Results of aortic bifurcation grafts for aortoiliac occlusive disease: a meta-analysis

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Authors' objectives
To summarise mortality, morbidity, and long-term patency data of bifurcated aortoiliac or aortofemoral bypass graft procedures in aortoiliac occlusive disease.

Searching
MEDLINE was searched from January 1970 to June 1996 for studies published in the English language, using the combination of terms 'aorto' and 'patency'. References were sought in review articles, original studies and a vascular surgery textbook. Only the most recent publication from any institution was included, unless there was evidence that the patient populations did not overlap.

Study selection
Study designs of evaluations included in the review
Studies reporting long-term primary patency data of aortic bifurcation grafts were included if they fulfilled the following criteria:

results for patients who had aortoiliac occlusive disease were presented separately from those patients who had aneurysms and other indications;

the abdominal aorta was used for the proximal anastomosis;

the primary patency data were presented in a life table format that met the criteria of the International Society for Cardiovascular Surgery and used yearly (or smaller) intervals, or life tables could be reconstructed from the presented data;

the characteristics of the patients and studies were reported in sufficient detail to allow adjustment for the case-mix and the reporting methods in the analysis.

Specific interventions included in the review
Aortobifemoral, aortobiiliac, aortofemoral bypass grafts and other procedures, mostly endarterectomy, were included. The distal anastomoses studied included iliac and others.

Participants included in the review
Patients of both genders presenting with claudication or ischaemia. The mean age across the studies ranged from 45 to 68 years, and the proportion of females ranged from 1 to 68%.

Outcomes assessed in the review
The following outcomes were assessed:

operative mortality, defined explicitly as death within 30 days or otherwise;

systemic morbidity, defined as nonfatal damage or disease with a major health impact that is related to the procedure and involves any organ or tissue other than the peripheral arterial system or the surgical wound;

local morbidity, defined as nonfatal procedure-related damage or disease that involves the peripheral vascular system or the surgical wound, excluding early graft failures; and

patency, with the unit of observation being both the patient and limb.
How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
The authors do not state that validity was formally assessed, although aspects of validity were examined in the analysis.

Data extraction
Two authors independently extracted the mortality, morbidity, and life table data. Any discrepancies were resolved by discussion. Life tables were, where necessary, reconstructed from patency curves. The following data were extracted using a standard form: characteristics of study design; reporting methods; study population; intervention; operative mortality probabilities; systemic and local complication probabilities; and the definition used for mortality.

Methods of synthesis
How were the studies combined?
The morbidity and mortality risks were pooled using a fixed-effect model weighted for study size.

The patency data were aggregated using a meta-analytical technique that incorporated the following study characteristics as covariates: symptomatic status of patient before the intervention (claudication or critical ischaemia); and unit of observation (patient or limb). The methods used were described in an appendix and referenced (see Other Publications of Related Interest).

How were differences between studies investigated?
Sensitivity analyses were undertaken to examine the effect of alternative modelling assumptions on the aggregated patient estimates and the goodness of fit of the model. The analysis of the patency rates was repeated for the following subgroups:

- studies starting before 1975 versus studies starting after 1975 (same number of studies in each group);
- country, i.e. North America versus Europe;
- average age of study population, i.e. more than 55 years versus a younger age;
- the proportion of women, i.e. more than 30% versus others;
- the inclusion of procedures other than aortic bifurcation graft versus non inclusion;
- arteries used for distal anastomosis, i.e. femoral only versus mixed iliac and femoral.

The comparison of the aggregated patency data of the subgroups was based on the log-rank test.

Results of the review
Thirteen studies reporting patients as the unit of observation were included (6,250 patients). In addition, 12 studies reporting the limb as the unit of observation were included (11,474 limbs).

The male-to-female ratio differed markedly between the studies. The indication for operation was, in most studies, intermittent claudication. Few authors provided an explicit definition of the patency criterion used, and the definitions that were reported varied.

The pooled estimate of operative mortality risk from all studies was 4.4%. The pooled mortality estimate was 4.8% for those studies (N=10) reporting 30-day mortality rates versus 4.1% for other studies (P=0.13). The pooled mortality estimate was higher for studies starting before 1975 than for those starting at a later date, 4.6 and 3.3%, respectively.
The pooled risk estimate for systematic morbidity was 12.1%. The pooled risk estimate was higher for studies starting before 1975 than for those starting at a later date, 13.1 and 8.3%, respectively (P<0.001).

The pooled risk estimate for local morbidity was 7.6%. The pooled risk estimate was lower for studies starting before 1975 than for those starting at a later date, 6.7 and 11.4%, respectively (P<0.001).

The pooled patency curves, adjusted for symptomatic status for both patient-based and limb-based reporting, were presented. The 5-year limb-based patency rate was 91% for patients who had intermittent claudication, compared with 87.5% for those with critical ischaemia. The corresponding figures for patient-based data were 85.8 and 80.4%, respectively. An improved goodness of fit statistic was obtained after adjusting for symptomatic status and unit of observation.

Sensitivity analyses: estimates were stable after omitting each study in turn and after repeating the analysis with different assumptions about the withdrawals.

Subgroup analysis: there was no statistically-significant difference in the patency curves of a number of subgroups. These included: the year in which the study started (P=0.58); North America versus Europe (P=0.37); average age; gender ratio of the study population; use of iliac artery for distal anastomosis; and separate analysis of studies in which the results of aortic bifurcation grafts were mixed with those of a minority percentage of other procedures versus other studies.

**Authors' conclusions**

The analysis suggested a trend towards lower operative mortality and systemic morbidity rates.

No evidence was found of substantial worldwide improvement in the long-term patency rates over the years.

**CRD commentary**

This was a thoughtful, clearly written and presented review. The inclusion criteria and the definition of the outcomes were clearly stated. The stability of the results were verified by several sensitivity analyses, exploring the effect of using different assumptions. Analyses were performed using both limb- and patient-based data. Some characteristics of the included studies were tabulated. The methods used to extract the data were described. Potential sources of bias in the review were discussed. These included the following: differences between studies that were not accounted for; problems with the reconstruction of life study tables from patency curves in the primary studies; the lack of an explicit definition of the patency criteria used; variability in definitions used for patency and morbidity; overlap of studies begun but not completed before 1975; more conscientious documentation of morbidity in recent years; and studies reporting results for a mixture of procedures.

By limiting the literature search to studies published in the English language, as retrieved from one database, other relevant studies may have been omitted. Fifty of the 88 studies retrieved were excluded because it was not possible to reconstruct a life table from the data reported. The validity of the studies was not formally assessed, though various aspects of it were examined in the analysis. The methods used to select the studies for inclusion were not stated.

The authors' conclusions are supported by the evidence presented.

**Funding**

Netherlands Organization for Scientific Research.

**Bibliographic details**

PubMedID
9357455

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Aged; Aorta, Abdominal /surgery; Arterial Occlusive Diseases /surgery; Blood Vessel Prosthesis Implantation /mortality; Female; Humans; Iliac Artery /surgery; Intermittent Claudication /surgery; Ischemia /surgery; Leg /blood supply; Life Tables; Male; Middle Aged; Risk Factors; Vascular Patency

AccessionNumber
11997001402

Date bibliographic record published
30/06/1999

Date abstract record published
30/06/1999

Record Status
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.