Intermittent claudication: functional capacity and quality of life after exercise training or percutaneous transluminal angioplasty. Systematic review

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CRD summary
The authors assessed exercise training and percutaneous transluminal angioplasty (PTA) for intermittent claudication. They concluded that functional capacity improves significantly after PTA, but found no difference after exercise training. Both PTA and exercise training improve quality of life. The evidence to support the conclusions is weak. Better research is needed to determine the relative effectiveness of the two treatments.

Authors' objectives
To assess the effectiveness of exercise training and percutaneous transluminal angioplasty (PTA) on functional capacity and quality of life in patients with intermittent claudication.

Searching
MEDLINE, CINAHL, the Cochrane Controlled Trials Register, the Cochrane Anaesthesia Group's specialised register of trials and PiCarta were searched; the search terms were reported. Studies published in English from 1980 onwards were eligible for inclusion.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and prospective and retrospective cohort studies were eligible for inclusion. Case reports were excluded.

Specific interventions included in the review
Studies of treatment with exercise training (walking or gymnastics) or PTA with or without stent placement in lesions in the aortoiliac or femoropopliteal arterial segments were eligible for inclusion. Supervised and unsupervised exercise training programmes lasting 12 or 24 weeks were included. The type of exercise varied between studies, frequency ranged from 3 to 7 days per week, and duration (where reported) ranged from 15 to 60 minutes per session. Characteristics of the PTA interventions in the included studies were not reported.

Participants included in the review
Studies in patients with intermittent claudication were eligible for inclusion. Studies that also included patients with ischaemia were excluded if the results for patients with intermittent claudication were not reported separately. The mean age of the patients was 68 years for those who underwent exercise training and 64 years for those who underwent PTA. Around 70% in each group were men.

Outcomes assessed in the review
Studies that reported both functional capacity and quality of life were eligible for inclusion. Functional capacity had to be assessed by walking distance on a treadmill or as reported by the patient, or using the ankle-brachial index (ABI). Studies that reported dichotomous outcomes were excluded. Generic and specific quality-of-life scores were eligible but studies that did not report SF-36 or SF-20 health survey data were excluded. The review reported ABI at rest and the maximum treadmill walking distance and focused on four quality-of-life dimensions: physical functioning, physical role functioning, bodily pain and general health. Studies had to report outcomes with at least 3 months' follow-up to be included. The duration of follow-up in the included studies ranged from 3 to 24 months.

How were decisions on the relevance of primary studies made?
Two reviewers applied the inclusion criteria independently and reached agreement on the final selection of studies.
Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Two reviewers extracted the data independently using a standardised form. Any disagreements in the evaluation of exercise training programmes were resolved by discussion.

Demographic data extracted included the number of patients in each study group with cardiac disease, hypertension, diabetes, pulmonary disease, hyperlipidaemia, stroke, history of smoking and current smoking.

Mean values of measures of functional capacity and quality-of-life scores were extracted from each study group included in the review. Data for ABI at rest, maximum treadmill walking distance in metres, and each quality-of-life dimension at baseline and at 3 and 6 months' follow-up were extracted. Twelve-month follow-up data were used to represent 6-month follow-up values for PTA whereas the actual 6-month follow-up data were extracted for the exercise training study groups.

Methods of synthesis
How were the studies combined?
Individual treatment and control groups that underwent one of the two interventions of interest in the included studies were separated to compile the two treatment groups (exercise training and PTA) that were analysed in the review. Data on demographics and patient characteristics were pooled within the exercise training group and the PTA group using a random-effects model (Laird and Mosteller).

A weighted mean with 95% confidence interval (CI) was calculated for each outcome within the exercise training group and the PTA group (the method used was unclear). Improvement in functional capacity and quality of life from baseline to the 3- and 6-month follow-up within the exercise training group and the PTA group was tested using Student's t-test (p<0.05 indicated statistical significance). The statistical method used to compare the results of the two treatment groups was not described.

Separate funnel plots, one for the exercise training group and one for the PTA group, using 3- or 6-month follow-up data as available were used to investigate publication bias.

How were differences between studies investigated?
The statistical homogeneity of the baseline characteristics within the exercise training group and the PTA group was tested using the chi-squared test (p<0.05 indicated statistical significance). Differences in the pooled patient characteristics between the exercise training group and the PTA group were tested using the chi-squared test and the paired Student's t-test (p<0.05). Differences in the components of the exercise training programmes across studies were tabulated and discussed in the text.

Results of the review
Seven studies were included: four RCTs and three prospective cohort studies. The analysis included 202 patients who underwent exercise training therapy and 470 patients who underwent PTA.

Patient characteristics were similar between the two treatment groups, except for a statistically significant higher proportion with hypertension and stroke in the PTA group compared with the exercise training group (64% versus 31% and 23% versus 11%, respectively).

Functional capacity.

At 3 and 6 months' follow-up, the ABI had significantly improved from baseline in the PTA group (mean change 0.18, p<0.01) but not in the exercise training group. The mean change between the two treatment groups was significantly different at 3 (p<0.01) and 6 months' (p<0.02) follow-up.
Quality of life.

At 3 months’ follow-up there was a statistically significant improvement in physical role functioning scores in the PTA group (mean change 30, \(p=0.03\)), and a significant improvement in physical functioning scores (mean change 18, \(p<0.01\)) and bodily pain (mean change 10, \(p<0.01\)) scores in the exercise training group. The mean change in scores was not significantly different between the exercise and the PTA groups.

The funnel plots were asymmetric but had too few studies for meaningful interpretation.

**Authors’ conclusions**

Functional capacity showed significant improvement after PTA, whereas quality of life showed significant improvement after PTA and exercise training. This was not based on a direct comparison of the interventions.

**CRD commentary**

The review stated clear inclusion criteria relating to each of the main components of the review question. Methods were used to minimise bias in the selection of studies for inclusion. A reasonable number of sources were searched for relevant studies but bias could have been introduced by the restrictions imposed on inclusion. First, relevant studies of exercise therapy might have been missed because of the restriction to studies published from 1980 onwards. Second, although restriction to studies published in English was justified by reference to empirical research showing no evidence that language-restricted meta-analyses of RCTs leads to biased estimates of the effectiveness of interventions, whether this was applicable to this review is unknown. Third, owing to the restriction to published studies and there being too few data to construct meaningful funnel plots, it is possible that the results were influenced by publication bias; this tends to overestimate treatment effects. The failure to assess the potential for bias in the individual included studies raised concern about the reliability of the results from each study and the estimates of effect obtained by pooling groups of patients from RCTs with groups from observational studies. Reliance on statistical significance tests to determine the comparability of the treatment groups is questionable and did not take account of potential differences in characteristics that were not known or not measured. Treatment and control groups were separated from their original studies in order to be regrouped for comparison by intervention: it is important to note that there was no randomised comparison of exercise training and PTA in the analysis in this review, hence no direct comparison of the effectiveness of the two interventions. The authors’ positive conclusions do not adequately reflect the limitations of the review or the questionable methods of analysis.

**Implications of the review for practice and research**

Practice: The authors did not state any implications for practice.

Research: The authors stated that an RCT of exercise training versus PTA with longer than 6 months’ follow-up is needed to determine the relative effectiveness of these interventions on functional capacity and quality of life. A standardised exercise training programme with standard measurement of maximum walking distance is desirable.

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