Cost-effectiveness of exercise training to improve claudication symptoms in patients with peripheral arterial disease

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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
The study examined exercise rehabilitation (ER) and iliac percutaneous transluminal angioplasty (PTA) in patients with peripheral arterial disease (PAD). ER consisted of a programme of two 30-minute supervised exercise sessions per week, continuing for 3 months and 6 months. Supervised graded treadmill walking was the main exercise modality. PTA was performed without primary stent placement.

Type of intervention
Rehabilitation and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of PAD patients with claudication, in whom ilio-femoral arterial disease was known.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The clinical data and some resource use data came from studies published in 1990 and 1996. The price year was 2001.

Source of effectiveness data
The effectiveness data was derived from a synthesis of completed studies and authors’ opinions.

Outcomes assessed in the review
The outcome estimated from the literature was the efficacy of ER and PTA. This was evaluated using two measures, the initial claudication distance (ICD) and the absolute claudication distance (ACD). The ICD is the treadmill-measured distance that a patient can walk before the onset of claudication pain. The ACD is the distance the patient can walk before being forced to terminate exercise due to claudication pain.

Study designs and other criteria for inclusion in the review
A systematic review of the literature was not carried out. The primary studies providing the data appear to have been identified selectively. The studies were all randomised clinical trials that were deemed to be the only available randomised, prospective studies of effectiveness of the two alternatives under examination.
Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
The validity of the primary studies was ensured by the use of clinical trials only.

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

Number of primary studies included
The effectiveness estimates were derived from two primary studies.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The changes in ICD from baseline were:

after 3 months, 53 m with ER and 134 m with PTA; and
after 6 months, 123 m with ER and 54 m with PTA.

The changes in ACD from baseline were:

after 3 months, 110 m with ER and 148 m with PTA; and
after 6 months, 250 m with ER and 113 m with PTA.

Methods used to derive estimates of effectiveness
The authors made some assumptions to derive the effectiveness estimates.

Estimates of effectiveness and key assumptions
It was assumed that no improvements or declines in global health (or of claudication symptoms) would occur for patients receiving no treatment.

It was also assumed that ER would not always achieve adequate clinical results, and that a fraction of these patients (6.25% of the total) would choose to undergo a PTA procedure with stent placement.

Measure of benefits used in the economic analysis
The summary benefit measures were the changes in ICD and ACD from baseline to the two timeframes (3 and 6 months) associated with either ER or PTA. These measures were directly derived from the clinical analysis.
Direct costs
The costs were analysed from a societal perspective. The health services included in the analysis of the direct costs were ER and PTA (with or without stent placement). ER included personnel time, treadmill depreciation, blood pressure monitor depreciation, defibrillator depreciation, overhead depreciation, education, disposables and utilities. PTA included the treatment of complications and follow-up. The costs of adverse events and the impact of compliance were also taken into consideration. The option of no treatment also incurred some costs, which were associated with physician visits. The unit costs and the quantities of resources used were presented separately for most cost items. Much of the data on resource consumption were based on authors' opinions. The bulk of the costs came from the Fairview-University Medical Center. When charges were used, a cost-to-charge ratio was applied to assess the true costs of the services. Other costs came from a published study. Discounting was not relevant because of the short timeframe of the study. All the costs were inflated to 2001 values using the Consumer Price Index.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs (i.e. time costs that patients would incur by travel to and from the hospital, and waiting for and receiving the two interventions) were included in the analysis of the costs. The unit costs were estimated from US national wage rates, while resource use data were mainly based on authors' opinions. The unit costs were presented separately from the quantities of resources used. The price year was 2001. No discounting was applied as the costs were incurred during a short timeframe.

Currency
US dollars ($).

Sensitivity analysis
The authors stated that they conducted a sensitivity analysis to assess the effect of variations in key parameters. Principally, the variation in the level of effectiveness achieved and in the measurement of effectiveness for which the true values were uncertain. However, the results of the sensitivity analyses were not reported.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The per patient costs were $290 with no treatment, $2,942 with ER for 3 months, $4,968 with ER for 6 months, and $9,303 with PTA (regardless of the timeframe).

