A systematic review of randomized trials comparing revascularisation rate and graft patency of off-pump and conventional coronary surgery

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CRD summary
This review concluded that patients undergoing off-pump coronary surgery had a lower rate of revascularisation and lower graft patency than patients undergoing conventional coronary surgery. The review has some methodological weaknesses and the generalisability of the results is potentially hindered by limited study details.

Authors' objectives
To evaluate the impact of off-pump coronary surgery on completeness of revascularisation and graft patency compared with conventional surgery.

Searching
MEDLINE (1966 to October 2005), EMBASE (1974 to October 2005) and the Cochrane Library (Issue 4, 2005) were searched; the search terms were reported. Handsearches of abstracts from major cardiology and cardiothoracic surgery scientific meetings (2003 to 2005) were also conducted. The reference lists of relevant studies were reviewed and authors of previous trials contacted.

Study selection

Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies evaluating off-pump coronary surgery in comparison with conventional surgery were eligible for inclusion. Trials of selective coronary angiography were excluded from the review. The authors did not define the term 'conventional surgery'.

Participants included in the review
Studies of patients undergoing off-pump coronary surgery were eligible for inclusion. Details of the participants included were not presented.

Outcomes assessed in the review
Studies that assessed revascularisation and vascular graft patency as primary outcomes were eligible for inclusion. If the same patient population appeared in other publications, the article providing the most complete follow-up angiographic data was selected. If vascular graft patency was assessed on more than one occasion, the results at the longest follow-up were used in the analysis. Graft patency was evaluated by angiography in all studies included in the review.

How were decisions on the relevance of primary studies made?
Two reviewers independently assessed studies for inclusion and any disagreements were resolved by consensus.

Assessment of study quality
The authors reported that studies were assessed on the basis of blind assessment of the outcome, expertise of the surgeons and the number of patients undergoing angiography. The authors did not report how the validity assessment was performed.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. [A: Three reviewers extracted the data using a standardised questionnaire. Disagreements were resolved by consensus.] Where mean values were reported, the results were transformed into absolute numbers by multiplication with the total number of patients who underwent angiography.

**Methods of synthesis**

**How were the studies combined?**
Meta-analysis was conducted using a fixed-effect model. Sensitivity analyses were conducted using a random-effects model, excluding data from abstracts and using early data in trials that reported more than one time point for graft patency.

**How were differences between studies investigated?**
Statistical heterogeneity was assessed using the chi-squared and I-squared tests.

**Results of the review**
Seven RCTs (n=1,448) were included in the review (the number of patients ranged from 104 to 400). The average angiographic follow-up time in the included studies varied from less than 21 days to 450 days.

Quality appraisal and study characteristics.

The number of participating surgeons varied (from 1 to 5) between studies, where reported. Analysis of the primary studies was by intention-to-treat in 6 trials. Intention-to graft with a pre-specified index was stated in 3 trials. Blind assessment of the outcome was stated in 5 trials. Graft method varied between studies. In most studies not all patients underwent angiography, which was used to evaluate graft patency.

Graft patency.

Initial analysis of all included trials found that patients receiving off-pump coronary surgery had a lower graft patency than patients receiving conventional surgery; the relative risk (RR) was 0.959 (95% confidence interval, CI: 0.936, 0.983, p=0.001). Evidence of clinical and statistical heterogeneity was present (chi-squared test p<0.001; variation in RR attributable to heterogeneity using I-squared test, 78.4%). After examination of heterogeneity, 1 trial that used exclusive composite inflow grafting was excluded from further analyses of graft patency. The remaining 6 trials found that patients receiving off-pump coronary surgery had a lower graft patency than those undergoing conventional surgery (RR 0.953, 95% CI: 0.927, 0.980, p<0.001). There was no further evidence of heterogeneity (chi-squared test, p=0.374). Sensitivity analyses produced similar results.

Revascularisation.

Patients receiving off-pump coronary surgery received fewer grafts than those undergoing conventional coronary surgery; the standardised mean difference was -0.164 (95% CI: -0.286, -0.043, p=0.008) in the 6 trials. There was no evidence of statistical heterogeneity (I-squared 0%).

**Authors’ conclusions**
Patients undergoing off-pump coronary surgery had a lower rate of revascularisation and lower graft patency than patients undergoing conventional coronary surgery.

**CRD commentary**
Inclusion criteria were stated clearly for the study design and outcomes, but not participants, and conventional coronary surgery was not defined. The authors searched a range of databases and also sought unpublished studies, thus limiting the risk of publication bias and maximising the likely retrieval of available data. Methods were used to minimise errors and bias in the selection of studies and data extraction. The authors did not report how the validity assessment was carried out, and it is therefore possible that reviewer error or bias may be present.
Details of the included studies were presented but there was no information on the patient population. The method of combining the studies was appropriate. The authors noted limitations in the study design which limit the generalisability of the study to wider clinical use. The review contains some methodological weaknesses and the generalisability of the results is potentially hindered by limited study details.

Implications of the review for practice and research
Practice: The authors stated that the potential benefits of off-pump coronary surgery need to be interpreted in view of reduced revascularisation, reduced graft patency, the impact of reduced graft patency on long-term survival, and the reported increase in repeat interventions. Practitioners should be encouraged to audit the outcomes as evidence from existing RCTs may not be generalisable because of the small number of surgeons undertaking this intervention.

Research: The authors stated that further trials should consider calculating sample size on the basis of equivalence design, as opposed to a noninferiority design. Further trials would help evaluate whether comparative patency improves with time and whether the review findings remain consistent with future results from practice.

Bibliographic details

PubMedID
17140968

DOI
10.1016/j.jtcvs.2006.08.012

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Coronary Artery Bypass, Off-Pump; Humans; Myocardial Revascularization; Randomized Controlled Trials as Topic; Vascular Patency

AccessionNumber
12006009436

Date bibliographic record published
31/03/2008

Date abstract record published
31/03/2008

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.