Meta-analysis of femoropopliteal bypass grafts for lower extremity arterial insufficiency

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CRD summary
This review assessed the long-term effects of above and below knee saphenous vein grafts, and above knee femoropopliteal polytetrafluoroethylene grafts, in patients with claudication or critical ischaemia. It concluded that saphenous vein grafts should be used whenever possible. Given several limitations, such as difficulties accessing study details and limitations of the data from the included studies, the authors' conclusions may be unreliable.

Authors' objectives
To assess the long term effects of above and below knee femoropopliteal bypass grafts in patients with lower extremity arterial insufficiency (claudication or critical ischaemia).

Searching
MEDLINE (January 1986 to December 2004), EMBASE and LILACS were searched for articles written in English, German, French, Italian, Spanish or Portuguese; the search terms were provided. In addition, the bibliographies of retrieved articles were checked.

Study selection
Studies assessing above-knee femoropopliteal polytetrafluoroethylene bypass grafts (AK-Ps), or above-knee femoropopliteal saphenous vein bypass grafts (AK-Vs) or below-knee saphenous vein bypass grafts (BK-Vs), in patients with claudication or critical ischaemia, and presenting primary and secondary graft patency as life tables, survival curves or suitable texts, and reporting 1-year follow-up for some grafts, were eligible for inclusion. Studies were required to include a minimum of 30 bypasses in at least one series, if more than one series was described. Studies involving repeat bypasses, a predominance of blind segments of popliteal artery, or composite bypass grafts or bypasses to the infrapopliteal arteries, were excluded. Where reported, the included studies used a variety of graft surveillance tools and also reported the number of non-standard patencies, including primary assisted patency, inappropriate primary patency, or cumulative patency. Some studies also reported the following outcomes: early mortality for combined AK-V and BK-V, and for AK-P; effects of runoff; late use of a vein bypass after AK-Ps; percentage of AK-Ps becoming infected.

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The included studies were assessed for study quality, including items on follow-up, attrition rates, reporting of outcomes, presentation of life tables, and demographic profiles for certain data (as reported in the review). The studies were given an overall score out of 15.

The authors did not state how many reviewers performed the validity assessment.

Data extraction
Two reviewers independently extracted the data, including survival data. Non-standard patencies were converted into primary or secondary patencies, and hazard rates were then calculated for each graft type and each month of follow-up. Any disagreements were resolved through discussion.

Methods of synthesis
Pooled hazard rates were calculated using either a fixed-effect or random-effects model, where appropriate. Monthly hazard rates were combined and presented as cumulative primary and secondary patencies by graft type for each condition, along with standard errors (SEs).

The authors stated that heterogeneity was investigated, but no further details were provided. Sensitivity analyses were
conducted to assess the robustness of the analyses by excluding series that used non-standard patencies, included heterogeneous clinical symptoms, or used AK-P and had a quality score greater than 9 for primary patency or greater than 10 for secondary patency. Further sensitivity analyses were conducted using a fixed-effect model. To adjust for flat tails, one failure was added and then distributed in equal parts to the months in the flat tail, ultimately to identify changes in the pooled outcomes and statistical inferences.

Results of the review
Seventy-three studies were reported in the review (161 series, 18,677 grafts): 24 prospective studies (6 randomised controlled trials and 18 non-randomised controlled trials) and 49 retrospective trials. The number of grafts performed in each study ranged from 576 to 3,194.

The quality scores for the included studies ranged from 7 to 10 for studies assessing claudication, and from 6 to 9 for studies assessing critical ischaemia.

Claudication (7,144 grafts: 2,900 AK-P, 1,156 AK-V and 3,088 BK-V).
Primary patency was greater for patients receiving AK-V than for patients receiving AK-P at 3 to 5 years’ follow-up; hazard rate 77.2 (SE=6.4) at 5 years (p<0.05). There were no significant differences at any time point between AK-P and BK-V for primary patency, or between any groups for secondary patency.

Critical ischaemia (11,533 grafts: 4,532 AK-P, 1,366 AK-V and 5,635 BK-V).
Primary patency was greater for patients receiving AK-V compared with AK-P up to 4 years' follow-up (hazard rate at 4 years 72.6, SE=5.4; p<0.05) and greater for patients receiving BK-V compared with AK-P up to 5 years' follow-up (hazard rate at 5 years 68.9, SE=4.7; p<0.05). Secondary patency was greater at 2 to 4 years’ follow-up for AK-V compared with AK-P (hazard rate at 4 years 76.9, SE=6.3; p<0.05) and greater up to 5 years' follow-up for BK-V compared with AK-P (hazard rate at 5 years 77.8, SE=4.5; p<0.05).

Results for the claudication group were significantly altered when patients with critical ischaemia were removed, and differences between the AK-P and AK-V groups were no longer significant. Further sensitivity analyses were reported in the review.

Authors' conclusions
The performance of above and below knee saphenous vein grafts (AK-V and BK-V) is greater than that of AK-P grafts.

CRD commentary
The review question was clear and was supported by inclusion criteria, although these were somewhat limited for study design. A relevant literature search was conducted using three electronic databases and another appropriate source. However, the searches were restricted by language, which means that the potential for language bias cannot be ruled out. There was also no apparent search for unpublished material, so it is possible that relevant papers were missed. Validity was assessed, but details on how this was performed were limited. Furthermore, since details of the methods used to select the studies were not provided, the potential for reviewer error and bias cannot be ruled out. It was not possible to retrieve the online data on study and population characteristics, or data on within-study and between-study variances, thus it is unclear whether the population included were relevant to the review question and whether pooling of the results was appropriate. It might also have been more appropriate to quantify the survival data using hazard ratios with 95% confidence intervals rather than hazard rates. The authors mentioned several limitations of the included studies, such as the selective reporting of outcomes and use of non-standard patencies, which might have affected the subsequent data synthesis. Given these considerations and the difficulties accessing the study details, the authors' conclusions may be unreliable.

Implications of the review for practice and research
Practice: The authors stated that AK-V and BK-V should be used whenever possible, but AK-Ps should be considered when no suitable saphenous vein is available, at least until effective alternatives are established.
Research: Although the authors did not make any explicit recommendations for further research, they did highlight a number of limitations and shortfalls in the current evidence. Specifically, the use of retrospective designs; not separating clinical symptoms appropriately; reporting outcomes selectively; describing AK-Vs and BK-Vs together; not using standard patencies; describing a short follow-up; omitting losses to follow-up and their effect on graft patency; showing a flat tail in the survival curve; and not mentioning the post-operative use of duplex scans, which, by implication, should be considered when designing future studies.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.