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Abstract. Antiplatelet agents for preventing thrombosis after peripheral arterial bypass surgery.

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Date of most recent substantive amendment: 31 March 2003

Peripheral arterial disease (PAD) may cause occlusions in the main arteries of the lower limbs. It is frequently treated by implantation of either an infrapopliteal autologous venous or artificial graft. A number of factors influence occlusion rates, including the material used. To prevent graft occlusion, patients are usually treated with either an antiplatelet or antithrombotic drug, or a combination of both.

Objectives

To evaluate whether antiplatelet treatment in patients with symptomatic PAD undergoing infrapopliteal bypass surgery improves graft patency, limb salvage and survival.

Search strategy

The reviewers searched the Cochrane Peripheral Vascular Diseases Group Specialised Register, (last searched April 2003), and the Cochrane Central Register of Controlled Trials (CENTRAL) (last searched Issue 1, 2003). Additional trials were sought through reference lists of papers and by reviewing proceedings from vascular surgical society meetings.
Selection criteria

The methodological quality of each trial was assessed independently by two reviewers with emphasis on concealment of randomisation.

Data collection and analysis

Details of the studies selected were extracted independently by two reviewers and an ‘intention-to-treat’ analysis performed. The treatment and control groups were compared for important prognostic factors and differences described. If any data were not available, further information was sought from the author. Data were synthesized by comparing group results.

Main results

The administration of a variety of platelet-inhibitors resulted in improved venous and artificial graft patency compared to no treatment. However, analysing patients for graft-type indicated that patients receiving a prosthetic graft were more likely to profit from administration of platelet-inhibitors than those treated with a venous graft.

Reviewers’ conclusions

Antiplatelet therapy with aspirin had a slight beneficial effect on the patency of peripheral bypasses, but seemed to have an inferior effect on venous graft patency compared to no treatment. However, analysing patients for graft-type indicated that patients receiving a prosthetic graft were more likely to profit from administration of platelet-inhibitors than those treated with a venous graft.

Abstract. Antithrombotic agents for preventing thrombosis after infrainguinal arterial bypass surgery.

J. Dörfler-Melly, H.R. Büller, M.M. Koopman, M.H. Prins

Date of most recent substantive amendment: 2 December 2002

Background

Peripheral arterial disease (PAD) is frequently treated by either an infrainguinal autologous or artificial graft. The rate of occlusion after one year is between 15 and 75%. To prevent occlusion, patients are treated with an antiplatelet or antithrombotic drug, or a combination of both. Little is known about which drug is optimal to prevent infrainguinal graft occlusion.

Objectives

To evaluate whether antithrombotic treatment improves graft patency, limb salvage and survival in patients with chronic PAD undergoing infrainguinal bypass surgery.

Search strategy

The search strategy was that adopted by the Cochrane Review Group on Peripheral Vascular Diseases. Reference lists of papers resulting from the searches were also reviewed.

Selection criteria

Two reviewers independently assessed methodological quality of each trial using a standardised checklist, with emphasis on concealment of randomisation.

Data collection and analysis

An ‘intention to treat’ analysis was performed. Data collected included patient details, inclusion and exclusion criteria, type of graft, antithrombotic therapy, outcomes, and side effects. Treatment and control groups were compared for important prognostic factors and differences described. Missing data were sought from trial authors. Heterogeneity between trials could not be tested due to inaccessible data. Data were synthesized by comparing group results.

Main results

Four trials evaluating vitamin K antagonists (VKA) versus no VKA indicated that oral anticoagulation may favour venous but not artificial graft patency, as well as limb salvage and survival. Two other studies comparing VKA with aspirin or aspirin/dipyridamole supported evidence for a positive effect of VKA on the patency of venous but not artificial grafts. Subgroup analysis for artificial grafts as performed in one trial showed a favourable effect of antiplatelet agents on synthetic bypasses. In two trials, a small number of patients treated with low molecular weight heparin showed a lower incidence of early postoperative graft occlusion.
thrombosis compared to unfractionated heparin. In one trial, infusion of antithrombin concentrate was reported to have a negative effect on intraoperative graft thrombosis requiring the study to be stopped before completion. Perioperative administration of ancrrod showed no greater benefit when compared to unfractionated heparin.

Reviewers’ conclusions

Patients undergoing infrainguinal venous graft procedures might benefit from treatment with VKA, whereas patients receiving an artificial graft might profit more from platelet inhibitors (aspirin). However, the evidence is not conclusive. Randomised controlled trials with larger patient numbers comparing antithrombotic therapies with either placebo or antiplatelet therapies are needed in the future.

Abstract. Balloon angioplasty versus medical therapy for hypertensive patients with renal artery obstruction

A.J. Nordmann, A.G. Logan

Date of most recent substantive amendment: 3 May 2003

Background

Atherosclerotic renal artery stenosis is the most common cause of secondary hypertension. Balloon angioplasty is widely used for the treatment of hypertensive patients with renal artery stenosis.

