Conclusions: This analysis from a very large US hospital database suggests that the use of bivalirudin anticoagulation for PAI may confer significant clinical benefits over heparin. These results require confirmation in a prospective randomized trial.

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Bivalirudin versus Heparin for Percutaneous Coronary Intervention: An Updated Meta-Analysis of Randomized Controlled Trials

Michael J. Lipinski1, Thibault Thermuster1, Ricardo O. Escarega2, Nevin C. Baker3, Marco A. Magalhaes2, Rebecca Torguson3, William O. Suddath4, Lowell F. Satler5, Augustine Pichard6, Ron Waksman6
1Medstar Washington Hospital Center, Washington, DC, 2MedStar Washington Hospital Center, Washington, DC, 3Washington Hospital Center, Washington, DC, 4Medstar Washington Hospital Center, Washington, United States, 5Medstar Washington Hospital Center, Washington, DC, 6Washington Hospital Center, Washington, United States

Background: Controversy exists regarding the optimal choice of anticoagulation regimen for percutaneous coronary intervention (PCI). We performed a meta-analysis of randomized controlled trials (RCT) to compare bivalirudin (bival) versus heparin with provisional or routine glycoprotein IIb/IIIa inhibitor (GPI) use on 30-day outcomes following PCI.

Methods: Medline/Pubmed and Cochrane CENTRAL were searched along with recent abstract presentations at national meetings for all RCTs comparing BIV with heparin. These results require confirmation in a prospective randomized trial.

Results: A meta-analysis was performed on 30 variable studies that had randomized to either bivalirudin with provisional GPI use (n=14,869) or heparin with provisional GPI use (n=6,451) or heparin with routine GPI use (n=9,126). There was no significant difference between anticoagulation with bival compared with heparin for 30 day death (OR 0.94 [0.78-1.14]), myocardial infarction (OR 1.11 [0.97-1.27]), Early stent thrombosis (OR 0.85 [0.49-0.69]), and TIMI major bleeding (OR 0.58 [0.47-0.71], p=0.0001) compared with heparin. Meta-regression analysis demonstrated that bleeding risk with use of heparin significantly increases with increasing GPI use (p=0.02).

Conclusions: Meta-analysis of 14 RCTs with 30,446 patients demonstrated that bivalirudin is associated with higher risk of stent thrombosis but lower risk of major bleeding compared with heparin.

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Predictors Of Stent Thrombosis After Primary Percutaneous Coronary Intervention And Risk for 30-Day Mortality: Analysis from the HORIZONS-AMI and EURO-AMX trials

George Dangas1, Philippe G. Sieg2, Rosana Mehran1, Arnoud van ‘t Hof1, Mikkil Schoen1, Janne Prats1, Debra Bernstein4, Efthymios N. Delangre3, Gregg W. Stone1
1Mount Sinai, New York, New York, NY, 2Hospital Bichat, Paris, France, 3Union School of Medicine at Mount Sinai, New York, NY, 4Iola Klinikum Zwoolle, Netherlands, 5Mount Sinai Medical Center, New York, New York, USA, 6Copenhagen, Denmark, 7The Medicines Company, Parsippany, NJ, 8The Medicines Company, Parsippany, NJ, 9Columbia University Medical Center and the Cardiovascular Research Foundation, New York, United States

Background: The risk of early (<30 day) stent thrombosis (ST) is considerable after primary PCI at 188 sites, randomized to either bivalirudin or heparin ± a glycoprotein IIb/IIIa inhibitor (GPI). Predictors of ST were determined by multivariate logistic regression, and 30-day mortality was evaluated according to timing of ST and antithrombotic treatment received.

Methods: In a patient-level pooled analysis from the HORIZONS-AMI and EURO-AMX trials, we studied 5,800 patients undergoing primary PCI at 188 sites, randomized to either bivalirudin or heparin ± a glycoprotein IIb/IIIa inhibitor (GPI). Predictors of ST were determined by multivariate logistic regression, and 30-day mortality was evaluated according to timing of ST and antithrombotic treatment received.

Results: Of 101 patients (1.7%) who developed early ST, 20 (20%) died within 30 days of enrollment. By logistic regression, independent predictors of early ST were pre-PCI TIMI grade flow 0-1 and Killip class ≥2 at presentation. Bivalirudin was associated with higher rates of early ST (2.1% vs. 1.4%, RR=1.51, adj. p-value=0.07) driven by a higher incidence of acute ST (1.2% vs. 0.2%, RR=6.04, p<0.0001) with similar rates of subacute ST (0.9% vs. 1.2%, RR=0.74, p=0.24) in comparison to heparin ± GPI. However, 30-day mortality rates among patients with ST were lower in the bivalirudin-treated subset; this was consistent for both acute and subacute ST (Table). As a result, only 42,889 bivalirudin-treated patients died within 30 days after early ST compared to 162,911 heparin ± GPI treated patients (0.14% vs. 0.56% respectively, P<0.001).

Conclusions: Killip class ≥2 during acute MI presentation and pre-procedure TIMI grade flow 0-1 are independent predictors of early ST after primary PCI. Although the risk of ST within 30 days is higher among patients treated with bivalirudin due to a greater hazard of acute ST, death attributable to early ST is substantially less common in patients having received bivalirudin compared to heparin ± GPI.

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