The main categories of costs associated with ER were (in decreasing order) patient time, rehabilitation sessions, expected costs of PTA with stents (for unsuccessful ER treatment) and follow-up visits.

The main category of costs associated with PTA was hospital procedure charge.

Synthesis of costs and benefits
Average and incremental cost-effectiveness ratios (ACERs and ICERs, respectively) were calculated to combine the costs and benefits of the alternative strategies.

When the ICD was used as the summary benefit measure, the ACER was $50/m with ER after 3 months, $67/m with PTA after 3 months, $167/m with PTA after 6 months, and $38/m with ER after 6 months. The incremental analysis
showed that the ICER with PTA in comparison with ER was $79/m when the time horizon was 3 months. However, over a timeframe of 6 months, ER was dominant because it was less costly and more effective than PTA.

Similar results were obtained when the ACD was used as the summary benefit measure. The ACER was $24/m with ER after 3 months, $61/m with PTA after 3 months, $80/m with PTA after 6 months, and $19/m with ER after 6 months. The incremental analysis showed that the ICER with PTA in comparison with ER was $167/m when the time horizon was 3 months. However, over a timeframe of 6 months, ER was dominant because it was less costly and more effective than PTA.

Authors’ conclusions
Exercise rehabilitation (ER) was an effective and cost-saving alternative to percutaneous transluminal angioplasty (PTA) for patients with peripheral arterial disease (PAD) over a 6-month timeframe. When a shorter time horizon was used in the analysis (i.e. 3 months), PTA was more effective but also more expensive than ER. However, owing to the lack of a specific threshold for the initial or absolute claudication distance (ICD and ACD, respectively), it was not possible to draw any robust conclusions on the cost-effectiveness over a 3-month timeframe.

CRD COMMENTARY - Selection of comparators
The authors provided a justification for the choice of the interventions examined in the study. No treatment was also considered as a reference strategy for comparative purposes. The authors noted that pharmacologic therapies or combination options were not considered. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from two published clinical trials. No information on the design and characteristics of the patients was provided. The validity of the primary studies was ensured by the randomised design. The studies appear to have been identified selectively, thus a review of the literature was presumably not undertaken. The methods used to combine and extract the primary data were not reported. Similarly, the issue of potential differences between the two studies was not addressed.

Validity of estimate of measure of benefit
The summary benefit measures were specific to the disease considered in the study. They are not easily compared with the benefits of other health care interventions. The authors attempted to assess the impact of the interventions on quality of life, but stated that data on quality-adjusted life-years for walking impairment were not available.

Validity of estimate of costs
The widest perspective was adopted in the study, thus all relevant categories of costs were included in the economic evaluation. Extensive information on the unit costs, quantities of resources used, source of the data, resource use assumptions and price year was reported. This enhances the possibility of replicating the results of the analysis and performing reflation exercises in other settings and time periods. However, the costs were treated deterministically and were specific to the study setting. The impact of using alternative cost estimates was not investigated. Some costs were estimated using hospital charges, but a cost-to-charge ratio was applied. The authors stated that the costs of pre-treatment non-invasive vascular testing strategies were not considered, but such costs were likely to increase PTA-associated costs.

Other issues
The authors did not compare their findings with those from other studies. They also did not explicitly address the issue of the generalisability of the study results to other settings. The results of the sensitivity analysis were not reported, although the authors stated that one was performed. The results of their analysis apply to individuals presenting with classical claudication symptoms, thus caution is required when extrapolating the current results to individuals with atypical leg symptoms (or critical limb ischaemia). Finally, the authors stated that the published data used for estimating
the effectiveness results were relatively small in comparison with data available from large international coronary disease databases.

**Implications of the study**
The study results supported the notion that the use of ER might be cost-effective among PAD patients. The authors suggested that a prospective long-term study should be conducted to measure the quality of life gains by PAD patients treated with PTA and supervised ER.

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None stated.

**Bibliographic details**

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**Other publications of related interest**


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