Cost and dressing evaluation of hydrofiber and alginate dressings in the management of community-based patients with chronic leg ulceration

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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 hydrocolloid fibre dressings (hydrofiber; Aquacel, ConvaTec Ltd., UK) in the treatment of patients with chronic leg ulceration. There were two sizes of dressing, 5 x 5 cm and 10 x 10 cm.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with moderately to heavily exuding leg ulcers. Patients with a history of poor compliance with medical treatment, and/or wounds too large for the sizes of dressing available, and/or dry eschar on the wound were excluded.

Setting
The setting was not explicitly stated, although it is likely to have been primary care. The study was performed in the UK.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported. The unit prices related to 1999 and 2000. The price year was 2000.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
Resource use was obtained from the same sample population as that used in the effectiveness analysis. The resource use data may have been collected prospectively.

Study sample
In the planning phase of the study, it was estimated that a sample size of 90 patients would be required to give 80% power to show a mean difference of one day in the wear time between the treatment groups. Patients with moderately to heavily exuding leg ulcers who met the inclusion criteria, and who had not been studied before, were included in the effectiveness analysis. Patients were excluded if their wound became infected and needed topical antimicrobial
treatment. In total, 131 patients were included. Of these, 66 received the hydrofiber dressing and 65 the alginate dressing. The study sample was not shown to be representative of the study population, although the authors stated that it reflected the types of chronic leg ulcers treated in the community.

Study design
This was an open, randomised, multi-centred controlled study (patients from four centres were included). Therefore, the method used to assess the outcomes was not blinded. The patients were followed up until the wounds healed or for a maximum of 12 weeks. The number of patients lost to follow-up was not reported.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The health outcomes assessed for the intervention and the control groups were:

- the number of patients who achieved healing and the mean time to healing;
- the percentage reduction in the ulcer area;
- the mean dressing wear time;
- the performance of the dressing in terms of overall ease of application and removal, overall ability to contain exudate, adhesion to the wound, and pain.

Generally, the investigators and patients assessed the performance of the dressing using a four-point scale, ranging from "poor" to "excellent". The exception was the ability to contain exudates, which only the investigators assessed. Compared with the hydrofiber group, the alginate group contained more women, older patients, a higher percentage of arterial ulcers and a lower percentage of venous ulcers. The number of diabetic patients was the same in both groups.

Effectiveness results
The only significant clinical difference between the hydrofiber and alginate groups was found in the mean dressing wearing time. The mean wear times were 3.632 days (hydrofiber) and 3.271 days (alginate), respectively. The mean difference was 0.362 days (95% confidence interval, CI: 0.195, 0.529; p<0.001).

No significant differences were found in the number of patients who achieved healing, or the reduction in ulcer area. For those patients who achieved healing, the mean difference in time to healing was 14.767 days (95% CI: -29.74, 0.212) in favour of the hydrofiber group. This difference almost reached statistical significance, (p=0.053).

The hydrofiber dressing performed better in terms of:

- ease of application, with 76% of individuals reporting excellent versus 55% in the alginate group, (p=0.03);
- ease of removal, with 51% of individuals reporting excellent versus 24% in the alginate group, (p=0.006);
- the ability to contain exudates, with 44% of the dressing changes reported to be excellent versus 20% in the alginate group, (p=0.002);
- adhesion to the wound, with 74% of dressing changes reported to be excellent versus 74% in the alginate group, (p<0.001); and
- pain, with 82% of hydrofiber patients reporting no pain versus 62% in the alginate group, (p<0.001).

Clinical conclusions
There were no significant differences between the hydrofiber and the alginate dressings in terms of the number of

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patients healed or the reduction in ulcer area. However, the hydrofiber dressing was shown to have longer wearing times and better performance in terms of ease of application and removal, ability to contain exudates, adhesion to the wound, and pain.

**Measure of benefits used in the economic analysis**
The summary measures of benefits used were:

the number of patients who achieved healing,

the total reduction in ulcer area (in mm²) between baseline and final wound area assessment, and

the total percentage point reduction in ulcer area between baseline and final wound area assessment.

The last two measures were used as measures of partial success because, as the authors stated, not all patients can achieve healing. These measures of benefit were obtained directly from the effectiveness analysis.

**Direct costs**
Although the unit prices used to estimate the costs were reported, the resource quantities consumed were not given. The direct costs considered in the economic analysis were those of the hospital. These included the costs of materials used at each dressing change and those associated with nursing staff. The costs were estimated from actual data. The unit prices were obtained from the May 2000 Tariff prices and a published study. The price year was 2000. Discounting was not performed, which was appropriate as the follow-up period was very short (i.e. 2 weeks). The costs reported were the total costs per group.

