Results of an individual patient data pooled analysis reported at RCT Connect

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An individual patient data pooled analysis comparing the use of bivalirudin versus heparin in heart attack patients undergoing percutaneous coronary intervention (PCI) found that bivalirudin use was associated with similar overall rates of 30-day mortality across all heart attack patients, but lower rates of serious bleeding events. Moreover, mortality was reduced in patients with ST-segment elevation myocardial infarction (STEMI) who were treated with a post-PCI bivalirudin infusion.

Findings were reported today at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation (CRF). TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

Numerous randomized trials have examined the outcomes of anticoagulation with bivalirudin vs. heparin in patients undergoing PCI. These studies have reported conflicting results given varying patient populations, study designs (including access site, use of GPIIb/IIIa inhibitors with heparin and varying regimens of post-PCI bivalirudin infusions), sample size, endpoints, and follow-up durations. Study-level meta-analyses have been unable to address these limitations, nor can they evaluate events over time, perform multivariable adjustment, or examine outcomes in important subgroups.

In this analysis, researchers pooled the individual patient data from all eight randomized clinical trials of bivalirudin vs. heparin in patients with myocardial infarction (MI) (STEMI, or non-STEMI [NSTEMI]) undergoing PCI that enrolled 1,000 or more patients: MATRIX, VALIDATE-SWEDEHEART, EUROMAX, BRIGHT, HEAT-PPCI, ISAR-REACT 4, ACUITY, and HORIZONS-AMI. The final study cohort included 27,409 patients (13,346 randomized to bivalirudin and 14,063 randomized to heparin); 15,254 had STEMI and 12,155 had NSTEMI.

The pre-specified primary effectiveness endpoint was the 30-day risk of all-cause mortality and the primary safety endpoint was the 30-day risk of serious bleeding (TIMI major or minor if available; alternatively, BARC type 3 or 5).

Overall, bivalirudin was associated with similar rates of 30-day mortality (1.9% vs. 2.1%, HR 0.91, 95% CI 0.75-1.10) and lower rates of serious bleeding (3.4% vs. 5.7%, HR 0.60, 95% CI 0.52-0.68). Further analyses were performed stratified by presentation (STEMI or NSTEMI). In STEMI patients, all-cause mortality was lower with bivalirudin use compared to heparin use (2.5% vs. 2.9%, HR 0.80, 95% CI, 0.64, 1.01). The mortality rates were substantially reduced with bivalirudin when a post-PCI bivalirudin infusion was used (HR 0.67, 95% CI, 0.50, 0.89). Serious bleeding was also lower with bivalirudin use (3.5% vs. 6.0%, HR 0.57, 95% CI, 0.47, 0.68). In NSTEMI patients, bivalirudin use and heparin use had similar rates of mortality (1.2% vs. 1.1%, HR 1.21, 95% CI, 0.84, 1.73), although bivalirudin use was also associated

with lower rates of serious bleeding (3.3% vs. 5.3%, HR 0.63, 95% CI, 0.52, 0.76).

"This individual patient data pooled analysis aimed to determine the optimal anticoagulant to be used during PCI in patients with AMI," said Gregg W. Stone, MD. Dr. Stone is Director of Academic Affairs, Mount Sinai Heart Health System and Professor of Medicine at The Zena and Michael A. Wiener Cardiovascular Institute of the Icahn School of Medicine at Mount Sinai. "In patients with STEMI undergoing primary PCI, bivalirudin use was associated with reductions in the 30-day rates of mortality, serious bleeding and NACE, despite increased rates of MI and stent thrombosis compared with heparin. The mortality benefit of bivalirudin in STEMI was pronounced in patients treated with a post-PCI bivalirudin infusion (low-dose or high-dose); a high-dose infusion mitigated the MI and stent thrombosis risk."

"In patients with NSTEMI undergoing PCI, bivalirudin use was associated with a reduction in the 30-day rate of serious bleeding but similar rates of mortality, MI, and stent thrombosis compared with heparin," Dr. Stone added.

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