

Title: Bivalirudin in Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction (HORIZONS-AMI): 1-Year Results of a Randomised Controlled Trial

Topic: Interventional Cardiology

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Study Question: What is the 1-year outcome of patients undergoing primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) who are treated with bivalirudin compared with those who are treated with glycoprotein IIb/IIIa inhibitors (GPIs)?

Methods: The authors reported 1-year outcomes of the HORIZONS-AMI trial. This trial randomized 3,602 patients to receive bivalirudin (0.75 mg/kg intravenous bolus followed by 1.75 mg/kg/h infusion; n = 1,800) or heparin plus a GPI (control; 60 IU/kg intravenous bolus followed by boluses with target activated clotting time 200-250 seconds; n = 1,802). The two primary trial endpoints were major bleeding and net adverse clinical events (NACE; consisting of major bleeding or composite major adverse cardiovascular events [MACE; death, reinfarction, target vessel revascularization for ischemia, or stroke]).

Results: The rate of NACE was lower in the bivalirudin group than in the control group (15.6% vs. 18.3%; hazard ratio [HR], 0.83; 95% CI, 0.71-0.97; p = 0.022), and this was driven by a lower bleeding rate in the bivalirudin group (5.8% vs. 9.2%; HR, 0.61; 0.48-0.78; p < 0.0001). There was no difference in the rate of MACE between the two groups (11.9% vs. 11.9%; HR, 1.00; 0.82-1.21; p = 0.98). The 1-year cardiac mortality (2.1% vs. 3.8%; HR, 0.57; 0.38-0.84; p = 0.005) and all-cause mortality (3.5% vs. 4.8%; HR, 0.71; 0.51-0.98; p = 0.037) were lower in the bivalirudin group than in the control group.

Conclusions: Bivalirudin-based therapy provides a major reduction in bleeding events without any increase in thrombotic events in patients undergoing primary PCI for STEMI.

Perspective: GPIs are the most commonly used adjunct pharmacological therapy for patients undergoing primary PCI (*J Am Coll Cardiol* 2008;51:529-35), although the evidence base supporting this is somewhat limited. The follow-up data from the HORIZONS-AMI trial clearly demonstrate the benefits of bivalirudin for this indication, and interventionalists should consider using this drug especially for patients at high bleeding risk.