Use of a fibrous dressing in exuding leg 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 a fibrous dressing in exuding leg ulcers. The dressing maintains a moist, warm environment while absorbing all excess exudate, which is considered in the study to be a major advance in wound management.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Male and female patients with exuding leg ulcers, who were aged over 18 years with an ulcer equal to or less than 7.5cm in any diameter, of any aetiology and producing moderate to heavy amounts of exudate.

Setting
Hospital. The study was set in the UK and France.

Dates to which data relate
Effectiveness, resource use, and cost data were collected over a nine-month period. The price year was 1995.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
21 patients were randomised to the hydrofibre dressing and 23 to the alginate group. Male and female patients were chosen if they met the inclusion criteria (see study population). Subjects were randomised by the use of sealed envelopes opened in numerical order. No power calculations were reported in the determination of sample size.

Study design
The study was a prospective randomised controlled trial carried out at three centres. Patients were followed up for 6 weeks or until healing if sooner. 24% of patients in the hydrofibre group and 30% in the alginate group withdrew from the study.
Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes included the wear time, patient comfort, total wounds healed, and adverse events. At analysis, groups were shown to be comparable in terms of patient age and ulcer diagnosis. However, there was an imbalance in favour of the hydrofibre group in terms of ulcer area and duration.

Effectiveness results
The effectiveness results were as follows:

The difference in mean wear time was 1.029 days (95% CI: 0.385 - 1.672) in favour of the hydrofibre group.

There was a mean decrease in ulcer area of 42% in the hydrofibre group and of 26% in the alginate group.

43% of patients in the hydrofibre group achieved a seven-day wear time on at least one occasion during the study compared with 13% in the alginate group (difference of 30%; 95% CI: 5% - 55%).

No pain was experienced in 76% of dressing removals in the hydrofibre group compared with 83% in the alginate group.

Clinical conclusions
The results suggest that the new hydrofibre dressing has a significantly longer wear time and a reduced frequency of dressing change.

Measure of benefits used in the economic analysis
The number of healed ulcers was used as the measure of benefit.

Direct costs
Direct costs were not discounted due to the short time horizon of the study (less than 1 year). Quantities and costs were not reported separately. Direct costs related to the costs of primary dressings, compression treatment, saline wound cleanser, and nurse time. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Costs were collected from Drug Tariff prices and the manufacturers' costs for the hydrofibre dressing. The price year was 1995.

Indirect Costs
The authors stated that the indirect cost of nursing time (2.03) was used for dressing although it is not clear what this constituted.

Currency
Pound Sterling ( ).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
The number of healed wounds was 6 in the hydrofibre group and 2 in the alginate group.
Cost results
Total costs amounted to 1,425.97 in the hydrofibre group and to 1,374.61 in the alginate group. The cost to heal one ulcer was three times greater for the alginate dressing group.

Synthesis of costs and benefits
Cost to heal one ulcer. This was 1,425.97/6 for the Hydrofibre group, and 1374.61/2 for the Alginate group. This, in incremental cost-effectiveness terms is (1,425.97 - 1,374.61)/(6-2) = 12.84 (derived from the results by the abstractor). The cost to heal one ulcer was therefore, three times greater in the alginate group.

Authors' conclusions
The new hydrofibre dressing may have a significantly longer wear time and reduced frequency of dressing change. There was no difference in costs.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used, namely currently available treatment. You, as a user of the database, should decide if this health technology is relevant to your setting. The choice of comparator was appropriate.

Validity of estimate of measure of benefit
The analysis was based on a prospective, randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. Patient groups were not comparable in terms of some demographic characteristics. No appropriate statistical analyses were conducted to take account of differences between patient groups. Total wounds healed was used as the summary benefit measure, which was appropriate for the economic analysis. The authors acknowledged that some results may have been affected by the imbalance in numbers of patients with heavily exuding wounds.

Validity of estimate of costs
Good features of the cost analysis were that all relevant direct cost categories were included, and the price year was reported. However, no statistical or sensitivity analyses were reported on quantities or costs, quantities and costs were not reported separately, and charges were used to proxy prices. The authors indicated that they included indirect costs (nursing cost per ulcer change) but this may be a direct cost.

Other issues
The authors did not make appropriate comparisons of their findings with those from other studies and did not address the issue of generalisability to other settings. The authors did not, however, present their results selectively. The study considered patients with exuding leg ulcers and this was reflected in the authors' conclusions. More clarification regarding the inclusion of indirect costs would have helped to enhance the validity of the study.

Implications of the study
Confirmation by a clinical trial with larger sample size and healing outcome measures is indicated.

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Bibliographic details
Armstrong S H, Ruckley C V. Use of a fibrous dressing in exuding leg ulcers. Journal of Wound Care 1997; 6(7): 322-324