Cost effectiveness of using carboxymethylcellulose dressing compared with gauze in the management of exuding venous leg ulcers in Germany and the USA

Guest J F, Ruiz F J, Mihai A, Lehman A

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 a carboxymethylcellulose dressing (CMCD) for the treatment of exuding venous leg ulcers. CMCD is a hydrocolloid, composed entirely of sodium carboxymethylcellulose, and is an example of a moisture-retentive modern dressing.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of patients with exuding venous leg ulcers.

Setting
The setting was a hospital. The economic study was carried out in Germany and in the USA.

Dates to which data relate
The effectiveness data were derived from studies published between 1988 and 2001. No dates for resource consumption were reported. The costs referred to 2002/03 prices.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of published studies.

Modelling
A decision tree model was constructed to assess the clinical and economic impact of the two dressings for the treatment of a hypothetical cohort of patients with exuding venous leg ulcers. Two equivalent models were used for the two countries, but with different probabilities associated with resource use. The time horizon of the model was 18 weeks. Patients receiving a CMCD or gauze could heal or not heal at 6 weeks. Those healed could remain healed or experience a recurrence, thus requiring new dressings, and at 18 weeks they could heal or not heal. Patients not healing at 6 weeks could further heal or not at 12 weeks. Subsequently, they could remain healed or experience a recurrence (requiring new dressings). Unhealed patients at 12 weeks could be healed or not at 18 weeks. The structure of the decision tree and the probability of healing and recurrence were reported.

Outcomes assessed in the review
The outcomes estimated from the literature were the healing rates and recurrence rate with a CMCD or gauze.

**Study designs and other criteria for inclusion in the review**
A systematic review of the literature was undertaken to identify primary studies on venous leg ulcers. The search strategy was limited to studies in which the primary research question focused on the role of the wound contact dressing in wound management. Thus, studies on delivery of compression were excluded. Only English-language studies were considered. The number of patients included in each study (from a minimum of 14 to a maximum of 67) and the duration of follow-up (6 or 12 weeks) were reported.

**Sources searched to identify primary studies**
MEDLINE, EMBASE, HealthSTAR, Current Contents, NHS EED and Cochrane databases were searched for relevant studies. A manual literature search was also undertaken, based on citations in the published papers.

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

**Methods used to judge relevance and validity, and for extracting data**
Not reported.

**Number of primary studies included**
Nine primary studies provided the data.

**Methods of combining primary studies**
Primary data (with same follow-up periods) were pooled into single estimates based on weighted averages.

**Investigation of differences between primary studies**
Not reported.

**Results of the review**
The healing rate at 6 weeks was 19% with the CMCD and 14% with gauze.

The healing rate at 12 weeks was 26% with the CMCD and 14% with gauze.

The probability of recurrence was 0.10, regardless of the treatment.

**Measure of benefits used in the economic analysis**
The summary benefit measure used was the overall healing rate at 18 weeks. This was estimated using the decision model.

**Direct costs**
The analysis of the costs was carried out from the perspective of the health care payer. It included the costs associated with dressing, nurse and physician visits, diagnostic tests and hospital stay. A breakdown of the cost items was provided, and there was extensive information on resource consumption and unit costs. Resource use was derived from interviews with a randomly selected sample of German (n=10) and American (n=10) clinicians with experience in venous leg ulcers. The costs came from Medicare reimbursement rates for US data and from official national sources for German
data. The German model assumed that everyone was funded by the sickness funds and an RMB surcharge of 21% was applied to pharmacy-dispensed items. Discounting was not relevant as the costs were incurred during a very short timeframe. The costs were estimated using 2002/03 prices.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
Euros (EUR) and US dollars ($).

**Sensitivity analysis**
A probabilistic sensitivity analysis was carried out by means of a Monte Carlo simulation (1,000 iterations of the model), which simultaneously varied all the clinical probabilities and resource use values. Clinical probabilities were varied according to a beta distribution between the published confidence interval, while economic inputs were varied according to a log normal distribution by assuming a 100% standard deviation around the mean. Univariate sensitivity analyses and threshold analyses were also carried out by varying the most relevant model inputs (both clinical and resource use parameters).

**Estimated benefits used in the economic analysis**
The overall healing rate at 18 weeks was 30% with the CMCD and 13% with gauze, (p=0.003).