Objectives

To compare the effectiveness of balloon angioplasty (with and without stenting) with medical therapy on blood pressure control, renal function, frequency of renovascular complications, and side effects in hypertensive patients with atherosclerotic renal artery stenosis.

Search strategy

MEDLINE, EMBASE, Science Citation Index, the Cochrane Central Register of Controlled Trials, and personal files were searched to identify randomised controlled trials (RCTs) comparing balloon angioplasty with medical therapy in hypertensive patients with renal artery stenosis. Bibliographies resulting from the searches were also reviewed, and authors of published trials were contacted for more information.

Selection criteria

RCTs comparing balloon angioplasty with medical therapy in hypertensive patients with haemodynamically significant renal artery stenosis (greater than 50 per cent reduction in luminal diameter) and minimal follow-up of six months).

Data collection and analysis

Two investigators independently extracted data on trial design, participants, interventions, and outcome measures. Data quality precluded a formal meta-analysis to assess the effect on blood pressure, renal function, number and defined daily doses of antihypertensive drugs. Peto’s odds ratios (OR), and corresponding 95% confidence intervals (CI) were calculated for dichotomous outcomes, e.g. vessel patency and renovascular complications.

Main results

Three RCTs involving 210 patients met the inclusion criteria. In unselected patients there was a consistent, but statistically non significant trend towards lower blood pressure in the balloon angioplasty group. Patients treated with balloon angioplasty required less antihypertensive drugs in two trials, and were more likely to have patent renal arteries after 12 months (OR 4.2, 95% CI 1.8 to 9.8). There were no differences in renal function. There were significantly fewer cardiovascular and renovascular complications in patients treated with angioplasty (OR 0.32, 95% CI 0.15 to 0.70, test for heterogeneity $p > 0.1$).

Reviewers’ conclusions

Available data are insufficient to conclude that balloon angioplasty is superior to medical therapy in lowering blood pressure of patients with renal artery stenosis and pharmacologically controlled blood pressure. Where hypertension is refractory to medical therapy, there is weak evidence that balloon angioplasty lowers blood pressure more effectively than medical therapy. Balloon angioplasty appears to be safe and shows fewer cardiovascular and renovascular complications. Randomised controlled trials are needed to compare the effect of balloon angioplasty and medical therapy on the preservation of renal function in the long term.
Abstract. Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia
D.T. Ubbink, H. Vermeulen

Date of most recent substantive amendment: 8 April 2003

Background

Patients suffering from inoperable chronic critical leg ischaemia (NR-CCLI), face amputation of the leg. Spinal cord stimulation (SCS) has been proposed as a helpful treatment in addition to standard conservative treatment.

Objectives

To find evidence for an improvement of limb salvage, pain relief and clinical situation using SCS compared to conservative treatment alone.

Search strategy

The reviewers searched the Cochrane Peripheral Vascular Diseases Group Specialised Register, (last searched November 2002), the Cochrane Central Register of Controlled Trials (CENTRAL) (last searched Issue 4, 2002). Additional data were obtained from research institutes.

Selection criteria

Controlled studies comparing additional SCS with any form of conservative treatment in patients with NR-CCLI.

Data collection and analysis

Two reviewers independently assessed the quality of the studies and extracted the data.

Main results

Six studies comprising nearly 450 patients were included. In general the quality of the studies was good, although none of them was blinded due to the nature of the intervention.

Limb salvage after 12 months was significantly higher in the SCS group (risk ratio (RR) 0.71, 95% confidence intervals (CI) 0.56 to 0.90; risk difference (RD) −0.13, 95% CI −0.22 to −0.04). Significant pain relief occurred in both treatment groups, but was more prominent in the SCS group, in which the patients required significantly less analgesics. In the SCS group significantly more patients reached Fontaine stage II than in the conservative group (RR 4.9, 95% CI 2.0 to 11.9; RD 0.33, 95% CI 0.19 to 0.47). Overall, no significantly different effect on ulcer healing was observed between the two treatments.

Complications of SCS treatment consisted of implantation problems (9%; 95% CI 4 to 15%) and changes in stimulation requiring re-intervention, (15%; 95% CI 10 to 20%). Infections of the lead or pulse generator pocket occurred less frequently (3%; 95% CI 0 to 6%). The overall risk of complications of additional SCS treatment was 17%, 95% CI 12 to 22%, indicating a number needed to harm of six (95% CI 5 to 8).

A cost comparison was made in only one study. The average overall costs at two years were 36,500 Euros, (SCS group) and 28,600 Euros, (conservative group). The difference (7900 Euros) was significant ($p < 0.009$).

Reviewers’ conclusions

There is evidence to favour SCS over standard conservative treatment to improve limb salvage and clinical situation in patients with NR-CCLI. The benefits of SCS against the possible harm of relatively mild complications, and costs must be considered.

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