Cochrane Collaborative Review Group on Peripheral Vascular Diseases: Review Abstracts

Introduction

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The following abstracts are part of an ongoing quarterly series of articles produced by the Cochrane Collaborative Review Group on Peripheral Vascular Diseases. The reviews are published in full on the Cochrane Library, a quarterly electronic journal available on CD ROM. This format allows Cochrane reviews to accommodate new data as it becomes available, making the library a consistently up-to-date source of information over time.

If you are interested in writing a Cochrane review or becoming a member of the Peripheral Vascular Diseases Group please contact:

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Any comments or criticisms on Cochrane PVD reviews/abstracts should be made through the comments/criticisms facility on the Cochrane Library, or by contacting the group directly at the above address.

Key areas for review
- Thrombolysis for critical limb ischaemia
- Laser versus other types of angioplasty
- Antibiotics for bypass surgery
- Antibiotics for amputations
- Rutosides for chronic venous insufficiency
- Surgery for PAOD
- Vasodilators for peripheral arterial disease
- Compression stockings for the prevention of DVT
- Prostanoids for the treatment of arterial/mixed ulcers
- Calcium antagonists for Raynaud’s disorder
- Sclerotherapy for varicose veins
- Steroids, cyclophosphamide and plasma exchange for Polyarteritis Nodosa

Reviews in progress
- Optimum conduit for femoro-popliteal bypass grafting
- Grafts used in abdominal aortic aneurysm repair
- IV fluids in abdominal aortic surgery
- Fibrinolytic agents for thrombolysis of arterial and graft occlusion
- Surgery versus thrombolysis for acute limb ischaemia
- Surgical treatment of deep venous incompetence
Abstract: Angioplasty (Versus Non-surgical Management) for Intermittent Claudication
F.G.R. Fowkes and I.N. Gillespie

Date of most recent substantive amendment: 19 February 1998

Objectives
To determine if angioplasty of arteries in the leg is more effective than non-surgical therapy or no therapy in patients with mild to moderate intermittent claudication.

Search Strategy
Trials were identified using the search strategy of the Peripheral Vascular Diseases Review Group, reviewing lists in papers and conference proceedings, and corresponding with selected authors.

Selection Criteria
Trials were selected for inclusion by one reviewer and comprised only trials of mild or moderate intermittent claudication in which patients were randomly allocated to angioplasty or conservative treatment. Lesions amenable to angioplasty had to be demonstrated on angiography or duplex scanning.

Data Collection and Analysis
Data from each trial were obtained by one reviewer and included the following outcomes: treadmill walking distances, ankle brachial pressure index, duplex scanning results, complications of angioplasty and quality of life.

Main Results
Data were obtained from two trials. At 6 months of follow-up, mean ankle brachial pressure indices were higher in the angioplasty groups than control groups. WMD 0.17 (95% confidence interval (CI) 0.11, 0.24). In one trial walking distances were greater in the angioplasty group, but in the other trial in which controls underwent an exercise programme, walking distances did not show a greater improvement in the angioplasty group. At 2 years of follow-up in one trial the angioplasty group were more likely to have a patent artery, OR 5.5 (95% CI 1.8, 17.0) but not a significantly better walking distance or quality of life. In the other trial, long-term follow-up at 6 years demonstrated no significant differences in outcome between the angioplasty and control groups.

Conclusions
These limited results suggest that angioplasty may have had a short-term benefit, but this may not have been sustained. Further large scale trials are required. Meanwhile, widespread use of angioplasty for mild to moderate claudication cannot be recommended.

Abstract: Fixed dose subcutaneous low molecular weight heparins versus adjusted dose unfractionated heparin for venous thromboembolism
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Date of most recent substantive amendment: 14 January 1998

Objectives
To evaluate the efficacy and safety of fixed-dose subcutaneous low molecular weight heparins compared to adjusted dose intravenous or subcutaneous unfractionated heparin for the initial treatment of patients with acute deep venous thrombosis or pulmonary embolism.

