Cost effectiveness of community leg ulcer clinics: randomised controlled trial

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
Clinic-based weekly treatment of leg ulcers with four layer bandaging or usual home-based care by district nurses.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had had a venous ulcer below the knee to the foot for at least 3 months and who were able to travel to the clinic.

Setting
Community and primary care. The economic study was carried out in Sheffield, UK.

Dates to which data relate
The effectiveness data and resources use data were gathered between September 1994 and May 1995. 1995 prices were used.

Source of effectiveness data
The evidence for the final outcomes was 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 study.

Study sample
Power calculations were used to determine the sample size. A total of 328 subjects attended for assessment, of whom 233 were randomly assigned: 113 to the home group and 120 to the clinic group. Patients (93) from the original 328 with an ankle brachial pressure index of <0.8 were excluded from the clinic group and returned to home care. Two patients refused to participate and were returned to home care.

Study design
The study was a randomised controlled trial carried out in eight centres (Sheffield, Nottingham, Derby and Sutton-in-Ashfield). The duration of the follow-up was 1 year and the drop out rates were 14.2% for the clinic and 20.3% for the
home group. A random assignment schedule and serially numbered, sealed, opaque allocation envelopes were prepared in advance for each of the eight clinic sites.

Analysis of effectiveness
The analysis of the effectiveness study was based on intention to treat. The primary health outcomes were the initial healing time of the ulcers, the cumulative percentage of ulcer healed at 12 weeks, the ulcer recurrence rate from the initial ulcer healed time to first ulcer recurrence, the average ulcer-free time over the 12 month follow-up period, and health status measured by the 36 item short form health survey (SF-36), the EuroQol (EQ), the McGill short form pain questionnaire (SF-MPQ), and the Frenchay activities index. The groups were shown to be comparable in health status and demographic features. The effects of confounding variables such as age, ulcer area, ulcer duration, and history of deep vein involvement on healing times were adjusted using Cox proportional hazards regression analysis.

Effectiveness results
The clinic group had a better record in initial healing times (P= 0.03) and had a higher rate of cumulative percentage of ulcer patients healed at 12 weeks (34% versus 24% in the home group, 95% CI for the difference was -2% to 22%). The patients in the clinic group were 1.45 times more likely to be healed from the initial ulcer (95% CI: 1.04 - 2.03). When adjusted for confounding variables the clinic group were 1.65 times (1.15 to 2.35) more likely to be healed. The clinic group experienced a higher rate of ulcer recurrence after the initial healing (35% versus 23% in the home group). The study revealed no difference in the time to first ulcer recurrence between the groups (log rank test 0.78; df=1; P=0.38). The average ulcer-free time over a one year follow-up period was 20.1 weeks for the clinic group and 14.2 weeks for the home group (95% CI for the difference was 1.2 to 10.5). According to the health status measures, no significant differences between the groups were identified.

Clinical conclusions
The study revealed that the clinic-based treatment using four layer bandaging supplied by specially trained nurses was more effective than the usual home-based care provided by district nurses.

Measure of benefits used in the economic analysis
Ulcer-free time (weeks) was considered by the authors as the most appropriate measure to be included in the economic analysis.

Direct costs
Quantities were reported separately from costs for the home group but not for the clinic group (reported in a separate paper). The average annual total costs were divided into leg ulcer treatment cost per year including staff time, materials, transport, and overheads; the cost of GP services per year; and the cost hospital services per year. The average cost per clinic attendance and per home visit were reported. The cost calculations were undertaken from an NHS point of view. The cost data related to overhead costs were obtained from the service managers. 1995 prices were used. Indirect costs of the patients were not considered.

Statistical analysis of costs
Permutation tests were performed to compare the average costs between the groups.

Indirect Costs
Not included.

Currency
UK pounds Sterling (£).
Sensitivity analysis
A series of one-way sensitivity analyses was carried out on treatment costs and overhead costs to assess the effects of changes in baseline values on the average total costs.

Estimated benefits used in the economic analysis
The average ulcer-free time over a one year follow-up period was 20.1 weeks for the clinic group and 14.2 weeks for the home group (95% CI for the difference was 1.2 to 10.5).

Cost results
The average (SD) total costs for the clinic group were 877.6 (674.3) versus 863.09 (865.32) for the home group.

Synthesis of costs and benefits
A synthesis of costs and benefits was carried out by calculating a cost-effectiveness ratio (additional cost required per additional ulcer-free week). The value of the ratio was 2.46 (-31.94 to 99.12) per ulcer free week. None of the parameters in the sensitivity analysis had significant effects on the average costs of the alternative health technologies. The authors pointed out that, if the grade of the nurses reduced from G or H to E, and if throughput per session increased to more than 10 patients, the clinic-based treatment would dominate the usual home-based care.

Authors’ conclusions
Community-based leg ulcer clinics with specially trained nurses, using four layer bandaging, were more effective than traditional home based treatment. This benefit was achieved at a small additional cost and could be delivered at reduced cost if certain service configurations were used.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear. The comparator was chosen because it represented the routine care provided for patients with venous leg ulcers. You should consider whether this is a widely used technology in your own setting.

Validity of estimate of measure of benefit
The estimates of the measure of benefit are likely to be valid because of randomisation and accounting for the effects of confounding variables. 93 patients were excluded from the trial as they were contraindicated for four layer compression bandages. Additionally, the care provided in the community was not a standard treatment as in the case of the clinic group. These factors may tend to bias the benefit results in favour of the clinic group.

Validity of estimate of costs
The resource quantities were not reported for the clinic-based treatment. As the authors noted, it would have been more appropriate to have included the indirect costs of the alternative health technologies. The exclusion of indirect costs might have biased the results in favour of the home-based treatment. Indirect cost analysis would have permitted the adoption of a societal as well as an NHS perspective.

Other issues
The issue of generalisability to other settings was partially addressed by performing sensitivity analyses on the cost items.

Implications of the study
The findings of the study suggest that for venous leg ulcer clinics (using four-layer compression bandaging) to be a cost-effective option for the NHS, they should only be implemented if they are staffed by appropriately trained nurses in the relevant grades, with an optimal flow of patients.

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