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Cochrane Database of Systematic Reviews 2017, Issue 12. Art. No.: CD000990.
DOI: 10.1002/14651858.CD000990.pub4.

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[Intervention Review]

Exercise for intermittent claudication

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Editorial group: Cochrane Vascular Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 12, 2017.

Citation: Lane R, Harwood A, Watson L, Leng GC. Exercise for intermittent claudication. *Cochrane Database of Systematic Reviews* 2017, Issue 12. Art. No.: CD000990. DOI: 10.1002/14651858.CD000990.pub4.

ABSTRACT

Background

Exercise programmes are a relatively inexpensive, low-risk option compared with other, more invasive therapies for treatment of leg pain on walking (intermittent claudication (IC)). This is the fourth update of a review first published in 1998.

Objectives

Our goal was to determine whether an exercise programme was effective in alleviating symptoms and increasing walking treadmill distances and walking times in people with intermittent claudication. Secondary objectives were to determine whether exercise was effective in preventing deterioration of underlying disease, reducing cardiovascular events, and improving quality of life.

Search methods

For this update, the Cochrane Vascular Information Specialist searched the Specialised Register (last searched 15 November 2016) and the Cochrane Central Register of Controlled Trials (CENTRAL; 2016, Issue 10) via the Cochrane Register of Studies Online, along with trials registries.

Selection criteria

Randomised controlled trials of an exercise regimen versus control or versus medical therapy for people with IC due to peripheral arterial disease (PAD). We included any exercise programme or regimen used for treatment of IC, such as walking, skipping, and running. Inclusion of trials was not affected by duration, frequency, or intensity of the exercise programme. Outcome measures collected included treadmill walking distance (time to onset of pain or pain-free walking distance and maximum walking time or maximum walking distance), ankle brachial index (ABI), quality of life, morbidity, or amputation; if none of these was reported, we did not include the trial in this review.

Data collection and analysis

For this update (2017), RAL and AH selected trials and extracted data independently. We assessed study quality by using the Cochrane 'Risk of bias' tool. We analysed continuous data by determining mean differences (MDs) and 95% confidence intervals (CIs), and dichotomous data by determining risk ratios (RRs) and 95% CIs. We pooled data using a fixed-effect model unless we identified significant heterogeneity, in which case we used a random-effects model. We used the GRADE approach to assess the overall quality of evidence supporting the outcomes assessed in this review.

Main results

We included two new studies in this update and identified additional publications for previously included studies, bringing the total number of studies meeting the inclusion criteria to 32, and involving a total of 1835 participants with stable leg pain. The follow-up period ranged from two weeks to two years. Types of exercise varied from strength training to polestriding and upper or lower limb exercises; supervised sessions were generally held at least twice a week. Most trials used a treadmill walking test for one of the primary outcome measures. The methodological quality of included trials was moderate, mainly owing to absence of relevant information. Most trials were

small and included 20 to 49 participants. Twenty-seven trials compared exercise versus usual care or placebo, and the five remaining trials compared exercise versus medication (pentoxifylline, iloprost, antiplatelet agents, and vitamin E) or pneumatic calf compression; we generally excluded people with various medical conditions or other pre-existing limitations to their exercise capacity.

Meta-analysis from nine studies with 391 participants showed overall improvement in pain-free walking distance in the exercise group compared with the no exercise group (MD 82.11 m, 95% CI 71.73 to 92.48, P < 0.00001, high-quality evidence). Data also showed benefit from exercise in improved maximum walking distance (MD 120.36 m, 95% CI 50.79 to 189.92, P < 0.0007, high-quality evidence), as revealed by pooling data from 10 studies with 500 participants. Improvements were seen for up to two years.

Exercise did not improve the ABI (MD 0.04, 95% CI 0.00 to 0.08, 13 trials, 570 participants, moderate-quality evidence). Limited data were available for the outcomes of mortality and amputation; trials provided no evidence of an effect of exercise, when compared with placebo or usual care, on mortality (RR 0.92, 95% CI 0.39 to 2.17, 5 trials, 540 participants, moderate-quality evidence) or amputation (RR 0.20, 95% CI 0.01 to 4.15, 1 trial, 177 participants, low-quality evidence).

