The effects of cadexomer iodine paste in the treatment of venous leg ulcers compared with hydrocolloid dressing and paraffin gauze dressing

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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
Using cadexomer iodine (Iodosorb) in the treatment of patients with non-infected, venous leg ulcers.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients experiencing an exuding or sloughy venous leg ulcer of 1-100 square cm on the lower leg.

Setting
Hospital. The economic study was carried out in Sweden and Denmark.

Dates to which data relate
The dates corresponding to the collection of the effectiveness and resource use data were not reported. The fiscal year was 1994.

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

Link between effectiveness and cost data
The costing was prospectively performed on a sub-sample (n=38) of the patient sample used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 153 patients randomly allocated to the cadexomer iodine group (n=56) with an average age of 74 years, hydrocolloid group (n=48) with an average age of 74 years, or paraffin gauze group (n=49) with an average age of 72 years.

Study design
Randomized open controlled, multicentre, multinational trial, carried out in Sweden, Denmark, the Netherlands, and the UK. The duration of follow-up was for 12 weeks or until cessation of exudation. The total number of cases of
withdrawals because of reasons unrelated to efficacy was 28 patients (12, 7, and 9 cases in the cadexomer iodine, hydrocolloid, and paraffin gauze groups, respectively). The total number of cases of withdrawals because of reasons related to efficacy (increase in ulcer size, ulcer infection, use of antibiotics due to ulcer infection) was 17 patients (1, 8, and 8 cases in the cadexomer iodine, hydrocolloid, and paraffin gauze groups, respectively). The withdrawals unrelated to efficacy were excluded from the effectiveness analysis, while those related to efficacy were included in the analysis.

Analysis of effectiveness
The principle used in the analysis of effectiveness was treatment completers only since the cases with protocol violation or poor compliance were excluded from the final analysis. The mean reduction in ulcer size in all patients at end-point (cessation of exudation) was the primary clinical outcome assessed in the study. Other clinical outcomes reported were the mean reduction in ulcer size in patients treated for 12 weeks, mean ulcer area reduction per week, and adverse events. The patient groups were comparable in terms of demographic features and ulcer size at inclusion.

Effectiveness results
The cadexomer iodine group had a mean reduction in ulcer size (in all patients at end-point (cessation of exudation)) of 62% versus 41% for the hydrocolloid group and 24% for the paraffin gauze group, (NS). The corresponding values for the mean reduction in ulcer size in the patients treated for 12 weeks were 66% (cadexomer), 18% (hydrocolloid), and 51% (gauze), (the p-value for the difference between the cadexomer iodine group and the hydrocolloid group was 0.0127). The respective figures in terms of the mean ulcer area reduction (cm) per week were 0.64, 0.97, and 0.19, (the p-value for the difference between the cadexomer iodine group and the paraffin gauze group was 0.0353). The corresponding number of adverse events was reported to be 19 (cadexomer), 33 (hydrocolloid), and 26 (gauze).

Clinical conclusions
There was a trend towards better healing of ulcers treated with cadexomer iodine at all time points, although the primary efficacy variable (ulcer area reduction at end-point) was not significantly different between the three groups.

Measure of benefits used in the economic analysis
The benefit measure was the mean reduction in ulcer size.

Direct costs
Costs were not required to be discounted due to the short time frame of the study. Quantities of resource use were reported separately from the costs but only for some of the components. The cost items were reported separately. The cost analysis covered the costs of staff, travelling, and materials. The collection of resource use data was carried out, using specific forms, by the person changing the dressings. The cost analysis was only performed on a sub-sample of study patients (n=38) in Sweden and Denmark. The perspective adopted in the cost analysis was not explicitly specified. The date of the price data was 1994.

Statistical analysis of costs
It is not clear whether a statistical analysis of costs was performed.

Indirect Costs
Indirect costs were not considered since most of the patients were retired.

Currency
Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
The cadexomer iodine group had a mean reduction in ulcer size at end-point of 62% versus 41% for the hydrocolloid group and 24% for the paraffin gauze group, (NS). The corresponding values for the mean reduction in ulcer size in the patients treated for 12 weeks were 66%, 18%, and 51%, respectively, (the p-value for the difference between the cadexomer iodine group and the hydrocolloid group was 0.0127).

Cost results
The mean total weekly cost of the cadexomer iodine group (n=10) was $45.2 (range: 3.21 - 70.5) versus $40.7 (range: 8.1 - 77.9) for the hydrocolloid group and $49.0 (range: 23.7 - 87.0) for the paraffin gauze group.

Synthesis of costs and benefits
When the mean reduction in ulcer size in all patients at end-point (cessation of exudation) was considered as the benefit measure and the total weekly cost as the measure of cost, the alternative health technologies were shown to be equally cost-effective. However, when the mean reduction in ulcer size in the patients treated for 12 weeks was considered as the benefit measure, the cost-effectiveness ratio in terms of cost per percentage ulcer reduction was calculated to be $8.8 for the cadexomer iodine, $32.5 for the hydrocolloid, and $12.9 for the paraffin gauze group, (NS).

Authors' conclusions
The study shows that cadexomer iodine paste is an efficient, cost-effective and safe alternative to hydrocolloid dressing and paraffin gauze dressing for the treatment of venous leg ulcers.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of hydrocolloid dressing as the comparator. It was regarded as the commonly used health technology in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The estimates of benefit measure is likely to be internally valid due to the use of a randomized design, although it is not clear whether the sample size was sufficient to detect differences in the clinical effectiveness of the health technologies. The analysis of effectiveness was based on treatment completers only, while an intention to treat basis may have produced different results.

Validity of estimate of costs
Insufficient details were given of resource use. Adequate details of methods of cost estimation were given. The cost analysis was not performed on all the patients considered in the effectiveness analysis.

Other issues
The issue of generalisability to other settings or countries was not addressed.

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None stated.
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