Economic implications of thrombolysis or operation as the initial treatment modality in acute peripheral arterial occlusion

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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
Thrombolysis and surgical intervention in acute peripheral arterial occlusion.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with acute peripheric occlusions (acute symptoms less than or equal to 7 days, limb-threatening ischemia (class II)), aged 18 years or older.

Setting
Hospital. The economic study was conducted in Mississippi, USA.

Dates to which data relate
Effectiveness and resource use data were collected between August 1989 and April 1992. 1992 prices were used in the economic analysis.

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

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations were not reported as being used to determine the sample size. The study sample comprised 114 patients with acute limb ischemia of less than 7 days duration. Exclusion criteria were: contraindication to thrombolysis or operation, class I or III ischemia, echocardiographic cardiac thrombus, or a positive urinary pregnancy test. The patients were randomly assigned to receive urokinase (n=57) or to undergo an operation (n=57) as the initial therapeutic intervention.

Study design
This was a randomised clinical trial, carried out in a single centre. The duration of the follow-up was not explicitly specified. 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 study were cumulative limb salvage, and survival rates (calculated from Kaplan-Meier curves) at 12 months, and in-hospital cardiopulmonary complications. The study groups were shown to be comparable in terms of demographics, comorbid conditions, and cardiac risk index.

**Effectiveness results**
The two groups had approximately identical cumulative limb salvage rates (82% at 12 months by Kaplan-Meier analysis). The thrombolysis group had a cumulative survival rate of 84% versus 54% in the operative group, (p=0.01). The frequency of in-hospital cardiopulmonary complications in the operative group was 49% versus 16% in the thrombolytic group, (p=0.001).

**Clinical conclusions**
There were clinical benefits associated with thrombolytic treatment of acute peripheral arterial occlusion.

**Measure of benefits used in the economic analysis**
The benefit measure was life expectancy (years).

**Direct costs**
Costs were not discounted although the reason for not discounting was not specified. Resource utilisation was not reported separately from the costs. The cost items were reported separately. Direct health services costs were considered such as hospital costs, pharmacy and professional services. The perspective adopted in the cost analysis was that of hospital, patient or payer. Hospital costs data were collected from the computerised records of the hospital finance department. The number and magnitude of professional services were tabulated from the patients' charts and multiplied by the Medicare Part B allowed fee to determine the professional charges (to the patient). The date of the price data was 1992.

**Statistical analysis of costs**
Statistical comparisons between the two groups were made using the Student t test for continuous, normally distributed data.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
Not conducted.

**Estimated benefits used in the economic analysis**
Life expectancy was 12.4 (+/- 1.3) years for the thrombolysis group versus 9.4 (+/- 1.3) years for the operative group.
Cost results
The total treatment costs did not differ significantly between the two treatment groups: $22,171 (+/- $4,959) in the thrombolytic group and $19,775 (+/- $5,253) in the operative group. The total hospital charges were similar between the two groups with the average total charges being $40,823 (+/- $8,764) for the thrombolytic group and $41,930 (+/- $10,398) for the operative group.

Synthesis of costs and benefits
The cost per life saved was $49,508 for the thrombolysis group and $70,295 for the operative group. The cost per life-year saved was $3,980 for the thrombolysis group and $7,489 for the operative group.

Authors' conclusions
The economic analysis confirmed that the total economic impact of thrombolysis approximated that of initial operative therapy. The improved clinical outcome in patients treated with thrombolysis suggests that this modality might be appropriate as the initial therapeutic intervention in the select group of patients seen within the first few hours of an acute peripheral arterial occlusive event.

CRD COMMENTARY - Selection of comparators
No specific health technology was explicitly specified as the comparator.

Validity of estimate of measure of benefit
In spite of the relatively small sample size, the estimate of benefit is likely to be internally valid given the use of a randomised design.

Validity of estimate of costs
Quantities were not systematically reported separately from the costs, although, adequate details of the methods of cost estimation were given. The study lacked a prospective cost analysis.

Other issues
As regards the issue of generalisability, the authors pointed out that the results "must not be generalised to the larger population of patients presenting with occlusions of a more chronic nature."

Implications of the study
The authors pointed out the need for large, well-controlled clinical trials in order to find the most appropriate therapy in the context in question.

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