**Statistical analysis of costs**
No statistical analyses of the costs were performed.

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

**Currency**
UK pounds sterling (£) and US dollars ($). The exchange rate was 1 = $1.44.

**Sensitivity analysis**
No sensitivity analyses were performed.

**Estimated benefits used in the economic analysis**
In both the intervention and control groups, 17 patients achieved healing of the ulcers.

The total reduction in ulcer area between baseline and final wound area assessment was 28,427.36 mm² among patients treated with the hydrofiber dressing versus 20,837.84 mm² among those treated with the alginate dressing.

The total percentage point reduction in ulcer area between baseline and final wound area assessment was 2,100.28 for the hydrofiber group versus 1,832.56 for the alginate group.

**Cost results**
The total costs were 20,129.52 (£28,897.93) for the hydrofiber group versus 20,412.40 (£29,304.45) for the alginate group.
Synthesis of costs and benefits
The estimated costs and benefits were combined through cost-effectiveness ratios.

The average cost per patient achieving ulcer healing was 1,184.09 ($1,699.71) when treated with the hydrofiber dressing versus 1,200.73 ($1,723.59) when treated with the alginate dressing (i.e. the alginate group was 1% less cost-effective in these terms).

The average cost per 1-cm² reduction in ulcer size was 59.22 ($85.01) for the hydrofiber group versus 92.27 ($132.46) for the alginate group (i.e. the alginate group was 36% less cost-effective in these terms).

The average cost per 10-percentage point reduction in ulcer size was 80.15 ($115.06) for the hydrofiber group versus 104.92 ($150.62) for the alginate group (i.e. the alginate group was 24% less cost-effective in these terms).

Authors’ conclusions
Although no differences were found between the dressings in terms of their ability to heal more wounds, the hydrofiber dressing presented advantages in terms of dressing performance, dressing wear time and cost-effectiveness.

CRD COMMENTARY - Selection of comparators
The alginate dressing was chosen because, as the authors stated, it is a popular type of dressing material for wounds. However, other dressing materials could have been chosen for this study, such as film, hydrogel or foam. You must decide which dressing is the most commonly used to treat chronic leg ulceration in your own setting.

Validity of estimate of measure of effectiveness
A randomised controlled study was performed. The patients were randomly allocated using sealed envelopes. This may have been appropriate, but it did not guarantee an equal distribution of patients according to their gender and wound etiology. Since this was an open study, some results may have been biased as neither doctors or patients were blinded to the outcome assessment. The outcome used in the sample size calculations (i.e. dressing wear time) may not have been the most appropriate since it does not reflect direct health results on patients, but only the performance of the dressings. As the authors acknowledged, it may be of limited clinical relevance. The follow-up period was rather short and may have influenced the results obtained, as some ulcers require longer times for healing. The fact that patients from four different centres were included in the clinical analysis may have increased the likelihood of the study sample being representative of the study population.

Validity of estimate of measure of benefit
The estimation of benefits was obtained directly from the effectiveness analysis. The authors justified the measures used at analysis in that they reflected either the total or partial success of treatment in patients with ulceration. However, one of the measures, the percentage point reduction in wound area, may not be appropriate since one percentage point reduction could refer to different wound areas, depending on the initial area of the wound. Other measures of benefits, such as quality-adjusted life-years gained, would have been preferred. These would also have allowed the authors’ results to be compared with those of different interventions (although the short study period considered at analysis would have limited the estimation of such types of measures).

Validity of estimate of costs
The perspective adopted (the hospital) was rather limited, although all the relevant costs associated with it appear to have been included. Nevertheless, a broader perspective (i.e. social) would have been more appropriate to account for social costs such as the time the patients required to attend the dressing changes. The resource quantities used were not reported. The price year was reported. Discounting was, appropriately, not performed since the follow-up period was shorter than 2 years. Prices rather than costs were used in the cost estimation, which may reflect the true opportunity costs of the dressings under analysis if the hospital considered at analysis was private. The interpretation of the study
findings may be limited, as statistical or sensitivity analyses were not performed to address uncertainty in the results.

**Other issues**
No appropriate comparisons with other studies were reported, although the authors commented that no other studies had been able to show any difference in the effectiveness of the wound dressings used to treat patients with chronic wounds. Since the patients included in the study sample may reflect the type of chronic ulcers treated in the community, the results may be generalisable to similar settings.

**Implications of the study**
The authors suggested that the use of the hydrofiber dressing would be beneficial to the overall management of patients with chronic leg ulceration in the community setting.

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Supported by ConvaTec, a Bristol-Myers Squibb Company.

**Bibliographic details**

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by CRD

**MeSH**
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