Cost-effective faster wound healing with a sustained silver-releasing foam dressing in delayed healing leg ulcers: a health-economic analysis

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 compared four treatment protocols for venous leg ulcers.

Protocol A used Contreet Foam (manufactured by Coloplast A/S), a new sustained silver-releasing wound contact dressing, for up to 4 weeks.

Protocol B used Aquacel Ag as a wound contact dressing and Combiderm-N as an absorbent dressing (both manufactured by Convatec) for up to 4 weeks.

Protocol C used Actisorb Plus as a wound contact dressing and Tielle Plus Borderless as an absorbent dressing (both manufactured by Johnson & Johnson) for up to 4 weeks.

Protocol D used Iodoflex as a wound contact dressing and N-A Dressing as an absorbent dressing (both manufactured by Smith & Nephew).

In all protocols, compression therapy was provided using short stretch bandages (size 10 cm x 5 cm) (Comprilan; Beiersdorf, AG) over the dressing, which were reused ten times. Compression therapy was also provided using a four-layer bandage (Profore; Smith & Nephew). It was reported that all wound infections were treated with 500 mg amoxicillin, administered three times a day for 10 days.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
As this was a modelling study, the target population comprised a hypothetical cohort of patients with delayed healing venous leg ulcers. No further inclusion or exclusion criteria were reported.

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

Dates to which data relate
The effectiveness data were derived from studies published between 1991 and 2005. The cost data were derived from official sources published in 2003 and 2004. The price year was not explicitly reported.

Source of effectiveness data
NHS Economic Evaluation Database (NHS EED)
Produced by the Centre for Reviews and Dissemination
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The effectiveness data were derived from completed studies, augmented by experts' opinions.

**Modelling**
The authors initially constructed a decision analytic model to assess the costs and the effectiveness, in terms of wound area reduction, of the four treatment protocols. The model had a 4-week time horizon. The authors also constructed a Markov model to estimate the costs and effects of each treatment protocol in the complete healing of patients. The health states in the model were healed and unhealed, and the duration of each cycle was one week. Transition probabilities were based on the weekly probability of complete healing of each treatment protocol. The time horizon of the Markov model was 26 weeks (6 months). Complete healing data for treatment protocol B were not available, thus the protocol was not included in the Markov model.

The models were based on the assumption that a trained nurse performed all dressing changes in the patient's home. All patients were assumed to receive an initial wound assessment from a district nurse. In addition, the debridement used was assumed to be autolytical and, therefore, did not require extra resources.

**Outcomes assessed in the review**
The parameters derived from the literature for use in the models were the reduction in wound size after 4 weeks, the weekly healing rate and the frequency of dressing changes. All three parameters were estimated for each treatment protocol. In addition, the weekly healing rate and the dressing change frequency of the four-layer bandage system were used, as well as the weekly risk of infection.

**Study designs and other criteria for inclusion in the review**
The authors did not report any criteria pertaining to study design. Comparative multi-centre randomised controlled trials, non comparative multi-centre prospective studies and open multi-centre non-randomised studies were included in the review. The included studies involved a minimum of 15 patients with venous leg ulcers. The authors favoured studies where the wounds were described as critically colonised or delayed in healing. Studies where the dressing change frequency was based on pre-set time intervals were excluded from the review.

**Sources searched to identify primary studies**
MEDLINE, CINAHL and EMBASE were searched for studies published from 1966 to 2003. The database search was complemented by hand searches.

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

**Methods used to judge relevance and validity, and for extracting data**
The authors used the opinion of an expert panel of four wound experts to assess the validity of estimates used in the model. No specific methods were reported.

**Number of primary studies included**
Seven primary studies provided the effectiveness data.

**Methods of combining primary studies**
In relation to the parameters of the model, the results from individual studies were combined and the authors used the mean value.
Investigation of differences between primary studies
The authors seem to have investigated differences between the primary studies, but no statistical tests of homogeneity were performed.

Results of the review
With treatment protocol A, the reduction in wound size after 4 weeks was 50.2% and the dressing change frequency was 2.19 per week.

With treatment protocol B, the reduction in wound size after 4 weeks was 23.9% and the dressing change frequency was 1.9 per week.

With treatment protocol C, the reduction in wound size after 4 weeks was 44.63% and the dressing change frequency was 3.6 per week.

With treatment protocol D, the reduction in wound size after 4 weeks was 36% and the dressing change frequency was 2.7 per week.

