Meta-analysis of polytetrafluoroethylene bypass grafts to infrapopliteal arteries

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CRD summary
This review assessed the effect of polytetrafluoroethylene (PTFE) bypass grafting to the popliteal arteries on long-term graft patency and foot preservation. PTFE bypass grafts to popliteal arteries have moderate success, but the effect of adjunctive procedures at the distal anastomosis is uncertain. Although not without some limitations, the evidence appears to support the authors' conclusions.

Authors' objectives
To determine the effect of polytetrafluoroethylene (PTFE) bypass grafting to the infrapopliteal arteries on long-term graft patency and foot preservation (FP).

Searching
PubMed was searched from January 1980 to December 2001, but only studies published from 1982 to 2001 were included; the search terms were stated. The reference lists of identified studies were also checked. The authors were prepared to consider articles published in Spanish, French, Italian or Portuguese, in addition to English.

Study selection
Study designs of evaluations included in the review
Studies that reported at least 15 cases were eligible for inclusion. All of the included studies were case series.

Specific interventions included in the review
Studies of PTFE bypass grafting to the infrapopliteal arteries were eligible for inclusion. The included studies used pure PTFE grafts and PTFE grafts with adjunctive procedures (including composite PTFE-vein grafts, patches, cuffs, arteriovenous fistulas, or two or more of these).

Participants included in the review
The inclusion criteria were not specified in terms of participants.

Outcomes assessed in the review
Studies that reported primary graft patency (PGP) or secondary graft patency (SGP) using survival analysis of any type were eligible for inclusion if the follow-up was for at least 2 years. The review defined PGP as uninterrupted patency with no further intervention in the graft or its anastomoses; SGP after graft occlusion was defined as restoration of patency with most of the original graft and at least one anastomosis retained in continuity. The review also assessed FP.

How were decisions on the relevance of primary studies made?
Three investigators selected the studies.

Assessment of study quality
Validity was assessed and scored using the following criteria: reason given for using PTFE; reported proportion of patients requiring PTFE graft; use of life tables rather than graphs; follow-up at 1-month intervals; reported losses to follow-up; PGP, SGP and FP described; demographic details linked to survival analysis; reported rates of previous operations and loss of tissue; use of post-operative anticoagulant therapy; reported perigraft infection; and reported further bypass grafting. Studies were awarded one point for each criterion, giving a maximum possible score of 14 points. The authors did not state who performed the validity assessment.

Data extraction
At least two reviewers independently extracted the data from standard life tables, actuarial survival curves, or Kaplan Meier survivor curves. The senior author checked all extracted data and resolved any differences. Attempts were made to avoid the inclusion of duplicated data. The authors of missing data were contacted, but the response was poor. Survival times and cumulated success rates were estimated for studies that only presented survival curves (the methods were described). For some studies, SGP rates were inferred from available data on PGP; SGP was assumed to be the same as the reported cumulative patency rates; FP rates were inferred from survivor curves for PGP or SGP; and PGP rates were inferred from SGP in two studies.

Data from studies that did not report outcomes at one month were only included in analyses from the second follow-up period onwards. For each study presenting adequate data, the success rates were calculated for each month of follow-up.

**Methods of synthesis**

How were the studies combined?
The data were pooled in a meta-analysis. A pooled weighted monthly success rate and 95% confidence interval (CI) was calculated using a random-effects model. A pooled cumulative success rate and 95% CI were also calculated. Details of the methods used were given. The Weibull model that best fitted the pooled survival curves was investigated. The possibility of publication bias was explored using a funnel plot.

How were differences between studies investigated?
Sensitivity analysis, inputing median values for PP, SP, and FP obtained from other studies into the Weibull model, was used to calculate the absolute decrease in graft failure at 5-year follow-up. The influence of rates of losses to follow-up was explored by assuming 60% of the grafts lost within the first year were additional failures, and that the relative risk for failure of below-knee popliteal grafts was 0.75 (details of the methods used were given). The influence of adjunctive procedures was explored by analysing data for PTFE grafts used with any adjunctive procedure and for PTFE grafts plus adjunctive procedures containing arteriovenous fistulas. The influence of study quality on the results was examined by analysing higher quality studies (scoring 7.5 or more on quality) separately. It was not possible to explore the influence of demographic and risk factors on the results, owing to insufficient studies.

**Results of the review**

Forty-three case series (3,600 patients) that assessed PGP were included. Thirty-five of these case series assessed SGP and 31 assessed FP.

The meta-analysis showed that PTFE grafts gave 5-year PGP rates of 30.5% (95% CI: 22.9, 38.2), SGP rates of 39.7% (95% CI: 28.9, 50.5) and FP rates of 55.7% (95% CI: 45.9, 65.5).

The funnel plot was symmetrical, suggesting that publication bias was unlikely.

The Weibull models adequately fitted the random-effects plots. The sensitivity analysis with the models showed an absolute decrease at the 5-year follow-up of 2.9% for PGP, 3.0% for SGP and 4.9% for FP. Assumptions about loss to follow-up were the main contributors to such decreases: 94% for PGP, 97% for SGP and 96% for FP.

The subgroup analyses showed that the pooled estimates were slightly higher for PTFE grafts with adjunctive procedures, compared with PTFE grafts alone. At 18 months, PGP was 56.8% (95% CI: 49.9, 63.6) for PTFE with adjunctive procedures (27 studies) versus 45.3% (95% CI: 35.8, 54.8) for PTFE alone (13 studies).

Higher quality studies showed higher rates of PGP and FP but not SGP (the results were reported).

**Authors’ conclusions**

PTFE bypass grafts to popliteal arteries have moderate success, but the effect of adjunctive procedures at the distal anastomosis is uncertain.
CRD commentary
The review question was clear in terms of the study design, intervention and outcomes. The inclusion criteria were not defined in terms of participants. Only one database was searched and this may have resulted in the omission of other relevant studies. In addition, no attempt was made to locate unpublished studies, thus raising the possibility of publication bias. Studies published in any of five languages were considered for inclusion and the search terms were stated. Three reviewers selected the studies, but it was unclear whether they selected the studies independently. At least two reviewers independently extracted the data, which reduces the potential for bias and errors. Validity was assessed and scored using defined criteria. However, the methods used to assess validity were not reported, so it is not known whether any efforts were made to reduce errors and bias.

Some relevant information on the included studies was tabulated, but no details of the patients' characteristics were given. Thus, it was not possible to judge whether the studies differed with respect to patient characteristics. The studies were appropriately combined in a random-effects meta-analysis. However, a considerable amount of data for the outcome measures of PGP, SGP and FP at differing time points was input. The authors acknowledged this as a limitation, but it is not possible to judge how these inferred values could impact on the results. The authors also based their analysis on the assumption that 60% of cases that were lost to follow-up represented failed grafts. No further analysis to test this assumption was undertaken. Sensitivity analyses were, however, used to test the robustness of the results and to explore the influence of study quality on the results. The authors also discussed some limitations of the review. The evidence appears to support the authors' conclusions, but these results may not apply to all populations in all settings.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that further studies are required to assess the place of adjunctive procedures.

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the reliability of the review and the conclusions drawn.