Is noncontact normothermic wound therapy cost effective for the treatment of stages 3 and 4 pressure 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.

Health technology
The use of noncontact normothermic wound therapy (NNWT; Warm-Up Therapy, Augustine Medical Inc.) for the treatment of stages 3 and 4 pressure ulcers. NNWT was administered three times a day for one hour. In addition, all of the patients received standard care. Standard care consisted of cleansing the wound, using a pressure-reducing surface, debridement, and repositioning the patient eight times per day.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The hypothetical type of patient considered in the baseline analysis was a 72-year-old continent man, living in a nursing home, and with a stage 3 pressure ulcer. A stage 3 pressure ulcer referred to full-thickness skin loss involving damage to subcutaneous tissue extending down to, but not through, the underlying fascia. The same type of patient, but with a stage 4 pressure ulcer, was considered in a secondary analysis. A stage 4 pressure ulcer referred to full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures.

Setting
The setting appears to have been community care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data were mainly collected from studies published between 1990 and 2001. The cost data were obtained from studies published between 1992 and 2000, and from several authors’ assumptions. The price year was 2000.

Source of effectiveness data
The effectiveness data were derived from a systematic review of published studies.

Modelling
A Markov model was used to estimate the incremental cost-effectiveness of NNWT compared with standard practice. The six health states considered were stage 3 ulcer, stage 4 ulcer, healing wound, closed wound healed back to normal, complications requiring hospitalisation, and death. The transition probabilities were assumed to be constant across time. The time horizon considered in the baseline analysis was 40 months and each cycle was 8 weeks in duration. The cycle length was chosen to approximate, as closely as possible, the length of a therapeutic treatment.
Outcomes assessed in the review
The health outcomes assessed for patients with stage 3 or 4 pressure ulcers, treated with either standard care or NNWT, were:

the percentage surface area reduction;

the healing rate at 8 and 12 weeks;

the absolute percentage change in wound area differences; and

the fraction of patients with a wound at 25% of the original area.

The authors also reported the transition probabilities through the health states for patients with stage 3 and stage 4 pressure ulcers when treatment was initiated.

Study designs and other criteria for inclusion in the review
The studies included in the review were controlled trials of at least 4 weeks’ duration. The studies had to include a minimum of one of the relevant end points assessed in the review.

Sources searched to identify primary studies
MEDLINE was searched from 1986 to 2000 for English studies performed on humans. Manual searches of citations of review articles and abstracts presented at national meetings were also carried out. Some authors and experts were contacted for further information and unpublished data.

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

Methods used to judge relevance and validity, and for extracting data
The lead author of the paper extracted the data. However, the methods used to judge the relevance and validity of the data were not reported.

Number of primary studies included
The number of studies included in the review could not be clearly inferred, but at least 13 published studies (four randomised trials and two studies reporting statistical data) and a website (the National Center for Health Statistics) were considered.

Methods of combining primary studies
Some of the estimators were obtained from individual studies. When data from different studies were combined to obtain a single estimate, the method used was reported.

Investigation of differences between primary studies
The authors reported differences relating to the type of patients, duration of the study, and sample size for the randomised trials included in the review. Some estimates were calculated by weighting the estimates from individual studies by their sample sizes.

Results of the review
The percentage reductions in surface area were 19% for standard care versus 61% for NNWT in patients initiating treatment with stage 3 pressure ulcers, and 23% with standard care versus 55% with NNWT for patients initiating treatment with stage 4 pressure ulcers. Therefore, the surface area of the stage 3 and stage 4 ulcers was reduced by an average of 2.5 fold (standard deviation, SD=59%) with NNWT when compared with standard care.

The healing rates for patients with stage 3 pressure ulcers were 54% with standard care versus 71% with NNWT after 8 weeks, and 38% with standard care versus 50% with NNWT after 12 weeks. The corresponding rates for patients with stage 4 pressure ulcers were 0% (standard care) and 38% (NNWT) after 8 weeks, and 0% (standard care) and 25% (NNWT) after 12 weeks of treatment.

The fraction of patients with a wound at 25% of the original area was 20% with standard care and 55% with NNWT.

The authors stated that no complications associated with NNWT were reported.

**Methods used to derive estimates of effectiveness**
The authors made assumptions to derive some estimates of effectiveness.

**Estimates of effectiveness and key assumptions**
The authors reported that some transition probabilities were derived when data from individual studies were not available, based on the assumption that NNWT accelerates wound healing by 2.5 fold.

**Measure of benefits used in the economic analysis**
The summary measure of benefit used was the number of quality-adjusted life-years (QALYs) gained with each one of the alternative treatments considered. The Rosser and Kind valuation matrix was used to obtain the required utilities for the estimation of QALYs. The Health Utilities Index-2 multi-attribute utility function was used to check the obtained utilities. The utilities finally used were 0.84 for stage 3 ulcer, 0.73 for stage 4 ulcer, 0.5 for complications or hospitalisation, 0.9 for healing wound, 1 for a normal health state, and 0 for death. The authors also reported the percentage of patients whose wounds were expected to heal after the study period with standard care and with NNWT.

