Cost effectiveness analysis of larval therapy for 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**
The objective was to assess the cost-effectiveness of larval therapy compared with hydrogel in the management of leg ulcers. The authors concluded that debridement of leg ulcers with larval therapy was likely to produce similar health benefits and have similar costs to treatment with hydrogel. The methodology was good and the methods and results were well reported. The authors’ conclusions were appropriate given the scope of the analysis.

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

**Study objective**
The objective was to assess the cost-effectiveness of larval therapy compared with hydrogel in the management of leg ulcers.

**Interventions**
This study compared three debridement treatments: hydrogel, loose larvae, or bagged larvae.

**Location/setting**
UK/primary care.

**Methods**

**Analytical approach:**
The effectiveness and resource use data were derived from a randomised controlled trial. The study protocol determined that, if no statistically significant difference was found in the debridement time between loose and bagged larvae, these two groups would be combined. As a result, the economic analysis compared hydrogel with larvae. The time horizon of the analysis was 12 months. The authors reported that the perspective adopted was that of the National Health Service (NHS).

**Effectiveness data:**
The effectiveness data were derived from a single randomised controlled trial, the leg ulcer trial VenUS II, the details of which were published elsewhere (Dumville, et al. 2009, see ‘Other Publications of Related Interest’ below for bibliographic details). A total of 267 patients were recruited into the trial with 94 allocated to loose larvae, 86 to bagged larvae, and 87 to hydrogel. The randomised treatments were administered to 88 (94%) loose larvae, 82 (95%) bagged larvae, and 78 (90%) hydrogel patients. The mean follow-up time was 167 days for the loose larvae, 170 days for the bagged larvae, and 175 days for the hydrogel group. The main clinical estimate in the effectiveness study was the mean time to healing.

**Monetary benefit and utility valuations:**
The quality of life was derived from the European Quality of life (EQ-5D) questionnaire, which was administered to patients at baseline and at three, six, nine, and 12 months. The utility scores were calculated using societal preferences elicited from a random population sample, using a time trade-off technique.

**Measure of benefit:**
The measures of benefit were quality-adjusted life-years (QALYs) and the mean time to healing.

**Cost data:**
The direct costs were those relating to: bagged and loose larvae; hydrogel applications; nurse and doctor visits at home, clinics and hospital; and compression therapy. The resource use data were derived from nurse-completed and participant-completed questionnaires. The unit costs for debriding agents were derived from the British National Formulary. The unit costs for other items were derived from a compendium of unit costs of health care in the UK. The price year was 2006 and all costs were reported in UK pounds sterling (£).

Analysis of uncertainty:
The 95% confidence intervals (CIs) for the differences in costs and effectiveness were calculated using non-parametric bootstrap estimates. The uncertainty surrounding the incremental cost-effectiveness and incremental cost-effectiveness ratios was evaluated, using cost-effectiveness acceptability curves. A series of one-way sensitivity analyses were also performed by varying the unit costs and the duration of debridement.

Results
The mean time to healing with larval therapy was 204.1 days (95% CI: 207.9 to 248.3) compared with 206.5 days (95% CI: 202.7 to 260.2) with hydrogel, which was a reduction of 2.42 days (95% CI: -41.0 to 31.9).

The mean QALYs gained were 0.551 (95% CI: 0.505 to 0.591) with larval therapy compared with 0.540 (95% CI: 0.489 to 0.589) with hydrogel, which was an increase of 0.011 QALYs (95% CI: -0.067 to 0.071).

The mean annual costs were £2,073 (95% CI: 1,724 to 2,433) in the larval therapy group compared with £1,976 (95% CI: 1,521 to 2,500) with hydrogel, which was an increase of £97 (95% CI: -492 to 686).

When compared with hydrogel, larval therapy was associated with an incremental cost of £40 per ulcer-free day and £8,826 per QALY gained. At a willingness-to-pay threshold of £30,000 per QALY gained, the probability of larval therapy being cost-effective was 63%.

Authors’ conclusions
The authors concluded that debridement of leg ulcers with larval therapy was likely to produce similar health benefits and have similar costs to treatment with hydrogel.

CRD commentary
Interventions:
The interventions were reported clearly. An explicit justification was given for using hydrogel as the comparator, which was that it could be considered to be the standard therapy for the removal of necrotic tissue.

Effectiveness/benefits:
The effectiveness data were derived from a randomised controlled trial, which, if they are well conducted, are considered to be the gold standard study design when comparing health interventions. Although only brief details of the trial were given, because it was published elsewhere, it appears to have been adequately conducted. The authors reported that the outcome measures were censored and they adjusted their analysis to take account of this censoring, using inverse probability weighting. The measures of benefit adequately captured the health outcomes.

Costs:
The perspective was reported appropriately. The resource use data were derived from data collected as part of the trial. The methods used to collect the resource use data were adequately reported. All the sources of unit costs were also adequately reported and the resource quantities were reported separately from their unit costs. The price year and time horizon were reported.

Analysis and results:
The costs and benefits were adequately combined using incremental cost-effectiveness and cost-utility ratios. The impact of uncertainty was investigated using non-parametric bootstrap techniques, by means of cost-effectiveness acceptability curves, and using one-way sensitivity analyses for uncertain data. The limitations of the study were reported by the authors.
Concluding remarks:
The methodology was good and the methods and results were well reported. The authors' conclusions were appropriate given the scope of their analysis.

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