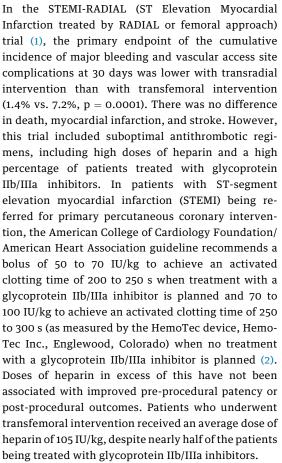
Letters

Re-Examination of the Antithrombotic Regimen in the STEMI-RADIAL Trial



Bivalirudin, a direct thrombin inhibitor shown to decrease bleeding and improve outcomes compared with heparin and glycoprotein IIb/IIIa inhibitors in patients undergoing an invasive strategy, was not used in the STEMI-RADIAL trial (3). The HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) trial, which compared patients with STEMI randomized to treatment with heparin plus glycoprotein IIb/IIIa inhibitors or bivalirudin, reported a 34% reduction in mortality in patients treated with bivalirudin (p = 0.047), driven by a reduction in major bleeding of 40% (p < 0.001).

The applications of the trial findings are suspect given the suboptimal antithrombotic regimens and the liberal use of potent parenteral antiplatelet agents (4). This is an important consideration especially for patients with acute coronary syndrome, in whom the negative implications of major bleeding are even greater. Ultimately, a trial comparing transradial with transfemoral intervention in patients treated with bivalirudin, with potent antiplatelet therapy, and without adjunctive glycoprotein IIb/IIIa inhibitors as well as possibly incorporating ultrasound guidance for vascular access is needed (5,6).

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REPLY: Re-Examination of the Antithrombotic Regimen in the STEMI-RADIAL Trial



We are pleased to address Dr. Lee's comments on the results of the STEMI-RADIAL (ST Elevation Myocardial Infarction treated by RADIAL or femoral

approach) trial published in the Journal (1). First, this letter has already been published twice with almost identical content (2,3). Second, responses to Dr. Lee's comments are already included in our report. In brief, Dr. Lee contends that unfractionated heparin was not used in accordance with guideline recommendations and that bivalirudin should have been used instead. As explained in the Methods section and in accordance with the most recent guidelines, an initial unfractionated heparin bolus dose of 70 IU/kg or a maximum dose of 5,000 IU was given (sometimes in the ambulance). Further adjustments were made according to the activated clotting time results, leading to a mean total dose of 104 \pm 32 IU/kg with no difference between groups. Platelet glycoprotein IIb/IIIa receptor inhibitors were used in 45% of the cases when required during percutaneous coronary intervention as judged by the operators (provisional use). This rate is similar to the current experience with ST-segment elevation myocardial infarction (STEMI) in the United States (4,5). As explained in the Study Limitations section, bivalirudin was not used because it is not available in the Czech Republic. Furthermore, the recent results of the HEAT-PPCI (How Effective Are Antithrombotic Therapies in Primary Percutaneous Coronary Intervention) trial cast serious doubt on the claimed overwhelming superiority of bivalirudin over heparin in patients with STEMI undergoing primary percutaneous coronary intervention (6). Further studies such as SAFARI-STEMI (The Safety and Efficacy of Femoral Access Versus Radial for Primary Percutaneous Coronary Intervention in ST-Elevation Myocardial Infarction), which will evaluate the benefits of a radial compared with a femoral approach in patients with STEMI on a background of bivalirudin, and EASY-B2B (EArly Discharge After Transradial Stenting of Coronary Arteries in High-Risk Patients of Bleeding), which will compare bivalirudin with heparin monotherapy in all comers at high risk for bleeding undergoing transradial percutaneous coronary intervention, should provide new insight into the interaction between anticoagulation and access site in the near future.

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