**Direct costs**
The direct costs considered in the economic analysis were those of the health service. These were the costs directly related with treatment (e.g. drugs, saline, skin cleansing preparations), nursing and physician costs, supplies and equipment, and costs associated with complications (e.g. antibiotic treatment due to systemic infections). The direct costs were obtained from published studies and some authors' assumptions. The authors' assumptions appear to have been justified with reference to the manufacturers' recommendations on the use of the analysed treatments. Therefore, the costs were estimated through modelling, which appears to have been based on actual data. The resource quantities were not reported separately from the costs. Discounting was performed using a rate of 3%. This was appropriate as the time horizon considered was longer than 2 years (i.e. 40 months). The price year was reported. The authors reported the incremental costs.

**Statistical analysis of costs**
The mean and standard error (SE) of the costs were given.

**Indirect Costs**
No indirect costs were reported.

**Currency**
US dollars ($).
Sensitivity analysis
Sensitivity analyses were carried out to assess the robustness of the results when the model parameters, or the authors’ assumptions, were modified. A probabilistic sensitivity analysis using Monte-Carlo simulation was performed in which all probabilities, utilities and costs were varied simultaneously. Moreover, an alternative time horizon of 20 months was considered in the sensitivity analyses. Therefore, the area of uncertainty investigated was variability in the data. The ranges used were obtained from the literature and from authors’ assumptions (see 'Modelling' and 'Estimates of Effectiveness and Key Assumptions' sections).

Estimated benefits used in the economic analysis
Compared with standard care, NNWT increased the number of QALYs by 0.10 (SE=0.0005) for patients with stage 3 pressure ulcers and by 0.14 (SE=0.001) for patients with stage 4 pressure ulcers.

Cost results
Compared with standard care, NNWT saved $6,630 (SE=98) for patients with stage 3 pressure ulcers and $15,216 (SE=186) for patients with stage 4 pressure ulcers.

Synthesis of costs and benefits
Since NNWT proved to be a dominant strategy in the baseline analysis when compared with standard treatment, no incremental cost-effectiveness ratios were reported. The incremental benefits and costs were left disaggregated.

The most sensitive parameters within the model were the total cost per day of treatment with standard care, the probability of healing to a normal closed wound with standard care, the cost of the complication state, and the acquisition cost of the NNWT wound cover. NNWT was likely to reduce the costs and to increase QALYs for at least 75% (SE=0.4) of patients with stage 3 ulcers, and for at least 81% (SE=0.4) of patients with stage 4 ulcers. NNWT would cost less and increase the QALYs as long as the healing rate with NNWT was greater than 1.5 times that of standard care.

Authors’ conclusions
Noncontact normothermic wound therapy (NNWT) for the treatment of patients with stage 3 and stage 4 pressure ulcers improved quality of life and decreased costs in comparison with standard care.

CRD COMMENTARY - Selection of comparators
The comparator was chosen to represent current practice in the authors’ setting, as defined in the guidelines published by the Agency for Healthcare Quality and Research. The authors reported that some other available treatments of pressure ulcers are electric energy, external negative pressure, low airloss beds, various dressings, skin substitutes and growth factors. These other treatments were not considered in the analysis. You must therefore decide which health technology is the most commonly used in your own setting.

Validity of estimate of measure of effectiveness
The authors did not report that a systematic review of the literature had been undertaken, although it appears that this has been the case. Most of the methods and conduct of the review were clearly reported. Language bias may be present in the analysis since only English publications were considered. A positive feature of the review was the effort made by the authors to manually retrieve further studies (published and unpublished). It was not reported whether two reviewers selected and reviewed the studies, as recommended for performing systematic reviews. Moreover, since a single reviewer extracted the data, this may represent a source of additional bias. The authors reported the methods used to derive most of the effectiveness estimates and, in some cases, adopted a weighting scheme to reflect differences in the sample sizes. The authors reported, and appear to have considered, the differences between some of the primary studies included in the review. Justifications were given for most of the choices made for modelling health outcomes (e.g.
timeframe, type of patient).

**Validity of estimate of measure of benefit**
The estimation of benefits was modelled. The instruments used to derive the summary measure of benefit appear to have been appropriate. The choice of the measure was also appropriate since it permits the results of this study to be compared with those from other interventions.

**Validity of estimate of costs**
The perspective adopted, as stated by the authors, was societal. However, the indirect costs (e.g. productivity losses, informal care) were not reported, and no justification for their exclusion was provided. It is worth pointing out that, given the type of baseline patient considered at analysis (institutionalised 72-year-old man), the exclusion of the indirect costs may be implicitly justified. The costs of malpractice were not considered because of their unknown incidence. All the other relevant direct costs appear to have been considered in the economic analysis. Appropriate sensitivity analyses were performed to assess the uncertainty surrounding the study results. The resource quantities and the costs were not reported separately, thus it would be difficult to perform reflation exercises in other settings.

**Other issues**
The authors compared their findings with those reported by other studies, showing that the costs of standard care and healing rates did not differ significantly. As the authors reported, the study focused on institutionalised patients and the results obtained may not be generalisable to those patients treated in their homes.

**Implications of the study**
The authors recommended further research (i.e. both well-controlled, blinded, "head-to-head" clinical trials and studies in a non-research protocol setting) to document the impact of NNWT on improving health-related quality of life, reducing infection rates, reducing pain, and reducing the need for mechanical debridement.

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**Bibliographic details**

**Other publications of related interest**

**Indexing Status**
Subject indexing assigned by CRD

**MeSH**
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