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Angioplasty versus stenting for superficial femoral artery lesions

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Abstract

Background

Lower limb peripheral arterial disease (PAD) is a common, important manifestation of systemic atherosclerosis. Stenoses or occlusions in the superficial femoral artery may result in intermittent claudication as an early consequence, which may be treated by balloon angioplasty with or without stenting.

Objectives

The objective was to determine the effect of percutaneous transluminal angioplasty (PTA) when compared with PTA with stenting for lesions of the superficial femoral artery, for people with intermittent claudication or critical limb ischaemia.

Search strategy

The Cochrane Peripheral Vascular Diseases (PVD) Group searched their trials register (last searched February 2009) and the Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library* (2009, Issue 1) for publications describing randomised controlled trials (RCTs) of percutaneous angioplasty with or without stenting.

Selection criteria

Randomised trials of angioplasty alone versus angioplasty with stenting for the treatment of superficial femoral artery stenoses.

Data collection and analysis

Two authors (CT, JC) independently selected suitable trials, assessed trial quality and extracted data. A third author (AS) ranked the concealment of allocation and checked the final manuscript. The fourth author (DM) cross checked all stages of the review process.

Main results

Eight trials with 968 participants were included. The average age was 67 and all trials included men and women. Participants were followed for up to two years.

There was a small but statistically significant improvement in primary angiographic and duplex patency at six months in patients treated with PTA plus stent over lesions treated with PTA alone (three trials and four trials, respectively). However, primary angiographic patency was non-significant 12 months (five trials, $P = 0.23$) and 24 months (two trials, $P = 0.45$). A similar but lesser effect was seen for ankle brachial pressure index (ABPI), while a more pronounced improvement in treadmill walking distance in patients with PTA plus stent insertion was observed at six and 12 ($P < 0.0001$), but not 24 months ($P = 0.81$). Only one trial reported quality of life, which showed no significant difference between patients treated with PTA alone or PTA with stent insertion at any time interval. Antiplatelet therapy protocols and inclusion criteria between trials showed marked heterogeneity.

Authors' conclusions

There is limited benefit to stenting lesions of the superficial femoral artery in addition to angioplasty, however this cannot be recommended routinely based on the results of this analysis.

Plain language summary

Angioplasty versus angioplasty and stenting for lesions of the superficial femoral artery

Intermittent claudication is pain in the leg that is brought on by walking and which is relieved by rest. The pain is a result of insufficient blood flow to the muscles of the leg due to narrowing of the arteries by atherosclerosis. Patients who have narrowing of the main artery in the thigh, the superficial femoral artery, and intermittent claudication

which severely restricts their quality of life or causes dangerous tissue changes in the leg may undergo a procedure known as angioplasty to widen this narrowing. This procedure involves passing a balloon into the narrowed segment and inflating the balloon to push the artery open. In addition to this, a cylindrical piece of metal mesh called a stent may be inserted at the site where the artery has been pushed open with the aim of holding the narrowing open in the future. While stents work well in the arteries of the heart and other arteries, it is not clear whether adding stents following angioplasty to narrowings of the superficial femoral artery has any benefit to the patient.

The review authors identified eight randomised controlled trials with a total of 968 participants. Their average age was 67 and all trials included men and women. The participants were randomised to have either balloon angioplasty alone or balloon angioplasty with stent placement. At one year, blood flowing through the narrowing in the arteries was no greater in patients with a stent inserted when compared to those without. There was a small improvement in the distance that the patients with a stent could walk up to one year later. However, when asked about their quality of life there was no improvement, whether a stent was placed or not, up to one year later. There were differences in the included trials; in some trials patients with narrowings in other leg arteries were included. There were also differences in the blood thinning drugs given after stent placement between trials, which may change results as these agents are important in keeping stents working in other parts of the body. These factors led to the conclusion that there is a small benefit to adding a stent when performing balloon angioplasty in certain patients with superficial femoral artery narrowing. However, this could not be recommended as routine practice in all patients.

<http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD006767/frame.html>

Ginkgo biloba for intermittent claudication

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Abstract

Background

People with intermittent claudication suffer from pain in the muscles of the leg occurring during exercise which is relieved by a short period of rest. Symptomatic relief can be achieved by (supervised) exercise therapy and pharmacological treatments. Ginkgo biloba is a vasoactive agent and is used to treat intermittent claudication.

Objectives

To assess the effect of Ginkgo biloba on walking distance in people with intermittent claudication.

Search strategy

The Cochrane Peripheral Vascular Diseases (PVD) Group searched their Trials Register (last searched 3 February 2009) and the Cochrane Central Register of Controlled Trials

(CENTRAL) in *The Cochrane Library* (last searched 2009, Issue 1). We searched MEDLINE/PUBMED (January 1966 to May 2008) and EMBASE (January 1985 to May 2008) and contacted manufacturers.

Selection criteria

Randomised controlled trials of Ginkgo biloba extract, irrespective of dosage, versus placebo in people with intermittent claudication.

Data collection and analysis

Two authors independently assessed trials for selection, assessed study quality and extracted data. We extracted number of patients, mean walking distances or times and standard deviations. To standardise walking distance or time, caloric expenditures were used to express the difference between the different treadmill protocols, which were calculated from the speed and incline of the treadmill.

Main results

Fourteen trials with a total of 739 participants were included. Eleven trials involving 477 participants compared Ginkgo biloba with placebo and assessed the absolute claudication distance. Following treatment with Ginkgo biloba at the end of the study the absolute claudication distance increased with an overall effect size of 3.57 kilocalories (confidence interval -0.10 to 7.23, $P = 0.06$), compared with placebo. This translates to an increase of just 64.5 (confidence interval -1.8 to 130.7) metres on a flat treadmill with an average speed of 3.2 km/h. Publication bias leading to missing data or "negative" trials is likely to have inflated the effect size.

Authors' conclusions

Overall, there is no evidence that Ginkgo biloba has a clinically significant benefit for patients with peripheral arterial disease.

Plain language summary

Ginkgo biloba for people with leg pain while walking (intermittent claudication)

The main symptom of peripheral arterial disease is leg pain in one or both calves while walking. Typically, this pain occurs during walking and is relieved by a short period of rest. This clinical phenomenon is called intermittent claudication. Peripheral arterial disease is caused by progressive narrowing of the arteries in one or both legs and is a manifestation of systematic atherosclerosis, possibly leading to cardiovascular events. Conservative treatment consists of treatment for cardiovascular risk factors and symptomatic relief by exercise therapy and pharmacological treatments. One of the pharmacotherapeutical options is Ginkgo biloba extract, which is derived from the leaves of the Ginkgo biloba tree and has been used in traditional Chinese medicine for centuries. It is a vasoactive agent which is believed to have a positive effect on walking ability in patients with peripheral arterial disease. This review shows that people using Ginkgo

biloba could walk 64.5 metres further, which was a non-significant difference compared with the placebo group. Overall, there is no evidence that Ginkgo biloba has a clinically significant benefit for patients with peripheral arterial disease.

<http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD006888/frame.html>

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