Evaluation of a diabetic foot screening and protection programme
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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
Clinical foot-screening and protection programme for people at high risk of diabetic foot complications.

Type of intervention
Screening and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients suffering from diabetes mellitus.

Setting
Hospital diabetic clinic and the community. The economic study was conducted in the UK.

Dates to which data relate
Effectiveness and resource data were collected between 1989 and 1993. Cost data refer to constant 1991-1992 prices.

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

Link between effectiveness and cost data
Costing was undertaken retrospectively, but it was not clear whether costs referred to the same patient sample as that used in the effectiveness study. (Note: subsequent correspondence with the authors has established that costing was, in fact, undertaken on the same patient sample).

Study sample
There was no evidence of the use of power calculations to determine sample size. 2,001 diabetic patients attending an out-patient clinic were randomly allocated either to the intervention (1,001 patients) or the control group (1,000 patients). Only 4 patients with active ulcers were directly allocated to the intervention group. Patients at high risk of ulceration in the index group were determined according to the results of a primary screening examination using Semmes-Weinstein monofilaments, the biothesiometer, and palpation of pedal pulses and a further secondary screening examination consisting of the same test plus calculation of ankle-brachial index, subcutaneous oxygen levels and foot pressure. 127 patients with foot deformities, or a history of foot ulceration, or an ankle-brachial index \( \leq 0.75 \) were classified as at high risk of ulceration and were entered in the protection programme.
Study design
This was a single centre randomised controlled trial, with a two-year follow up period. The number of reported non-compliant patients with follow up appointments was 531 in the control group and 323 in the intervention group. Effectiveness data from these patients depended on hospital patient records.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary clinical outcomes used in the analysis were reductions in the incidence of ulcers and lower limb major and minor amputations. Information regarding process outcomes, (compliance with screening, and the use of chiropody services and prescribed foot wear) were also collected. No information regarding the comparability of the intervention and control groups was provided. The authors did not describe the randomisation process.

Effectiveness results
The difference (11) in the number of ulcers in the intervention (24, excluding the 4 active initial ulcers) and in the control (35) groups was not statistically significant, (p>0.14). Conversely, the difference in the total number of amputations in the intervention (7, 1 major and 6 minor) and control (23, 12 major and 13 minor) groups was statistically significant, (p<0.04), as was the difference in major amputations, (p<0.01). The difference in minor amputation was not statistically significant, (p>0.15). 33 patients (3.3%) did not complete the full screening programme. No statistically significant difference in the use of chiropody services was found, (p>0.25). Inconclusive results were reported concerning the use of protective footwear.

Clinical conclusions
The clinical foot screening programme was effective in reducing cases of ulceration and amputation (11 major amputations were prevented).

Measure of benefits used in the economic analysis
Benefit was measured in terms of the number of major amputations averted.

Direct costs
Costs and quantities were not reported separately. Costs were estimated making use of information provided by the hospital’s finance office. The cost of major amputation and the fitting of artificial limbs was retrieved from a study published in 1987, and adjusted for changes in costs using the Health Service Cost Index. The following direct cost categories were included in the analysis: labour, state, capital equipment, disposables, transport and administration. The total costs of the foot clinic over the second year of follow-up were discounted at a 6% rate.

Statistical analysis of costs
Cost were not treated stochastically.

Indirect Costs
Not stated.

Currency
UK pounds sterling (£).

Sensitivity analysis
No sensitivity analysis was performed on any of the variables.
Estimated benefits used in the economic analysis
11 major amputations were prevented.

Cost results
The total cost of the screening and foot clinic programme was 100,372. The cost of amputation and the fitting of artificial limbs was estimated in 1985-86 at 8,500, which, when adjusted for changes in costs, translates to 12,084 in 1991-92 prices.

Synthesis of costs and benefits
A mean cost per amputation averted of 9,125, was estimated. Comparing this cost to the 12,084 cost of a major amputation and the fitting of artificial limbs, cost savings of approximately 3,000 per patient were estimated.

Authors’ conclusions
Estimated cost savings of a little less than 3,000 per amputation averted were estimated. Based on this finding the authors concluded that the programme could be considered cost-effective in terms of major amputations averted alone.

CRD COMMENTARY - Selection of comparators
The comparator was usual practice in the authors’ setting.

Validity of estimate of measure of benefit
As the authors clearly indicated, the use of hospital patient records is an unreliable method of obtaining information about patients who did not attend follow-up visits. Primary health outcomes estimators should be treated with some caution, and, as the authors suggested, the benefits of the programme might have been underestimated.

Validity of estimate of costs
The estimation of potential cost savings was not transparent. The rationale behind the comparison of the total cost of the screening programme with the total cost of a major amputation and fitting of artificial limbs, obtained from another study, was not fully justified. Furthermore, no statistical or sensitivity analysis of costs was performed.

Other issues
The authors pointed out a few protocol violations which could have had a direct impact on primary outcomes. The effect of bias on the results should be further investigated. The authors did not discuss the generalisability of the study findings to other settings or countries and no comparison with other studies was made.

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