Amputation versus reconstruction in traumatic defects of the leg: outcome and costs

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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
Amputation versus reconstruction in traumatic defects of the leg.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients (between 15 and 45 years at the time of accident) with a grade B or C open fracture of the tibial shaft.

Setting
Hospital. The economic study was carried out in Switzerland.

Dates to which data relate
Effectiveness data were collected between 1978 and 1988. Resource use data were not reported. Cost data were related to the same period as the effectiveness data and covered between 2 to 4 years after amputation or reconstruction. The fiscal year was 1989.

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

Link between effectiveness and cost data
Costing was undertaken retrospectively on some of the patient sample used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. A total of 39 patients with a grade B or C open fracture of the tibial shaft were included in the study sample. The amputation group consisted of 18 patients with below-knee amputation with a median age of 23 year (range: 16 - 43) at the time of accident. The reconstruction group constituted 21 patients having lower leg reconstruction with a median age of 22 years (range: 16 - 37) at the time of accident. Inclusion criteria were age between 15 and 54 years at the time of the accident and minimum follow-up of 2 years. Exclusion criteria included drug addiction, associated injuries limiting rehabilitation beyond 2 years, presence of unrelated diseases and bilateral involvement. A total of 6 patients from the amputation group and 16 from the reconstruction group were excluded from the study sample.
Study design
This was a retrospective cohort study, carried out in a single centre. The minimum follow-up period was 2 years. No loss to follow-up was reported.

Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The main health outcomes used in the analysis were: number of interventions, rehabilitation time, changes in lifestyle (classified in objective changes: walking ability, standing, wearing the prosthesis, quadriceps muscle wasting, range of motion of ankle and knee joint in reconstructed patients and subjective changes: impairment in non-professional life, effects of altered body integrity, importance of past trauma in everyday life, effects on patient’s occupation). The groups were comparable in terms of age, type of accident, and follow-up but not in severity of the initial injury which was greater in the amputation group.

Effectiveness results
The mean number of interventions was 3.5 for amputation and 8 for reconstruction (p<0.009). Total rehabilitation time was 12 months for amputation and 30 months for reconstruction (p<0.009). Changes in lifestyle were consistently more important in the amputee group. 56% of the amputees and 19% of the reconstructed patients were retrained to a different profession (p<0.025).

Clinical conclusions
The complexity of the lesion determines if reconstruction is feasible. Objective data such as walking distance as well as subjective assessments were significantly in favour of reconstruction.

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

Direct costs
Costs were not discounted despite considering two to four years of follow-up in the cost analysis. Quantities were not reported separately from the costs. Cost components were not reported separately. Direct health service costs such as hospitalisation costs were considered. The source of cost data was medical reports. Gigy’s Swiss cost index for healthcare was used for calculations assuming a linear progression of 3.5 points from 1987 to 1989. Costs were indexed to 1989.

Statistical analysis of costs
Statistical calculations were carried out using Systat software. A p value equal to or less than 0.05 was considered significant.

Indirect Costs
Costs were not discounted despite at least two years of follow-up being considered in the cost analysis. Quantities were not reported separately from the costs. Cost components were reported separately. Loss-of-wages-benefits, indemnity for loss of integrity and pension costs were considered, using data from the Swiss Social Insurance head office (SUVA, Luzern). The date of the price data was 1989.

Currency
Swiss Francs (SFr).
Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The mean annual hospital costs for the first 4 years were SFr15,112 for patients undergoing amputation and SFr17,365 for those undergoing reconstruction (p<0.01). Total costs for reconstruction (including pensions) were far lower than for amputation (SFr184,000 versus SFr363,000).

Synthesis of costs and benefits
Not performed.

Authors' conclusions
For potentially salvageable legs, reconstruction is advisable because the functional outcome is better than for amputation and there is no permanent social disintegration due to the long treatment. Total costs (including pensions) were far lower for reconstruction than for amputation.

CRD COMMENTARY - Selection of comparators
The reason for not choosing any comparator was reported in "health technology" section.

Validity of estimate of measure of effectiveness
The internal validity of the estimates of effectiveness was weakened by the retrospective nature of the study and the relatively small sample size.

Validity of estimate of measure of benefit
Since the study did not identify an overall measure of benefit it has to be regarded as a cost-consequence study.

Validity of estimate of costs
Quantities were not systematically reported separately from the costs. Adequate details related to the cost items included in the hospital costs were not given and it was not reported whether these were charges or true costs. The inclusion of costs due to lost productivity was a positive feature of the cost analysis. The most important drawbacks of the cost analysis were its retrospective nature, the fact that the cost calculations were performed only on a sub-sample of that used in the effectiveness analysis and the lack of discounting.

Other issues
Given the lack of a prospective design and sensitivity analysis, the study results should be treated with some caution. The issue of generalisability to other settings or countries was not addressed.

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