Preoperative intra-aortic balloon pump in patients undergoing coronary bypass surgery: a systematic review and meta-analysis

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CRD summary
The authors concluded that preoperative intra-aortic balloon pump reduces mortality in high-risk patients undergoing coronary bypass surgery, with an acceptable complication rate. The review was well conducted in most respects with fairly consistent findings. However, as the volume of randomised evidence was small and study quality was suboptimal, a degree of caution might be required in interpreting these conclusions.

Authors' objectives
To assess the effectiveness of preoperative intra-aortic balloon pump (IABP) for patients undergoing coronary bypass surgery (CABG).

Searching
The following databases were searched: MEDLINE (1966 to January 2005), EMBASE (1980 to January 2005) and the Cochrane Central Register of Controlled Trials. Search terms were reported. The references of reviews and articles retrieved were hand searched and experts in the field were consulted.

Study selection
Randomised controlled trials (RCTs) and controlled cohort studies of preoperative IABP in adults (aged over 18 years) undergoing elective or urgent CABG were eligible for inclusion. Studies were required to report hospital mortality (death during index hospitalisation), which was the primary review outcome. Secondary outcomes were IABP-related complications (bleeding, leg ischaemia, aortic dissection). Controls were required to receive no preoperative IABP, but could receive intraoperative or postoperative IABP.

Participants in the included studies had risk factors such as reduced left ventricular ejection fraction (25% to 40% or less), left main coronary artery stenosis (over 70%), unstable angina and/or need for repeat CABG. The control groups in two cohort studies included patients needing emergency intraoperative or postoperative IABP. IABPs were inserted percutaneously in most cases. The timing of placement varied. Some controls received no IABP and others received intraoperative/postoperative IABP. Cointerventions commonly included inotropic and other drugs (where described). One study was excluded due to the nature of cointerventions used and the high proportion of IABP placement in controls.

Two reviewers independently selected studies for inclusion, with disagreements resolved by discussion and consensus.

Assessment of study quality
The following criteria were used to assess study validity: design, direction of inquiry (i.e. prospective or retrospective), quality of reporting of demographic data and intervention and (for RCTs) Jadad’s scale, which measures adequacy of randomisation, blinding, and management of withdrawals and drop-outs. Validity assessment was conducted by two reviewers, with disagreements resolved by discussion and consensus.

Data extraction
Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated from the numbers of events in the control and intervention groups of each study. Two reviewers independently extracted the data in a standardised format, with disagreements resolved by discussion and consensus.

Methods of synthesis
Studies were combined using a random effects model to calculate pooled ORs and 95% CIs. Pooled absolute risk reductions (ARRs) and numbers needed to treat (NNTs) were also calculated. Heterogeneity was assessed using the \( \chi^2 \) test. Publication bias was assessed using a funnel plot.
Results of the review
Ten studies were included (n=2,363); four RCTs (n=198) and six controlled cohort studies (n=2,165). One RCT scored two points and three scored three points (out of six points) on the Jadad scale. All RCTs used intention to treat analysis. No studies reported blinded outcomes assessment and all were underpowered. Cointerventions were poorly described in the cohort studies.

Hospital mortality: RCT evidence.
There was a significantly lower hospital mortality rate in the intervention group (OR 0.18, 95% CI: 0.06, 0.57, p=0.003; ARR 15%, NNT 7, 4 RCTs) without evidence of significant heterogeneity. The IABP group had significantly shorter hospital stay and cardiopulmonary bypass time and a lower rate of low cardiac output syndrome. No cases of IABP-related mortality or aortic dissection were reported. Leg ischaemia occurred in five patients in the intervention group (n=99) and five controls who received IABP (n=39). Leg infection and bleeding at the IABP insertion site were uncommon.

Hospital mortality: RCT and cohort evidence.
When all ten studies were pooled, there was a significantly lower hospital mortality rate in the intervention group (OR 0.41, 95% CI: 0.21, 0.82, p=0.01; ARR 6%, 95% CI: 2, 10, p=0.007; NNT 17, 95% CI: 10, 50), with significant heterogeneity (p=0.03). There was no evidence of publication bias on the funnel plot. There was no IABP-related mortality. Preoperative IAPB was associated with limb ischaemia or haematoma at the insertion site in 3.7% (13/349) of cases. Most complications resolved with discontinuation of IABP.

Authors’ conclusions
Preoperative IABP reduces mortality in high-risk patients undergoing CABG, with an acceptable IABP-related complication rate.

CRD commentary
The review question and inclusion criteria were clear but the exclusion of one eligible study post-hoc was a potential source of bias. Relevant sources were searched and, although there was apparently no specific effort to retrieve unpublished studies, publication bias was not evident in the funnel plot. Steps were taken to minimise bias and error by having more than one reviewer independently involved in study selection, validity assessment and data extraction. Suitable criteria were used to assess validity. Appropriate statistical techniques were used to combine studies and to assess for heterogeneity and publication bias. Potential sources of heterogeneity, in particular possible selection bias in the cohort studies, were well addressed in the text. The authors appropriately highlighted the randomised evidence but noted that sample numbers were small, three of the four RCTs were conducted by the same group of investigators, all studies were industry-funded and none reported blinded outcome assessment. The review was well conducted in most respects with fairly consistent findings. However, as the volume of randomised evidence was small and study quality was suboptimal, a degree of caution might be required in interpreting these conclusions.

Implications of the review for practice and research
Practice: the authors did not state any implications for research.
Research: the authors stated that more research is needed in this area, to define high-risk patients, define prophylactic versus therapeutic use of IABP and explore the timing of pre-operative insertion. They suggest that an RCT with 330 patients would provide enough power.

Funding
Not stated.

Bibliographic details

PubMedID
18290898
DOI
10.1111/j.1540-8191.2007.00499.x

Indexing Status
Subject indexing assigned by NLM

MeSH
Cardiac Output; Coronary Artery Bypass /mortality; Hospital Mortality; Humans; Intra-Aortic Balloon Pumping /adverse effects /mortality; Length of Stay; Outcome Assessment (Health Care); Preoperative Care; Quality Assurance, Health Care; Randomized Controlled Trials as Topic; Risk Factors

AccessionNumber
12008104782

Date bibliographic record published
01/12/2008

Date abstract record published
02/03/2009

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.