**Pulsatile versus nonpulsatile cardiopulmonary bypass flow: an evidence-based approach**

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**CRD summary**

The authors concluded that conflicting or insufficient evidence made it impossible to make recommendations about the routine use of pulsatile perfusion in patients undergoing elective coronary artery bypass grafting. The authors’ cautious conclusions appear appropriate given the limited evidence, but the lack of duplication in the review process makes it difficult to confirm the reliability of these conclusions.

**Authors’ objectives**

To evaluate the effects of pulsatile perfusion (PP) in patients undergoing elective coronary artery bypass grafting surgery (CABG).

**Searching**

MEDLINE, EMBASE and the Cochrane Controlled Trials Register were searched from inception to March 2005 for published studies. The search terms were reported and no language restrictions were applied. Reference lists were also screened.

**Study selection**

**Study designs of evaluations included in the review**

Randomised controlled trials (RCTs), non-randomised controlled clinical trials, case-control studies and cohort studies were eligible for inclusion in the review of efficacy. Case series and case reports could also be included in the assessment of adverse effects.

**Specific interventions included in the review**

Studies that compared a specified technique of PP with continuous or nonpulsatile perfusion (NPP) were eligible for inclusion in the review.

**Participants included in the review**

Studies of adults (aged over 18 years) undergoing elective CABG were eligible for inclusion in the review. Studies of patients undergoing emergency surgery were excluded.

**Outcomes assessed in the review**

Studies that specifically reported outcomes of interest during the hospital stay and used valid methods to measure these outcomes were eligible for inclusion. The primary review outcomes were total all-cause in-hospital mortality, myocardial infarction (MI), stroke and renal failure. MI was defined as new Q-wave and raised cardiac enzymes; stroke was defined as focal neurological deficit confirmed by brain imaging; renal failure was defined as the need for dialysis. The review also assessed adverse effects.

**How were decisions on the relevance of primary studies made?**

One reviewer selected studies for inclusion.

**Assessment of study quality**

The authors did not state how the validity assessment was performed.

Validity was assessed using criteria described by the United States Preventive Services Task Force (USPSTF) and the Canadian Task Force on Preventive Health Care (CTFPHC). RCTs and cohort studies were assessed for: baseline and maintenance of comparability of treatment groups; clear definition of intervention and outcomes; measurement of outcomes using valid and reliable measures; avoidance of cointerventions or similar cointerventions used in all groups;
adequate follow-up; and adequate power to detect a difference for all reported outcomes. RCTs were additionally assessed for adequacy of randomisation and intention-to-treat analysis. Based on these criteria, RCTs and cohort studies were classified as good, fair or poor quality (details of the classification system were reported).

Data extraction
One reviewer extracted the data using a predesigned form. Authors were contacted if required. For each study, the number of events of interest in each treatment group was extracted along with the level of statistical significance of treatment differences. If studies evaluated multiple treatment arms, data were extracted on comparisons between PP and NPP if possible.

Methods of synthesis
How were the studies combined?
The studies were grouped by outcome and study design and combined in a narrative.

How were differences between studies investigated?
Differences between the studies were discussed with respect to study quality.

Results of the review
Eight controlled studies (n=2,503) were included: 4 RCTs (n=554) and 4 non-randomised controlled studies (n=1,949).

One RCT and a controlled study were classified as fair quality; the other 6 studies (3 RCTs and 3 controlled studies) were classified as poor quality (full details of the quality assessment were reported).

Mortality (4 RCTs and 4 controlled studies).

The fair-quality RCT reported a significant reduction in hospital mortality in patients given PP compared with NPP: 1 (0.6%) out of 158 patients versus 8 (5.1%) out of 158 patients (p=0.018). The fair-quality controlled study reported a significant reduction in unadjusted hospital mortality in patients given PP compared with those given NPP (2.6% versus 1.55%, p<0.05), but after adjustment for confounding variables the difference was no longer statistically significant.

The 3 poor-quality RCTs and 3 poor-quality controlled studies reported no significant difference between treatments but were underpowered.

MI (3 RCTs and 1 controlled study).

The fair-quality RCT reported a significant reduction in MI in patients given PP compared with NPP: 1 (0.6%) out of 159 patients versus 9 (5.7%) out of 159 patients (p=0.01).

The 2 poor-quality RCTs and the fair-quality controlled study reported no significant difference between treatments; the 2 RCTs were underpowered.

Stroke (1 RCT and 1 controlled study).

Neither the RCT (rated fair overall but not powered to detect a difference in stroke) nor the fair-quality controlled study (after adjustment for confounding variables) reported any significant difference between treatments.

Renal failure (1 controlled study).

The fair-quality controlled study reported no significant difference between treatments after adjustment for confounding variables.

Adverse effects. One poor-quality RCT reported a significantly higher plasma haemoglobin level in patients given PP compared with NPP (80 mg/dL versus 56 mg/dL, p<0.01), but no significant difference in platelet levels.
The review stated that the other included studies did not report side-effects of PP.

**Authors' conclusions**
The evidence about the effects of PP on mortality and MI was conflicting and there was insufficient evidence about stroke and renal failure. It was therefore not possible to advise for or against the routine use of PP.

**CRD commentary**
The review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched, attempts were made to reduce language bias, but only published studies were included and this might have led to the omission of other relevant studies and publication bias. The lack of duplication in the study selection and data extraction processes left the review vulnerable to reviewer errors and bias. Validity was assessed using specified criteria and the results of the assessment were reported.

In view of the differences between the studies, a narrative synthesis that took account of study quality was appropriate. Apart from the lack of duplication in the review process, this review was well conducted and generally clearly reported. The review reported positive results in some studies and no significant treatment differences (possibly due to small sample size) in others, rather than conflicting results (that would tend to indicate a combination of significantly positive and significantly negative results). Otherwise, the cautious conclusion appears appropriate.

**Implications of the review for practice and research**
Practice: The authors stated that it was not possible to make recommendations about the routine use of PP based on the review findings.

Research: The authors stated that large good-quality RCTs are needed to examine the early and late effects of PP on relevant clinical outcomes and to identify any subgroups of patients that may benefit.

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