Intraaortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock: design and rationale of the Intraaortic Balloon Pump in Cardiogenic Shock II (IABP-SHOCK II) trial.

Abstract:

In current guidelines, intraaortic balloon pumping (IABP) is considered a class 1 indication in cardiogenic shock complicating acute myocardial infarction. However, evidence is mainly based on retrospective or prospective registries with a lack of randomized clinical trials. Therefore, IABP is currently only used in 20% to 40% of cardiogenic shock cases. The hypothesis of this trial is that IABP in addition to early revascularization by either percutaneous coronary intervention or coronary artery bypass grafting will improve clinical outcome of patients in cardiogenic shock. The IABP-SHOCK II study is a 600-patient, prospective, multicenter, randomized, open-label, controlled trial. The study is designed to compare the efficacy and safety of IABP versus optimal medical therapy on the background of early revascularization by either percutaneous coronary intervention or coronary artery bypass grafting. Patients will be randomized in a 1:1 fashion to 1 of the 2 treatments. The primary efficacy end point of IABP-SHOCK II is 30-day all-cause mortality. Secondary outcome
measures, such as hemodynamic, laboratory, and clinical parameters, will serve as surrogate end points for prognosis. Furthermore, an intermediate and long-term follow-up at 6 and 12 months will be performed. Safety will be assessed, by the GUSTO bleeding definition, peripheral ischemic complications, sepsis, and stroke. The IABP-SHOCK II trial addresses important questions regarding the efficacy and safety of IABP in addition to early revascularization in patients with cardiogenic shock complicating myocardial infarction.

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