Search Strategy
Computerised searches of MEDLINE, EMBASE and LilACS, and hand-searching relevant journals for all publications describing randomised clinical trials of low molecular weight heparins in the treatment of venous thromboembolism. Additionally, randomised clinical trials were searched through personal communication with colleagues and representatives of pharmaceutical companies.
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Selection Criteria

Only truly randomised clinical trials comparing fixed-dose subcutaneous low molecular weight heparin with adjusted dose intravenous or subcutaneous unfractionated heparin in patients with venous thromboembolism were included.

Data Collection and Analysis

The search strategy, the inclusion of studies, and the evaluation of outcome data on the change in venographic score comparing pre- and post-treatment venograms, the incidence of symptomatic recurrent venous thromboembolism during initial treatment and during follow-up, the frequency of major haemorrhagic episodes during the initial treatment period, and the overall mortality at the end of follow-up were performed by two independent reviewers.

The main analysis included all trials in patients with venous thromboembolism. Additional analyses were done for specific groups of patients including (i) patients with proximal deep venous thrombosis; (ii) patients with pulmonary embolism; and (iii) patients with malignant disease.

Main Results

Compared to the current standard therapy with unfractionated heparin in patients with venous thromboembolism, the therapy with low molecular weight heparin demonstrated a statistically non-significant reduction in recurrent venous thromboembolism of approximately 25% during the initial treatment, at 3 or 6 months’ follow-up, or at the end of follow-up. At the end of follow-up 76 (4.2%) of the 1803 patients allocated to low molecular weight heparin had thrombotic complications versus 101 (5.6%) of the 1816 patients allocated to unfractionated heparin (OR 0.75; 95% confidence interval (CI) 0.55–1.01). Of the patients included in this analysis, approximately 25% had pulmonary embolism. A statistically significant difference in venographic outcome was demonstrated in favour of low molecular weight heparin. A reduction of the thrombus size on venogram occurred in 62% of low molecular weight heparin treated patients and in 53% of patients treated with unfractionated heparin. The observed reduction with low molecular weight heparin in the frequency of major haemorrhagic episodes during the initial treatment was also statistically significant. At the end of the initial period 23 (1.1%) of the 2158 patients in the low molecular weight heparin group versus 43 (2.0%) of the 2196 patients in the unfractionated heparin group suffered a major haemorrhage. At the end of follow-up in the low molecular weight heparin group, 94 (5.2%) of the 1803 patients had died versus 125 (6.9%) of the 1816 patients in the unfractionated heparin group. This was also a statistically significant reduction.

The analysis of studies in patients with proximal deep venous thrombosis (five studies, 1636 patients) showed a statistically significant reduction in the incidence of recurrent venous thromboembolic events at the end of follow-up in favour of low molecular weight heparin (OR 0.60; 95% CI 0.40–0.89). At the end of follow-up 39 (4.8%) of the 814 patients allocated to low molecular weight heparin versus 64 (7.8%) of the 822 patients in the unfractionated heparin group had a recurrent venous thromboembolic event. In this specific group of patients the reduction in the frequency of major haemorrhagic episodes and in the overall mortality with low molecular weight heparin was also statistically significant. In patients with pulmonary embolism, however, the reduction in recurrent venous thromboembolic events was relatively small, with a wide 95% confidence interval (OR 0.91, 95% CI 0.42–1.97).

The analysis of studies with reported adequate concealment of treatment allocation prior to randomisation (six studies, 3218 patients) demonstrated a statistically non-significant reduction in recurrent venous thromboembolism during the initial treatment, and a statistically non-significant reduction in overall mortality at the end of follow-up in favour of low molecular weight heparin treatment.

Conclusion

The efficacy and safety of low molecular weight heparin treatment in patients with deep venous thrombosis and/or pulmonary embolism was shown to be at least as effective as unfractionated heparin treatment. The outcomes concerning the safety of low molecular weight heparin, the occurrence of major haemorrhage during the initial treatment and overall mortality at the end of follow-up, demonstrated a statistically significant reduction in favour of low molecular weight heparin. We conclude that low molecular weight heparin can be safely adopted as the standard therapy in patients with deep venous thrombosis. Therefore, studies comparing the individual low molecular weight heparins with each other in these patients will be justified. Although the results in patients with pulmonary embolism are promising, it would be prudent to await further results of new studies.