The weekly risk of infection was 2.3%.

Methods used to derive estimates of effectiveness
Owing to a lack of data in the literature, some estimates of effectiveness were based on expert opinion.

Estimates of effectiveness and key assumptions
It was assumed that 28% of the patients would not be healed within the first year of treatment, and that healing would be delayed in one third of the patients because of the presence of bacteria. In terms of health care resources, it was assumed that the initial wound assessment would take 30 minutes of nursing time and a typical dressing change wound need 40 minutes of nursing time.

Measure of benefits used in the economic analysis
The measures of benefit used were the reduction in wound area and the percentage of patients completely healed. These were derived directly from the model.

Direct costs
The direct costs included in the analysis were for the initial wound assessment (including nursing time), dressing changes, and systemic antibiotics used for treating wound infections. The costs of changing dressings covered the nurse's time and transportation time, wound cleansing and autolytical debridement, dressing materials and ancillary supplies. The costs and the quantities were reported separately. The costs were derived from official published sources, while the quantities of resources used were derived from the model. Discounting was not relevant as the costs were incurred during a short time. The price year was not reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
Although the authors stated that a societal perspective was adopted in the economic analysis, the indirect costs were not included.
Sensitivity analysis
A one-way sensitivity analysis was performed to test the variability in the estimates used. All input parameters for the model were varied by +/- 20%. The use of a gauze dressing (Mesorb; Molnycke Healthcare, AB) as an absorbent dressing, in place of Tielle Plus Borderless in protocol C, was also tested.

Estimated benefits used in the economic analysis
The mean relative reduction in wound area after 4 weeks of treatment was 50.2% for treatment protocol A, 23.9% for treatment protocol B, 44.6% for treatment protocol C and 36.0% for treatment protocol D.

The Markov model demonstrated that the proportion of healed wounds after a 6-month period would be 81.9% in protocol A, 81.9% in protocol B, 84.6% in protocol C and 75.7% in protocol D.

Cost results
The costs were reported per patient and per week of treatment.

The cost per week of treatment was 111.13 for protocol A, 96.86 for protocol B, 176.42 for protocol C and 140.15 for protocol D.

Synthesis of costs and benefits
The cost per percentage reduction in wound area after 4 weeks of treatment was 9.51 for protocol A, 17.58 for protocol B, 16.54 for protocol C and 16.48 for protocol D.

The cost per completely healed wound was 1,521 for protocol A, 1,892 for protocol C and 2,276 for protocol D.

The sensitivity analysis demonstrated the robustness of the results to variation in the data.

Authors’ conclusions
The analysis demonstrated that treatment protocol A was the most cost-effective option.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was explicitly justified. Contreet Foam is a new treatment option that was compared with the other three most commonly used treatment options in the authors’ setting. You should decide if this represents a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
It was unclear whether the review was conducted in a systematic way to identify relevant literature and minimise bias. Although this is common practice with models, it does not ensure that the best available data are used in the model. Some estimates of effectiveness from the available studies were combined and the mean value was used. However, it was unclear if the authors investigated differences between the available studies when estimating effectiveness. Some estimates of effectiveness were derived on the basis of expert opinion, although it was not reported how the members of the expert panel where chosen, or the specific methods they used to derive effectiveness estimates.

Validity of estimate of measure of benefit
The percentage reduction in wound area and percentage of patients completed healed were used the measures of benefit
in the effectiveness analysis. These were derived directly from the model.

**Validity of estimate of costs**

Although a societal perspective was adopted in the economic analysis, the indirect costs were not included. However, for direct health care costs, the costs and the quantities of resources used were reported separately, thus enhancing the reproducibility of the results to other settings. Some quantities of resources used were based on expert opinion and a sensitivity analysis was performed to ensure the robustness of the results. The costs were derived from official published sources and a sensitivity analysis was performed to assess the robustness of the estimates used. However, the price year was not explicitly reported, which may limit any future reflation exercises.

**Other issues**

The authors compared the results of their study with those of previous studies and reported consistency in the results. The issue of generalisability of the results to other settings was not directly addressed. The authors do not appear to have presented their results selectively. The study enrolled patients with critically colonised venous leg ulcers and this was reflected in the authors' conclusions. The authors reported as a limitation to their study that treatment protocol B could not be assessed for complete healing due to a lack of available data.

**Implications of the study**

The authors did not make any explicit recommendations for changes in policy or practice, or where further research is concerned. However, their discussion highlighted some areas where more information is needed.

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