A systematic review and meta-analysis of intra-aortic balloon pump therapy in ST-elevation myocardial infarction: should we change the guidelines?


CRD summary
The authors concluded that there was insufficient evidence to support current recommendations for the use of intra-aortic balloon pump therapy in ST-segment elevation myocardial infarction complicated by cardiogenic shock. Apart from a relatively limited search, this was a well-conducted and clearly-reported review, and the authors’ conclusions are likely to be reliable.

Authors' objectives
To evaluate intra-aortic balloon pump in patients with ST-segment elevation myocardial infarction.

Searching
MEDLINE (from 1966), the Cochrane Central Register of Controlled Trials (CENTRAL) and ClinicalTrials.gov were searched for studies published in English through December 2007. Search terms were reported. In addition, reference lists of eligible studies and previous reviews were screened.

Study selection
Randomised controlled trials (RCTs) that compared additional intra-aortic balloon pump with no intra-aortic balloon pump in patients with ST-segment elevation myocardial infarction (STEMI) were eligible for inclusion. Cohort studies that compared intra-aortic balloon pump with a concurrent group who received no intra-aortic balloon pump in STEMI complicated by cardiogenic shock were also eligible for inclusion. Studies had to report either in-hospital or 30-day mortality for at least 90% of patients (the review referred to either of these outcomes as 30-day mortality). The primary review outcome was all-cause 30-day mortality. For RCTs, secondary review outcomes included left ventricular ejection fraction and safety (stroke and bleeding).

The included studies used different types of reperfusion therapy (none, thrombolysis and primary percutaneous coronary intervention). Although inclusion criteria differed, all of the RCTs were in high-risk STEMI patients.

Two reviewers independently selected studies for inclusion in the review and resolved disagreements by discussion.

Assessment of study quality
The validity of RCTs was assessed using: adequacy of allocation concealment; intention-to-treat analysis; completeness of study and follow-up; adjudication of adverse events; funding source; and database controller. The validity of cohort studies was assessed using: control of confounders; measurement of exposure; and completeness of follow-up and blinding.

Two reviewers independently assessed validity.

Data extraction
Two reviewers independently extracted data.

Methods of synthesis
Pooled absolute risk differences and pooled absolute mean differences with 95% confidence intervals (CI) were calculated using Mantel-Haenszel or inverse variance fixed-effect models. The studies were also analysed grouped by type of reperfusion therapy. Heterogeneity was assessed using the Cochran Q statistic and the $I^2$ statistics. Publication bias was assessed using funnel plots.

Results of the review
Seven RCTs (n=1,009 patients with ST-segment elevation myocardial infarction) and ten cohort studies (n=10, 529 patients with ST-segment elevation myocardial infarction and cardiogenic shock) were included.

**RCTs in high-risk ST-segment elevation myocardial infarction (STEMI) patients:** Five RCTs reported randomisation methods, four used intention-to-treat analysis; in five the outcome assessors were blinded. There was no statistically significant difference between intra-aortic balloon pump and no intra-aortic balloon pump in 30-day mortality or change in left ventricular ejection fraction. Intra-aortic balloon pump was associated with a statistically significant increased risk of stroke, risk difference 2% (95% CI 0 to 4) and bleeding, risk difference 6% (95% CI 1 to 11). Results were similar when trials were analysed according to type of reperfusion therapy. No significant heterogeneity was found for any of the analyses. Funnel plots showed no evidence of publication bias.

**Cohort studies in STEMI patients with cardiogenic shock:** None of the studies properly controlled for confounders. Patients in the intra-aortic balloon pump groups were younger and more commonly male. Significant heterogeneity was found for the analysis of all cohort studies \( (I^2=94\%) \). For thrombolysis studies, adjunctive intra-aortic balloon pump treatment was associated with a statistically significant decrease in 30-day mortality, risk difference 18% (95% CI 16 to 20). For primary percutaneous coronary intervention studies, adjunctive intra-aortic balloon pump treatment was associated with a statistically significant increase in 30-day mortality, risk difference 6% (95% CI 3 to 10). Funnel plots showed no evidence of publication bias. Revascularisation rates (rescue percutaneous coronary intervention) were significantly higher in intra-aortic balloon pump compared to control patients, relative risk 4.0 (95% CI 3.6 to 4.5).

**Authors' conclusions**
There was insufficient evidence to support current recommendations for the use of intra-aortic balloon pump therapy in ST-segment elevation myocardial infarction complicated by cardiogenic shock.

**CRD commentary**
The review question was clearly stated and inclusion criteria were appropriately defined. Several relevant sources were searched, but no attempts were made to minimise publication or language bias. Appropriate methods were used to minimise reviewer error and bias during the review process.

Study validity was assessed and results were reported and taken into account when evaluating the evidence. Appropriate methods were used for the meta-analyses. Heterogeneity was assessed and subgroup analyses conducted.

Apart from a relatively limited search, this was well-conducted and clearly-reported review, and the authors’ conclusions are likely to be reliable.

**Implications of the review for practice and research**
**Practice:** The authors stated that review findings challenge current recommendations for the use of intra-aortic balloon pump therapy in ST-segment elevation myocardial infarction complicated by cardiogenic shock.

**Research:** The authors stated that a RCT is required to compare intra-aortic balloon pump with no support as an adjunct to primary percutaneous coronary intervention, and evaluate the role of intra-aortic balloon pump in the contemporary treatment of patients with ST-segment elevation myocardial infarction with cardiogenic shock. Adequately powered RCTs are also required to evaluate new assist devices such as percutaneous left ventricular assist devices.

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