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Abstract: In ISAR-REACT 3, 30-day outcomes in 4570 biomarker negative patients undergoing percutaneous coronary intervention (PCI) \( \geq 2 \) h after pre-treatment with 600 mg of clopidogrel revealed less bleeding with bivalirudin compared with unfractionated heparin, but no difference in 30-day net clinical benefit. The objective of the present analysis was to assess the impact of bivalirudin vs. heparin on 1-year outcomes in ISAR-REACT 3. The primary outcome for this analysis was the composite of death, myocardial infarction, or target vessel revascularization 1 year after randomization. The composite of death or myocardial infarction was a secondary outcome. At 1 year, the primary outcome occurred in 17.1% of patients assigned to bivalirudin vs. 17.5% assigned to heparin [hazard ratio (HR), 0.98; 95% confidence interval (CI), 0.86-1.13; \( P = 0.816 \)]. The combined incidence of death or myocardial infarction was 7.7% in the bivalirudin group vs. 6.7% in the heparin group (HR, 1.15; 95% CI, 0.93-1.43; \( P = 0.200 \)). The mortality rate was 1.9% in the bivalirudin group and 1.7% in the heparin group (HR, 1.10; 95% CI, 0.71-1.70; \( P = 0.667 \)). At 1 year, no significant differences in
the primary outcome were observed with bivalirudin and heparin in any of the subgroups analysed. Bivalirudin and unfractionated heparin during PCI provide comparable outcomes at 1 year in biomarker negative patients undergoing PCI after pre-treatment with 600 mg of clopidogrel. Clinical trial registration information: URL www.clinicaltrials.gov; Unique identifier NCT00262054.