**Cost results**
In Germany, the total costs per patient were EUR 2,020.33 with the CMCD and EUR 2,654.02 with gauze.

In the USA, the total costs per patient were $3,796.83 with the CMCD and $5,288.03 with gauze.

**Synthesis of costs and benefits**
An incremental analysis was carried out to combine the costs and benefits of the alternative strategies. However, an incremental cost-effectiveness ratio was not calculated since the CMCD dominated the gauze strategy, which was both less effective and more expensive.

The probabilistic analysis showed that dominance was expected in 49% of simulations in the German model and in 42% of simulations in the US model.

The analysis also highlighted that, in the German model, the inputs with the greatest impact on the cost-effectiveness results were the probability of remaining unhealed at 18 weeks, the frequency of dressing changes, and hospitalisation and use of drugs among CMCD-treated and gauze-treated patients who remained unhealed at 18 weeks.

The US model was most sensitive to hospitalisation and use of drugs and compression amongst CMCD-treated and gauze-treated patients who remained unhealed at 18 weeks.

The univariate sensitivity and threshold analyses showed that wide variations in the base-case values were required for the results of the base-case to change substantially.
Authors’ conclusions
The carboxymethylcellulose dressing (CMCD) was a cost-effective alternative to gauze in the treatment of exuding venous leg ulcers, as it improved healing rate and reduced health care costs both in Germany and the USA. The authors pointed out that the results were slightly sensitive to the frequency of dressing changes.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear in that the new dressing was compared with standard care in patients with exuding venous leg ulcers. The authors noted that gauze is currently the most widely used choice of wound dressing both in Germany and in the USA. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a synthesis of published studies. The authors reported some information on the method and conduct of a systematic review of the literature. Search methods were described and details of the number of patients and follow-up of the selected primary studies were given. However, there was no information on the type of studies included and it was unclear whether the studies actually included were clinical trials or observational studies. The primary estimates were combined using weighted averages but it was unclear whether the issue of heterogeneity among the primary studies had been addressed. The uncertainty surrounding the clinical estimates was extensively investigated in the sensitivity analysis.

Validity of estimate of measure of benefit
The summary benefit measure was specific to the disease considered in the study. It will not be comparable with the benefits of other health care interventions. The impact of the treatments on quality of life was not investigated, although this could have been relevant given the nature of the disease. However, it is likely that the inclusion of quality of life would have provided results even more favourable to CMCD, thus the analysis should be considered as conservative with respect to the new dressing method.

Validity of estimate of costs
The analysis of the costs was consistent with the perspective chosen for the study. Information on the unit costs and quantities of resources used was extensive and will help in replicating the analysis in other settings. The sources of the data were explicitly reported for all items and reflected the viewpoint of the payer in the two countries. The cost estimates were specific to the study setting, but key quantities of resources used were varied in the sensitivity analysis. The price year was given, thus enhancing the possibility of reflating the costs in different time periods. Statistical analyses of the costs were carried out in the sensitivity analysis. Resource consumption was derived from an expert panel, thus treatment patterns reflected a real-world setting. Differences between the two countries in the consumption of specific resources were observed.

Other issues
The authors stated that their study was the first to assess the cost-effectiveness of the CMCD, although results from published studies have shown other modern dressings to be more cost-effective than gauze. The issue of the generalisability of the study results to other settings was not addressed, but extensive sensitivity analyses were carried out to enhance the external validity of the analysis. The authors acknowledged some potential limitations of their analysis. First, owing to the lack of prospectively collected data, the study relied on expert opinion to assess treatment patterns. Second, the healing rates were based on pooled data from different studies since a head-to-head comparative study was not available. Third, all the studies on clinical effectiveness were carried out in Sweden or the UK, thus no data from Germany or the USA were found in the literature. Fourth, the time horizon of the model was restricted to 18 weeks, even though the treatment of leg ulcers generally requires a long timeframe; published studies had a short follow-up, and the extrapolation to a long time horizon would have required a number of untested assumptions.

Implications of the study
The study results suggest that the CMCD should replace gauze in the treatment of exuding venous leg ulcers. However, the authors stated that a decision between using CMCD and other modern wound dressings cannot be made on the basis of the results of this study.

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**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
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