A non-randomised controlled trial of the clinical and cost effectiveness of a supervised exercise programme for claudication

Lee H L, Mehta T, Ray B, Heng M S, McCollum P T, Chetter I C

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 the addition of a structured exercise programme, three times per week for 12 weeks, to conservative medical therapy for the treatment of intermittent claudication. The exercise programme consisted of six 2-minute exercise stations (walking up and down a 6-inch step, double heel raise, single leg press, exercise bicycle, knee extension and elbow flexion) with 2 minutes of walking in between each station.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with intermittent claudication.

Setting
The study setting was outpatient care in Hull, UK. The economic study was carried out in the UK.

Dates to which data relate
The dates to which the clinical effectiveness and resource use data referred were not reported. No price year was reported.

Link between effectiveness and cost data
The cost data would appear to relate to the same patient sample that provided the clinical data.

Study sample
The patients were recruited sequentially from the vascular clinic. A total of 70 patients were included in the study. Of these, 33 were in the structured exercise programme group and 37 were in the conservative medical therapy only group. No sample size or power calculations were reported. The paper did not indicate whether any patients refused to participate in the study, nor did they report any specific inclusion criteria for the patient sample.

Study design
This was a single-centred, prospective, comparative study. The patients were followed up for 6 months. Loss to follow-up was not reported. Blinding was not plausible in this study.
Analysis of effectiveness
The primary health outcomes analysed were:

- patient-reported walking distance;
- initial claudication distance and maximal walking distance on treadmill testing;
- ankle brachial pressure indices at rest and after exercise; and
- quality of life, as measured by the SF36.

The two groups were generally comparable, except for a lower patient-reported walking distance and higher scores in the SF-36 bodily pain and general health domains in the structured exercise programme group. It was unclear whether all the patients were included in the analysis.

Effectiveness results
The mean increase in walking distance was 500 metres in the structured exercise programme group compared with 25 metres in the conservative medical therapy only group, (p<0.01).

The mean initial claudication distance on a treadmill increased by 49 metres in the structured exercise programme group but decreased by 3.4 metres in the conservative medical therapy only group, (p<0.01).

The mean maximal walking distance on a treadmill increased by 182.4 metres in the structured exercise group compared with 32.8 metres in the conservative medical therapy only group, (p<0.01).

The differences in the change in ankle brachial pressure indices were not statistically significant.

The only domain of the SF36 to show a statistically significant difference between the two patient groups was the vitality domain. There was no change in score for the structured exercise programme group, but there was a reduction of 5 in the score for the conservative medical therapy only group, (p<0.01)).

Clinical conclusions
The authors concluded that the addition of a structured exercise programme to conservative medical therapy increased walking distances and improved quality of life.

Modelling
The authors extrapolated changes in quality of life measured 6 months after the start of the study to 1 year after the start of the study. Their methods were not reported in the paper.

Measure of benefits used in the economic analysis
The measure of health benefit used was the quality-adjusted life-years (QALYs). Health state valuations were estimated using the SF36 at baseline and after 6 months.

Direct costs
The marginal direct costs of the hospital were included in this study. The authors appear to have assumed that the costs of conservative medical therapy would be the same for both groups so only the cost of the structured exercise programme was considered. This cost was identified by the finance department of the study hospital. No details of the specific costs included in this figure were provided. A breakdown of resource use and unit costs was provided. No price year was reported.
Statistical analysis of costs
No statistical analysis of the costs or resource use was undertaken.

Indirect Costs
No productivity costs were included in this study.

Currency
UK pounds sterling (£).

Sensitivity analysis
No analysis was undertaken to assess the uncertainty around the economic analysis results.

Estimated benefits used in the economic analysis
The authors estimated that the structured exercise programme would result in an additional 0.027 QALYs in the first year.

Cost results
The total cost per patient (assuming full recruitment) was 48.06.

Synthesis of costs and benefits
The cost per QALY gained by the structured exercise programme was 1,780.00 at year 1.

Authors' conclusions
The addition of a structured exercise programme to conservative medical therapy is a cost-effective treatment for intermittent claudication.

CRD COMMENTARY - Selection of comparators
The authors compared the addition of a structured exercise programme to conservative medical therapy with conservative medical therapy alone. This comparator appears to have been chosen as it reflected previous usual practice in the authors' setting. You should consider how this compares with usual practice in your own setting before applying the results of this study.

Validity of estimate of measure of effectiveness
The clinical effectiveness data were taken from a prospective comparative study. This study design is associated with some limitations, such as a low internal validity. No details of loss to follow-up were given in the paper and the authors acknowledged that a longer follow-up period would have been preferable. These factors limit the internal validity of the study. The authors acknowledged that a randomised controlled trial would have provided a more robust estimate of the clinical effectiveness of the structured exercise programme. As neither sample size nor power calculations were reported, it is unclear whether the results obtained were due to the structured exercise programme or to chance.

Validity of estimate of measure of benefit
The measure of health benefit was QALYs measured using the SF36, with data taken from the patient sample that provided the clinical effectiveness data. The use of QALYs allows the results of this study to be directly compared with those from studies on other interventions that use QALYs as the health-related outcome of interest.
Validity of estimate of costs
The marginal costs to the hospital of providing the structured exercise programme were estimated. Although not explicitly stated, the authors seem to have assumed that the costs of conservative medical therapy were the same for the two patient groups. This assumption is unlikely to have altered the study findings. No statistical or sensitivity analyses were undertaken to assess the uncertainty around the economic data. A breakdown of the unit costs and resource use was not provided. These factors limit the generalisability and transferability of the study findings. No price year was reported, which will hinder any future reflaction exercises.

Other issues
The authors did not provide a comprehensive breakdown of their analysis (p-values for the statistical tests were not described). Their conclusion reflected the results presented but, as the level of uncertainty around their economic analysis has not been explored, the reliability of their findings is not clear. The authors did not consider how their findings might be generalised to other settings. Although they noted that other studies have considered the impact of structured exercise programmes on walking distances, they did not compare their findings with those from other similar studies.

Implications of the study
The authors recommended that randomised controlled trials with multiple follow-up points over a longer period should be undertaken.

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