions.

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