CRITICAL CARE

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Does intra-aortic balloon support for myocardial infarction with cardiogenic shock improve outcome?

Mohamed Y Khashan[1] and Michael R Pinsky*[1,2]

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Expanded abstract

Citation

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Background

In the current international guidelines, intra-aortic balloon pump (IABP) counterpulsation is considered a class I treatment for acute myocardial infarction complicated by cardiogenic shock. However, evidence is based mainly on registry data, and there is a paucity of randomized clinical trials.

Methods

Objective: To test the hypothesis that IABP counterpulsation, as compared with the best available medical therapy alone, results in a reduction in mortality among patients with acute myocardial infarction complicated by cardiogenic shock for whom early revascularization is planned.

Design: Randomized, prospective, open-label, multicenter trial.

Setting: Thirty-seven centers in Germany.

Subjects: All adults had acute myocardial infarction complicated by cardiogenic shock and were expected to undergo early revascularization (by means of percutaneous coronary intervention or bypass surgery).

Intervention: After enrollment, 600 patients were randomly assigned to intra-aortic balloon counterpulsation (IABP group, 301 patients) or no IABP counterpulsation (control group, 299 patients).

Outcomes: The primary efficacy endpoint is 30-day all-cause mortality.

Results

At 30 days, 119 patients in the IABP group (39.7%) and 123 patients in the control group (41.3%) had died (relative risk with IABP, 0.96; 95% confidence interval, 0.79 to 1.17; P = 0.69). There were no significant differences in secondary endpoints or in process-of-care measures, including the time to hemodynamic stabilization, the length of stay in the intensive care unit, serum lactate levels, the dose and duration of catecholamine therapy, and renal function.

Conclusions

The use of IABP counterpulsation did not significantly reduce 30-day mortality in patients with acute myocardial infarction complicated by cardiogenic shock for whom an early revascularization strategy was planned.

Trial registration

ClinicalTrials.gov number NCT00491036.

Commentary

Cardiogenic shock complicates 7% to 10% of patients with acute myocardial infarction and carries a mortality rate approaching 70% to 80% [1]. Intra-aortic balloon pump (IABP) counterpulsation has been used routinely as an adjuvant treatment for myocardial infarction complicated by cardiogenic shock on the basis of evidence that it is associated with hemodynamic improvements [2]. Given the lack of randomized clinical trials, recommendations for adjunctive therapy in this high-risk population have been based only on pathophysiological assumptions and expert opinion.

*Correspondence: pinskymr@ccm.upmc.edu
[1]Department of Critical Care Medicine, 606 Scaife Hall, 3550 Terrace Street, University of Pittsburgh, Pittsburgh, PA 15261, USA
Full list of author information is available at the end of the article

An IABP is a device placed in the descending thoracic aorta that inflates with diastole, increasing upstream coronary perfusion, and that deflates with systole, decreasing left ventricular (LV) afterload and, in turn, overall myocardial oxygen demand for a given cardiac output in the setting of cardiogenic shock. The use of IABPs as a bridge to support LV function originated in the 1960s, when coronary artery bypass surgery was just becoming available. Today, IABP counterpulsation is considered one of the most widely used mechanical assist devices in hemodynamically unstable cardiac patients.

The international guidelines endorsed the use of IABP in treating cardiogenic shock post-myocardial infarction with class 1 recommendation [3,4], despite the lack of adequately powered randomized trials and the recent meta-analysis data that show limited efficacy of IABP use [5].

The Intra-aortic Balloon Pump in Cardiogenic Shock II (IABP-SHOCK II) trial was a prospective multicenter randomized trial conducted at 37 German medical centers over a 3-year period. Six hundred patients with acute myocardial infarction complicated by cardiogenic shock were randomly assigned in a 1:1 ratio to either IABP or no IABP. There were no significant differences between the groups in terms of baseline characteristics or clinical course before random assignment. The major outcome was 30-day all-cause mortality. At 30 days, there was no significant difference in relative risk for death between the two groups (relative risk of death with IABP, 0.96; 95% confidence interval, 0.79 to 1.17; P = 0.69). There were no significant differences in secondary endpoints and process-of-care outcomes (that is, lactate, C-reactive protein levels, renal function, and Simplified Acute Physiology Score II). Importantly, IABP was not associated with any significant increase in adverse events, including similar rates of reinfarction, stent thrombosis, bleeding, sepsis, or stroke. This multicenter randomized controlled study was well designed in the setting of cardiogenic shock with excellent recruitment of subjects based on eligibility.

However, general issues with this trial deserve consideration. The control and IABP groups had similar low mortality rates of 40% compared with previous registries and randomized clinical trials, which reported mortality rates of over 65%. This suggests that the patients studied in this trial had less severe cardiovascular decompensation and may not represent the highest-risk patient cohort with severe cardiogenic shock. Second, there was crossover of 10% of the control group to IABP therapy and a more frequent use of left ventricular assist devices (LVADs) in control patients (7.4% versus 3.7%), and both of these factors might decrease the control group mortality if IABP and LVAD use is beneficial. Third, the timing of IABP insertion was not controlled for. Fourth, the study reports only short-term results. Clearly, cardiac mortality is best assessed by 6- and 12-month mortality rates, if not longer. For example, the SHOCK trial did not show survival differences at 30 days but did see a survival benefit at 6 months [6]. Those longer-term results from this trial are needed to confirm the neutral effect of IABP treatment.

Recommendation

In view of the lack of prior controlled clinical trials or other convincing evidence, this study challenges the current level I guideline recommendations for the use of IABP counterpulsation in patients with acute myocardial infarction complicated by cardiogenic shock. In this setting, the routinely used IABP counterpulsation need not be the default therapeutic approach.

Abbreviations

IABP, intra-aortic balloon pump; LV, left ventricular; LVAD, left ventricular assist device.

Competing interests

The authors declare that they have no competing interests.

Author details

[1]Department of Critical Care Medicine, 606 Scaife Hall, 3550 Terrace Street, University of Pittsburgh, Pittsburgh, PA 15261, USA. [2]The Clinical Research, Investigation, and Systems Modeling of Acute Illness (CRISMA) Center, 606 Scaife Hall, 3550 Terrace Street, University of Pittsburgh, Pittsburgh, PA 15261, USA.

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