Elective intra-aortic balloon counterpulsation during high-risk percutaneous coronary intervention: a randomized controlled trial.

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Source

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Abstract

CONTEXT:

Observational studies have previously reported that elective intra-aortic balloon pump (IABP) insertion may improve outcomes following high-risk percutaneous coronary intervention (PCI). To date, this assertion has not been tested in a randomized trial.

OBJECTIVE:

To determine whether routine intra-aortic balloon counterpulsation before PCI reduces major adverse cardiac and cardiovascular events (MACCE) in patients with severe left ventricular dysfunction and extensive coronary disease.

DESIGN, SETTING, AND PATIENTS:

The Balloon Pump-Assisted Coronary Intervention Study, a prospective, open, multicenter, randomized controlled trial conducted in 17 tertiary referral cardiac centers in the United Kingdom between December 2005 and January 2009. Patients (n = 301) had severe left ventricular dysfunction (ejection fraction < or = 30%) and extensive coronary disease (Jeopardy Score > or = 8/12); those with contraindications to or class I indications for IABP therapy were excluded.

INTERVENTION:

Elective insertion of IABP before PCI.

MAIN OUTCOME MEASURES:

Primary end point was MACCE, defined as death, acute myocardial infarction, cerebrovascular event, or further revascularization at hospital discharge (capped at 28 days). Secondary end points included all-cause mortality at 6 months, major procedural complications, bleeding, and access-site complications.

RESULTS:

MACCE at hospital discharge occurred in 15.2% (23/151) of the elective IABP and 16.0% (24/150) of the no planned IABP groups (P = .85; odds ratio [OR], 0.94 [95% confidence interval {CI}, 0.51-1.76]). All-cause mortality at 6 months was 4.6% and 7.4% in the respective groups (P = .32; OR, 0.61 [95% CI, 0.24-1.62]). Fewer major procedural complications occurred with elective IABP insertion compared with no planned IABP use (1.3% vs 10.7%, P < .001; OR, 0.11 [95% CI, 0.01-0.49]). Major or minor bleeding occurred in 19.2% and 11.3% (P = .06; OR, 1.86 [95% CI, 0.93-3.79]) and access-site complications in 3.3% and 0% (P = .06) of the elective and no planned IABP groups, respectively.

CONCLUSIONS:

Elective IABP insertion did not reduce the incidence of MACCE following PCI. These results do not support a strategy of routine IABP placement before PCI in all patients with severe left ventricular dysfunction and extensive coronary disease.