Cavity foot ulcers in diabetic patients: a comparative study of cadexomer iodine ointment and standard treatment An economic analysis alongside a clinical trial

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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
Cadexomer iodine ointment versus standard treatment (gentamicin solution; streptodornase/streptokinase; dry saline gauze) for diabetic patients with a foot cavity ulcer.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with previously known diabetes mellitus with an exudative foot ulcer (Wagner grade I-II), Caucasian, aged over 40 years, with an ulcer area (maximum length times maximum width) bigger than 1 square cm, and a systolic toe pressure higher than 30 mm Hg or a systolic ankle pressure higher than 80 mm Hg.

Setting
Hospital and community care. The economic study was carried out in Lund, Sweden.

Dates to which data relate
The dates to which the effectiveness analysis and resource use data referred were not reported. 1993 prices were used.

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

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

Study sample
No power calculations were reported. Forty-one patients were originally included in the sample. A total of 22 patients were randomly allocated to the intervention and 19 patients were treated by the standard treatment. All patients were treated by a multidisciplinary foot care team composed of a diabetologist, an orthopaedic surgeon, an orthotist, a podiatrist and a diabetes nurse.

Study design
The study was a Randomized controlled trial, carried out in a single centre. The duration of follow-up was 12 weeks. The wound evaluation was conducted blindly by two independent physicians. The subjects were allocated randomly by stratification according to size and type of ulcer (Wagner grade I-II). The overall loss to follow-up was 12% (5/41); 18% in the intervention group (4/22) and 5% (1/19) in the control group.

**Analysis of effectiveness**

The analysis of effectiveness was based on treatment completers only. The primary health outcomes used were the rate of success (defined as ulcer area reduction by more than 50% or an improvement in Wagner grade), the rate of healing (defined as intact skin), and possible side-effects. Colour photographs with scales, taken during visits to the foot care team, were evaluated at the end of the study. The groups were reported as having "no major differences" in terms of clinical characteristics (no statistical analysis reported).

**Effectiveness results**

The authors reported "no major differences" between the two groups in outcome measures at the end of the study period. The rates of healing during the observation time were 22.7% (5/17) and 10.5% (2/18) for the intervention and comparator, respectively. The rates of success were 54.5% and 68.4%, respectively. The p values of differences were not reported. It was reported that "no adverse reactions related to the topical treatment were documented".

**Clinical conclusions**

No major differences in clinical results regarding size and type of ulcer could be seen between the two treatment groups in this study.

**Measure of benefits used in the economic analysis**

No summary benefit measure was identified in the economic study, and only separate clinical outcomes were reported.

**Direct costs**

Quantities were reported separately. The operating costs (material and drugs, staff and transportation) and cost of complications were measured. The cost calculations were performed from a societal perspective. The estimation of quantities and unit costs was based on actual data (only average travel distance was assumed). The source of quantities was the study records. The dates during which the quantities were measured were not reported. The sources of unit costs and prices of drugs and materials were FASS and market prices (for drugs and materials) and average wages for 1991 (for nursing staff), adjusted to 1993 prices. The price date was 1993. The costs of outpatient visits, which were thought not to differ in frequency between treatment options, were excluded.

**Statistical analysis of costs**

The Mann-Whitney U-test (two-tailed) was used to compare the groups in terms of costs.

**Indirect costs**

Not included.

**Currency**

Swedish Kroner (SEK). A conversion to US dollars was performed using a 1993 exchange rate of US$1 = SEK8.10.

**Sensitivity analysis**

The parameters used in the analysis were costs for travelling expenses, type of staff performing the dressing, the ability of patients to change their ulcer dressings without help from the health care staff and strict compliance with physicians’
prescriptions. Also, one (originally excluded) hospitalisation was included in the analysis and the corresponding results were compared.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The total weekly cost of the intervention was SEK903 (range: SEK524 - SEK1,697). The total weekly cost of standard treatment was SEK1,421 (range: SEK428 - SEK2,679) (p<0.001).

**Synthesis of costs and benefits**
Although asynthesis of costs and benefits was not required due to the intervention being a (weakly) dominant strategy, the weekly cost per patient healed was calculated: SEK3,070 for the intervention and SEK12,790 for the comparator.

**Authors' conclusions**
"Cadexomer iodine ointment is a cost effective and useful addition in the treatment of exuding cavity ulcers in diabetic patients compared with standard treatment, including topical antibiotics."

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of the comparator is clear.

**Validity of estimate of measure of benefit**
The internal validity of the clinical results may be weakened by the small sample size (no power calculations were reported), a short follow-up period, and the fact that the analysis of effectiveness was based on treatment completers only.

**Validity of estimate of costs**
Resource use was reported separately from the prices. Adequate details of methods of cost estimation were given.

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

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