

SHOCK II: 12-month mortality post-IABP

Intra-aortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock (IABP-SHOCK II): final 12 month results of a randomised, open-label trial

Holger Thiele, Doreen Zeymer, Franz-Josef Neumann, Michaela Feneck, Hans-Georg Ollrich, Jörg Haendeler, Antoinette de Walder, Gert Richardt, Marcus Hennrich, Klaus Entgen, Georg Fuernau, Stefan Dorsch, Ingo Eitel, Rainer Hambrecht, Bernhard Lauer, Michael Böhm, Henning Thiele, Steffen Schneider, Karl Werdan*, Gerhard Schuler*, on behalf of the Intra-aortic Balloon Pump in cardiogenic shock II (IABP-SHOCK II) trial investigators†

Summary

Background In current international guidelines the recommendation for intra-aortic balloon pump (IABP) use has been downgraded in cardiogenic shock complicating acute myocardial infarction on the basis of registry data. In the largest randomised trial (IABP-SHOCK II), **IABP support did not reduce 30-day mortality** compared with control. However, previous trials in cardiogenic shock showed a mortality benefit only at extended follow-up. The present analysis therefore reports 6 and 12 month results.

Methods The IABP-SHOCK II trial was a randomised, open-label, multicentre trial. Patients with cardiogenic shock complicating acute myocardial infarction who were undergoing early revascularisation and optimum medical therapy were randomly assigned (1:1) to IABP versus control via a central web-based system. The primary efficacy endpoint was 30-day all-cause mortality, but 6 and 12 month follow-up was done in addition to quality-of-life assessment for all survivors with the Euroqol-5D questionnaire. A masked central committee adjudicated clinical outcomes. Patients and investigators were not masked to treatment allocation. Analysis was by intention to treat. This trial is registered at ClinicalTrials.gov, NCT00491036.

Findings Between June 16, 2009, and March 3, 2012, 600 patients were assigned to IABP (n=301) or control (n=299). Of 595 patients completing 12 month follow-up, 155 (52%) of 299 patients in the IABP group and 152 (51%) of 296 patients in the control group had died (relative risk [RR] 1·01, 95% CI 0·56–1·18, p=0·91). There were no significant differences in reinfarction (RR 2·60, 95% CI 0·95–7·16, p=0·05), recurrent revascularisation (0·91, 0·58–1·41, p=0·77), or stroke (1·50, 0·25–8·84, p=1·00). For survivors, quality-of-life measures including mobility, self-care, usual activities, pain or discomfort, and anxiety or depression did not differ significantly between study groups.

Interpretation In patients undergoing early revascularisation for myocardial infarction complicated by cardiogenic shock, IABP did not reduce 12 month all-cause mortality.

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