Modelling the cost-utility of bio-electric stimulation therapy compared to standard care in the treatment of elderly patients with chronic non-healing wounds in the UK

Clegg J P, Guest J F

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 study examined the use of bio-electric stimulation therapy for treating chronic, non-healing wounds of more than 6 months' duration.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The study population comprised elderly patients with chronic, non-healing wounds of more than 6 months' duration. The inclusion and exclusion criteria were not reported.

Setting
The setting was community care. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource data appear to have been collected in 2006. The price year was 2005/06.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample that provided the effectiveness data.

Study sample
Power calculations were not carried out. The sample comprised 18 patients, three of whom had 2 wounds. Of these 21 evaluable wounds, 11 were venous leg ulcers, 9 were pressure ulcers and 1 was trauma.

Study design
The study was a prospective, single-arm, non-blinded clinical evaluation. Clinical outcomes and resource use were recorded over a 16-week period before and after the start of bio-electric stimulation therapy. Five per cent of the patients were lost to follow-up due to death.

Analysis of effectiveness
The clinical end point was the percentages of healed, improved and unchanged patients at 16 weeks following the start
of the treatment.

**Effectiveness results**
Thirty-three per cent of all wounds (including 27% of venous leg ulcers and 44% of pressure ulcers) were expected to be healed, 38% to improve and 24% to remain unchanged within 16 weeks after start of the bio-electric treatment.

**Clinical conclusions**
Bio-electric therapy led to an improvement in healing within 16 weeks.

**Modelling**
A Markov model was constructed to assess the cost-effectiveness and cost-utility. The structure of the model, the time horizon (16 weeks), the cycle length (1 week), and transitions across health states were all extensively described and depicted. Patients in the model had five health states. These were "healed", "improved", "unchanged", "worsened" and "dead". The transition probabilities of the five states over the 16 weeks were derived from a clinical evaluation.

**Measure of benefits used in the economic analysis**
The summary benefit measure used was the number of quality-adjusted life-years (QALYs). The authors described the approach used to calculate the QALYs. The utilities were obtained using standard gamble methodology and utility scores were obtained for each of the five health states. The authors stated that the approach to obtaining utilities was described elsewhere (Hammerschmidt et al. 2004, see 'Other Publications of Related Interest' below for bibliographic details).

**Direct costs**
The study reported the direct costs to the health service. The initial costs included those of clinical visits, prescriptions and dressings. The unit costs and the resource quantities of resource quantities were reported separately. The costs were not discounted. The price year was 2005/06.

**Statistical analysis of costs**
Bootstrap re-sampling with 1,000 replicates was used to estimate the distribution of the expected costs, outcomes and utility ratio. A statistical analysis of the costs was carried out.

**Indirect Costs**
Productivity costs were not considered.

**Currency**
UK pounds sterling ( ).

**Sensitivity analysis**
The uncertainty in the expected costs, outcomes and utility ratio was examined using bootstrapping. In addition, one-way sensitivity analyses were performed to investigate the impact of varying the model parameters on the incremental cost-utility ratio.

**Estimated benefits used in the economic analysis**
Patients were expected to have an overall health gain of 0.190 QALYs with standard care and 0.213 QALYs with bio-electric stimulation therapy over 16 weeks.
The incremental gain was 0.213 QALYs (95% confidence interval, CI: 0.212 to 0.214).

Cost results
A 16% reduction in cost over 16 weeks was expected for patients treated with bio-electric stimulation therapy instead of standard care. The reduction in costs was from 2,287 (95% CI: 1,838 to 2,735) to 1,921 (95% CI: 1,609 to 2,233).

The reduction was 29% from 2,628 (95% CI: 2,004 to 3,252) to 1,859 (95% CI: 1,493 to 2,225) for venous leg ulcers, and 5% from 2,059 (95% CI: 1,484 to 2,634) to 1,949 (95% CI: 1,356 to 2,542) for pressure ulcers.

Synthesis of costs and benefits
An incremental analysis was carried out to combine the costs and benefits of the alternative strategies. Bio-electric stimulation therapy was found to be a dominant treatment strategy for all wounds, for venous leg ulcers and for pressure ulcers.

The bootstrapping analysis indicated that the majority of samples were located in the dominant quadrant. The cost-effectiveness acceptability curve revealed that bio-electric stimulation therapy was likely to be preferred to standard care, even for a willingness to pay of less than 5,000 per QALY gained.

One-way sensitivity analyses revealed that, irrespective of wound type, the relative cost-utility of bio-electric stimulation therapy improved as the acquisition cost of bio-electric stimulation therapy decreased. It also improved as the acquisition cost of the patients’ drugs increased and as the acquisition cost of the patients’ other dressings increased.

Authors’ conclusions
"Bio-electric stimulation therapy is expected to afford the National Health Service (NHS) a cost-effective dressing compared with standard care in the treatment of chronic non-healing wounds of more than 6 months' duration."

CRD COMMENTARY - Selection of comparators
The comparator of standard care is a natural comparator in the case of bio-electric stimulation therapy.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective, single-arm, non-blinded clinical evaluation of bio-electric stimulation therapy. The patients were not randomised to treatment, thereby increasing the possibility of confounding arising from variations in clinical expertise in different nursing homes.

Validity of estimate of measure of benefit
The summary measure of health benefit (i.e. QALYs) was derived appropriately using a Markov model. The methods used to estimate the utility weights were described and their source was explicitly stated. QALYs have the advantage of enabling comparisons to be made with other health care interventions that also use QALYs.

Validity of estimate of costs
The authors adopted the perspective of the UK NHS. All the relevant costs to this perspective were considered in the analysis. The sources of the resource use and cost data were reported. No discounting of the costs was carried out, which was appropriate given the short time horizon. The cost methods were adequately described. The unit costs and the resource quantities were reported separately and the price year was reported. This strengthens the generalisability of the results. The generalisability to other settings was addressed through the extensive sensitivity analysis and statistical analysis.

Other issues
The authors did not compare their findings with those from other studies. They do not appear to have presented their results selectively. The impact of variation in the patient population on the economic results was not investigated in a sensitivity analysis. The authors acknowledged several limitations of their study. First, randomisation was not used to assign the patients to treatment group or standard care. Thus, the study might have been confounded by variations in clinical expertise. Second, only the direct health care costs borne by the payer were taken into account; those borne by the patients were not considered in the model. Such factors as co-morbidities, underlying disease severity and pathology of underlying disease, which might have affected the model results, were also not considered.

**Implications of the study**

Bio-electric stimulation therapy appears to be the preferred option for the treatment of elderly patients with chronic non-healing wounds of more than 6 months' duration.

**Source of funding**

Funded by Biofisica LLC.

**Bibliographic details**

Clegg J P, Guest J F. Modelling the cost-utility of bio-electric stimulation therapy compared to standard care in the treatment of elderly patients with chronic non-healing wounds in the UK. Current Medical Research and Opinion 2007; 23(4): 871-883

**PubMedID**

17407644

**DOI**

10.1185/030079906X167705

**Other publications of related interest**

Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.


**Indexing Status**

Subject indexing assigned by NLM

**MeSH**

Aged; Aged, 80 and over; Chronic Disease /therapy; Cost-Benefit Analysis; Electric Stimulation Therapy /economics; Female; Forecasting; Great Britain; Health Resources /economics /utilization; Humans; Male; Markov Chains; Models, Economic; Skin Ulcer /therapy; Wounds and Injuries /economics /therapy
AccessionNumber
22007008077

Date bibliographic record published
31/08/2007

Date abstract record published
31/08/2007