Pharmacoeconomic considerations in peripheral arterial thrombolytic therapy

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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
Peripheral arterial thrombolytic therapy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
In the case of subacute PAO: Patients treated in Brigham and Women's Hospital for an isolated native peripheral artery or peripheral arterial graft occlusion between August 1981 and December 1985. In the case of acute PAO: patients aged 18 or older admitted to the University of Rochester Medical Centre, between August 1989 and April 1992 with acute limb ischemia of less than 7 days.

Setting
Hospitalised patients in the USA.

Dates to which data relate

Source of effectiveness data
Effectiveness data were derived from a review of two previously conducted studies, (Janosik et al, 1991 and Ouriel et al, 1994).

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same patient populations as that used in the primary studies.

Outcomes assessed in the review
Mean length of stay, 1-year-mortality rate and 1-year-limb salvage rate were assessed as health outcomes in the studies.

Study designs and other criteria for inclusion in the review
Not stated.
Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
Two primary studies were included. One was a prospective cohort study and the other was a randomised controlled trial. The patients were followed up for one year.

Methods of combining primary studies
Not applicable as the two primary studies examined different patient types.

Investigation of differences between primary studies
The main difference between the two studies was the time difference between the beginning of the symptoms. The first study included only subacute patients and the other included only acute patients.

Results of the review
Subacute PAO results: In the surgical interventions group revascularisation was successful in 100% of the patients. After 60 days the cumulative patency rate dropped to 76%. In the streptokinase (SK) group, 36.8% of the patients had successful treatment (confirmed complete clot resolution) and the cumulative patency rate was 32% after 60 days. In theurokinase (UK) group, the demonstrated initial success rate was 68.2%, and the cumulative patency rate was 64% after 60 days. The mean length of stay was 11.5 days for the UK group, which was significantly shorter than in the SK group (p<0.05). The average length of stay was 21.3 days for the SK group, and 21.1 days in the thrombectomy group (surgical intervention). There was no statistical difference between the two groups in terms of treatment failure rate and average length of stay.

Acute PAO results: In the operative group one patient died before undergoing the planned operation, 3 underwent primary amputation, and 53 patients (93%) underwent revascularisation. Among those 53 patients, 27 (51%) had a new bypass graft, 16 (30%) underwent thromboembolectomy alone, and 9 patients (17%) had a revision of the existing bypass graft, whilst one patient underwent balloon angioplasty. In the thrombolytic failure group, 15 patients underwent operative correction and two underwent primary amputations. At 30 days after treatment 40 of 57 patients (70%) in the thrombectomy group had event-free survival compared with 49 of 57 (86%) patients who underwent UK thrombolysis. In both groups the median length of hospital stay was 11 days and the 1-year cumulative risk of amputation was 18%. The operative intervention had a 24% annual readmission rate, compared with 17% in the thrombolysis group. The one-year mortality rates was significantly different between the two groups (P=0.01). The cumulative one-year risk of death was 62% less in the thrombolysis group (16%) than in the thrombectomy group (42%).

Measure of benefits used in the economic analysis
Benefits measured were the revascularisation rate (angiographically confirmed), the rate of treatment failure, the 30 day events-free survival rate, the average length of stay, the readmission rate, the 1-year limb salvage rate, and the 1-year mortality rate. In the subacute PAO study the 60 day patency rate was also measured.
Direct costs
Some of the costs and quantities were reported separately. The date to which data refer was not clearly stated, but presumably 1995 prices were used. Direct drug costs, hospital costs and professional fees were included. No discounting was stated.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Subacute PAO Results: In the surgical interventions group revascularisation was successful in 100% of the patients. After 60 days the cumulative patency rate dropped to 76%. In the streptokinase (SK) group, 36.8% of the patients had successful treatment (angiographically confirmed complete clot resolution) and the cumulative patency rate was 32% after 60 days. In the urokinase (UK) group, the demonstrated initial success rate was 68.2%, and the cumulative patency rate was 64% after 60 days. The mean length of stay was 11.5 days for the UK group, which was significantly shorter than in the SK group (p<0.05). The average length of stay was 21.3 days for the SK group, and 21.1 days in the thrombectomy group (surgical intervention). There was no statistical difference between the two groups in terms of treatment failure rate and average length of stay.

Acute PAO results: In the operative group one patient died before undergoing the planned operation, 3 underwent primary amputation, and 53 patients (93%) underwent revascularisation. Among these 53 patients 27 (51%) had a new bypass graft, 16 (30%) underwent thromboembolectomy alone, and 9 patients (17%) had a revision of the existing bypass graft whilst one patient underwent balloon angioplasty. In the thrombolytic treatment group (n=57), 40 patients (70%) had arteriographically confirmed successful therapy. Therapy failed in 17 patients (30%). Within the thrombolytic failure group 15 patients underwent operative correction and two underwent primary amputations. At 30 days after treatment 40 of 57 patients (70%) in the thrombectomy group had event-free survival compared with 49 of 57 (86%) patients who underwent UK thrombolysis. In both groups the median length of hospital stay was 11 days and the 1-year cumulative risk of amputation was 18%. The operative intervention had a 24% annual readmission rate, compared with 17% in the thrombolysis group. The one-year mortality rates were significantly different between the two groups (P=0.01). The cumulative one-year risk of death was 62% less in the thrombolysis group (16%) than in the thrombectomy group (42%). No discounting was performed on benefits.

Cost results
In the subacute PAO: the mean hospital charge was $25,449 for the successful cases and $26,317 for the failure cases in the SK group. The mean hospital charge was $16,818 for the successful cases and $40,295 for the failure cases in the UK group. The mean charge for the thrombolytic agent was $690 in the case of streptokinase and $6,429 in the case of urokinase: the difference was statistically significant (p<0.01). The mean hospital charges for the three groups were not significantly different: UK cost $22,203, thrombectomy cost $25,336, and SK cost $25,978.

In the acute PAO: the operative interventions hospital charge was $19,775, the urokinase treatment hospital charge was $22,171, and the thrombolytic drug was $2,653. When professional fees were added to the hospital charges the overall charges were $23,292 in the operative intervention group and $24,616 in the UK group. The difference was not statistically significant.

Synthesis of costs and benefits
The treatment of subacute and acute PAO with intraarterial thrombolytic therapy with urokinase was a dominant strategy.
Authors' conclusions
The treatment of subacute and acute PAO with urokinase led to a significant improvement in clinical outcome, including reduction in mortality and morbidity and shortened the length of hospital stay in the case of subacute PAO, but not in the case of acute PAO. Thrombolysis with urokinase may provide both clinically superior and cost-beneficial treatment of PAO compared with alternative treatment modalities (i.e. thrombectomy and streptokinase).

CRD Commentary
A justification was given for the comparators used. The selection of the primary studies was not clearly justified. The relevance and validity of the primary studies were not assessed by the authors. No quality of life issue has been considered. It is difficult to judge the quality of the cost data as no sources were mentioned.

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