Nature Reviews Cardiology **9**, 551 (2012); published online 11 September 2012; doi:10.1038/nrcardio.2012.132

INTERVENTIONAL CARDIOLOGY

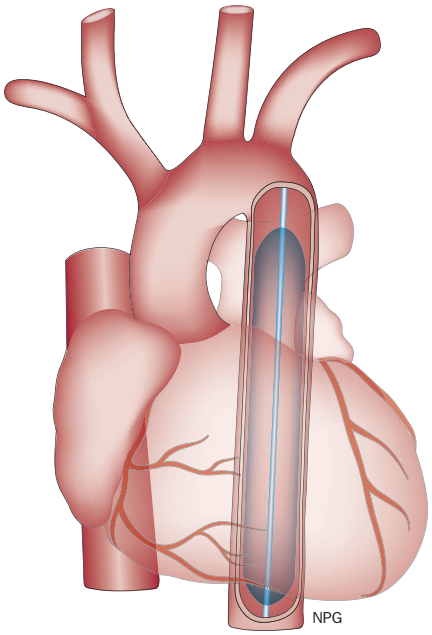
Intra-aortic balloon support for MI and cardiogenic shock—time to change the guidelines?

The results of the Intraaortic Balloon Pump in Cardiogenic Shock (IABP-SHOCK) II trial, presented at the 2012 European Society of Cardiology Congress and published in the *New England Journal of Medicine*, indicate that intra-aortic balloon pump (IABP) counterpulsation is safe, but does not reduce mortality in patients with acute myocardial infarction (MI) and cardiogenic shock. Current guidelines in which IABP support has a class I recommendation for use in these patients might, therefore, need revision.

Patients with MI and cardiogenic shock can die from one or more complicating factors, including hemodynamic deterioration, multiorgan dysfunction, and development of the systemic inflammatory response syndrome. Experimental and clinical studies have suggested that IABP support enhances hemodynamics by afterload reduction, diastolic augmentation, and improvement of coronary perfusion. However, few randomized clinical trials have been performed, and the class I recommendation in the guidelines was made mainly on the basis of registry data.

The IABP-SHOCK II investigators, therefore, performed a prospective, open-label, multicenter, randomized trial to assess the effect of the IABP on 30-day mortality in patients with MI and cardiogenic shock who were scheduled for early revascularization. Blinding was not possible in this study because of the nature of the intervention. The criteria for cardiogenic shock were satisfied if the patient had a systolic blood pressure <90 mmHg for >30 min or needed an infusion of catecholamines to maintain a systolic blood pressure >90 mmHg, clinical signs of pulmonary congestion, and impaired end-organ perfusion.

In total, 600 patients from 37 centers in Germany were randomly allocated either to receive or not to receive IABP support, in addition to optimal medical therapy. The most-common revascularization



modality was primary percutaneous coronary intervention (95.8% of patients); 3.5% of patients underwent CABG surgery, and no revascularization was performed in 3.2% of patients. In the active-treatment group, the IABP was inserted either before or immediately after revascularization, at the discretion of the investigator. Balloon inflation and deflation was triggered by the R wave using 1:1 electrocardiographic triggering, and was maintained until hemodynamic stabilization was sustained (systolic blood pressure >90 mmHg for >30 min without the need for catecholamines). The median duration of IABP support was 3.0 days.

In the IABP group, one patient was lost to follow-up, and another withdrew consent. Consequently, the final analysis contained 298 and 300 patients in the IABP and control groups, respectively. The primary end-point (30-day all-cause mortality) occurred in 39.7% and 41.3% of patients in each group (relative risk 0.96, 95% CI 0.79–1.17, $P = 0.69$). No significant differences were found in any of the safety end points, including major bleeding (3.3% vs 4.4%; $P = 0.51$), peripheral ischemic complications (4.3% vs 3.4%; $P = 0.53$), sepsis (15.7% vs 20.5%; $P = 0.15$), and stroke (0.7% vs 1.7%; $P = 0.28$).

In the IABP-SHOCK II trial, 30-day mortality was not reduced by IABP counterpulsation. Mortality, although high, was lower than in previous randomized trials and registries, which might suggest that this study population included more patients with mild or moderate shock. However, in a *post-hoc* analysis of patients with severe shock (systolic blood pressure <80 mmHg), IABP support did not reduce mortality. Moreover, IABP support is the most-widely used form of mechanical hemodynamic support in this clinical setting, but is currently used in only 25–40% of these patients, despite guideline recommendations. This low uptake suggests that clinicians might already suspect that the technique lacks efficacy.

In an accompanying editorial in the *New England Journal of Medicine*, Christopher O'Connell and Joseph Rogers from Duke University, Durham, NC, USA agree with the trial investigators that "the data do not support the routine use of IABP in patients with acute MI complicated by cardiogenic shock, and the level I guideline recommendation is now strongly challenged. Members of guideline committees and clinicians should take note of another example of a recommendation that is based on insufficient data." They believe that "we must recognize the opportunity to develop novel and innovative strategies to treat this condition. Integrated systems to ensure rapid reperfusion may reduce the incidence of shock".

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Original article Thiele, H. *et al*. Intraaortic balloon support for myocardial infarction with cardiogenic shock. *N. Engl. J. Med*. doi:10.1056/NEJMoa1208410