Outcome and cost analysis after femorocrural and femoropedal grafting for critical limb ischaemia

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 primary amputation versus revascularization for treating critical lower limb ischaemia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients fulfilling the European definition of critical lower limb ischaemia.

Setting
Hospital. The economic study was carried out in London, UK.

Dates to which data relate
The effectiveness and resource use data were collected between 1991 and 1994. The price year was not clearly reported.

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 prospectively undertaken on the same patient sample as that used in the effectiveness study.

Study sample
A total of 141 patients was included in the study. Of these, 101 underwent 109 revascularization procedures while a further 43 underwent amputation for rest pain, tissue loss or sepsis (11 after arterial intervention, 32 as a result of primary amputations). No power calculations were reported.

Study design
Nonrandomised trial with concurrent controls from a single centre. The duration of follow-up was 3 years.
Analysis of effectiveness
The principle used in the analysis (intention to treat or treatment completers only) was not clearly stated. The primary health outcomes were survival, knee and limb salvage, and patency rates. Kaplan-Meier methods were used to estimate survival. A list of variables were treated as the independent variables to explain the long-term graft patency in a univariate analysis.

Effectiveness results
The survival rate at three years was 62%, for patients with a functioning graft, 55% for secondary amputees (n=39) and 33% for primary amputees, (p>0.05 for all comparisons, although the primary amputation-patent graft group comparison had a p=0.061). The study revealed that at three years primary patency was 27%, primary assisted patency was 31%, secondary patency was 45%, limb salvage was 54%, and knee salvage was 73%. The univariate analysis demonstrated that the patency rate was dependant on inflow rate (P= 0.0001), availability of venous conduit (P=0.004), number of calf vessels(P= 0.39), the presence of straight flow to the foot (P<0.0001), and the presence of patent pedal vessels (P<0.0001).

Clinical conclusions
The study showed no significant differences between the study groups in terms of primary health outcomes.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis and only separate clinical outcomes were reported.

Direct costs
Some resource use quantities were reported separately from the costs. The cost items were not reported separately from the costs. The costs consisted of those for investigations, radiological procedures, theatre time, anaesthetic time, synthetic grafts, intensive care and in-hospital costs, all based on the NHS service criteria. For the 43 patients on whom an amputation was performed, the cost of the physiotherapy and initial rehabilitation, and the cost of the prosthesis were included. It was not explicitly specified from whose point of view the cost analysis was performed. The outpatient follow-up costs were omitted since they were considered to represent a small fraction of the total hospital costs.

Statistical analysis of costs
The Mann-Whitney U test was used to perform cost comparison.

Indirect Costs
Not considered.

Currency
UK pounds Sterling (€).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.
Cost results
The median total hospital cost by procedure performed was 4,320 for successful revascularization and 17,066 for failed grafts leading to amputation (p<0.001). The corresponding figure for primary amputation was 12,730 (p=0.083 for the comparison with the figure for failed grafts).

Synthesis of costs and benefits
A synthesis was not performed since the intervention was the weakly dominant strategy.

Authors' conclusions
The low cost of revascularization compared with amputation justifies attempted reconstruction. However, repeated attempts to reconstruct patients with severe distal disease who may benefit more from primary amputation will significantly increase the costs.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator is clear. It was the recommended option in most cases. You should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The internal validity of the study results is likely to be questionable because of the absence of randomisation.

Validity of estimate of costs
Some quantities of resource use were reported separately from the costs. Adequate details of methods of cost estimation were not given.

Other issues
Given the lack of randomisation and sensitivity analysis, the results need to be treated with some caution. The issue of generalisability needed to be further discussed. Appropriate comparisons were made with other studies.

Implications of the study
Further studies are needed in order validly to state the cost-effectiveness of revascularization, relative to amputation, as initial treatment option for patients with critical limb ischaemia. Prospective, controlled designs, which control for relevant differences in patient characteristics between groups (some of which can be spotted from the results of this study), would be desirable for that purpose.

Source of funding
None stated.

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