Researchers measured quality of life using Short Form (SF)-36 at three and six months. At three months, the domains 'physical function', 'vitality', and 'role physical' improved with exercise; however this was a limited finding, as it was reported by only two trials. At six months, meta-analysis showed improvement in 'physical summary score' (MD 2.15, 95% CI 1.26 to 3.04, P = 0.02, 5 trials, 429 participants, moderate-quality evidence) and in 'mental summary score' (MD 3.76, 95% CI 2.70 to 4.82, P < 0.01, 4 trials, 343 participants, moderate-quality evidence) secondary to exercise. Two trials reported the remaining domains of the SF-36. Data showed improvements secondary to exercise in 'physical function' and 'general health'. The other domains - 'role physical', 'bodily pain', 'vitality', 'social', 'role emotional', and 'mental health' - did not show improvement at six months.

Evidence was generally limited in trials comparing exercise versus antiplatelet therapy, pentoxifylline, iloprost, vitamin E, and pneumatic foot and calf compression owing to small numbers of trials and participants.

Review authors used GRADE to assess the evidence presented in this review and determined that quality was moderate to high. Although results showed significant heterogeneity between trials, populations and outcomes were comparable overall, with findings relevant to the claudicant population. Results were pooled for large sample sizes - over 300 participants for most outcomes - using reproducible methods.

Authors' conclusions

High-quality evidence shows that exercise programmes provided important benefit compared with placebo or usual care in improving both pain-free and maximum walking distance in people with leg pain from IC who were considered to be fit for exercise intervention. Exercise did not improve ABI, and we found no evidence of an effect of exercise on amputation or mortality. Exercise may improve quality of life when compared with placebo or usual care. As time has progressed, the trials undertaken have begun to include exercise versus exercise or other modalities; therefore we can include fewer of the new trials in this update.

PLAIN LANGUAGE SUMMARY

Exercise for reducing intermittent claudication symptoms

Background

Intermittent claudication is a cramping leg pain that develops when walking and is relieved with rest. It is caused by inadequate blood flow to the leg muscles caused by atherosclerosis (fatty deposits restricting blood flow through the arteries). People with mild to moderate claudication are advised to keep walking, stop smoking, and reduce cardiovascular risk factors. Other treatments include antiplatelet therapy, pentoxifylline or cilostazol, angioplasty (inserting a balloon into the artery to open it up), and bypass surgery.

Studies and key results

Review authors identified 32 controlled trials that randomised 1835 adults with stable leg pain to exercise, usual care or placebo, or other interventions (current until November 2016). Researchers measured outcomes at times ranging from two weeks to two years. Types of exercise varied from strength training to polestriding and upper or lower limb exercises; in general, supervised sessions were held at least twice a week. The quality of included trials was moderate, mainly because of absence of relevant information. Ten trials reported that in the exercise groups, pain-free walking distance and the maximum distance that participants could walk was increased. Improvements were seen for up to two years. Exercise did not improve ankle to brachial blood pressure index. No evidence of an effect of exercise was seen on death or need for amputation because data were limited. Researchers assessed quality of life using the SF-36 Questionnaire at three and six months. At three months, indicators of quality of life - 'physical function', 'vitality', and 'role physical' - had all improved with exercise, but these data are limited, as only two trials reported this. Five studies reported improved 'physical summary score' and four studies reported improved 'mental health score' following exercise at six months, with two trials also reporting improvements in 'physical function' and 'general health'. All other domains showed no improvement at six months following exercise.

Comparisons of exercise with antiplatelet therapy, pentoxifylline, iloprost, vitamin E, and pneumatic foot and calf compression were limited because numbers of identified trials and participants were small.

Quality of the evidence

The present review shows that exercise programmes appear to improve walking distance for people considered fit for exercise regimens. This benefit appears to be sustained over two years. Evidence presented in this review was of moderate to high quality. Although differences between trials were evident, populations and outcomes were comparable overall, and findings were relevant to people with intermittent claudication. Combined results were derived from large sample sizes - over 300 participants for most outcomes - using reproducible methods.