Titel des Beitrags:
ISAR-REACT 3A: a study of reduced dose of unfractionated heparin in biomarker negative patients undergoing percutaneous coronary intervention.

Abstract:
AIMS: Although a 140 U/kg dose of unfractionated heparin (UFH) was comparable with bivalirudin in terms of net clinical outcome in the Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment (ISAR-REACT) 3 trial, it was associated with a higher risk of bleeding. We designed this study to assess whether a reduction in the UFH dose from 140 to 100 U/kg is associated with improved net clinical outcome. METHODS AND RESULTS: A total of 2505 biomarker negative patients undergoing percutaneous coronary intervention (PCI) after clopidogrel pre-treatment received a single bolus of 100 U/kg UFH. The primary endpoint was net clinical outcome—a quadruple endpoint of death, myocardial infarction, urgent target-vessel revascularization within 30 days, or in-hospital REPLACE 2 defined major bleeding. The primary comparison was with the historical UFH group of ISAR-REACT 3 (2281 patients). In a second analysis, we checked for non-inferiority against the historical bivalirudin arm of ISAR-REACT 3 (2289 patients). The incidence of the primary endpoint was 7.3% in the lower UFH dose group.
compared with 8.7% in the higher UFH dose group [hazard ratio (HR) 0.81; 95% confidence interval (CI) 0.67-1.00; P = 0.045]. The incidence of major bleeding was 3.6% in the lower UFH dose group and 4.6% in the higher UFH dose group (HR 0.79; 95% CI 0.59-1.05; P = 0.11). The lower UFH dose met the criterion of non-inferiority compared with bivalirudin (P< 0.001). CONCLUSION: In biomarker negative patients undergoing PCI after clopidogrel loading, a reduced dose of 100 U/kg UFH provided net clinical benefit compared with the historical control of 140 U/kg UFH in the ISAR-REACT 3 trial. The benefit was mostly driven by reduction in bleeding. CLINICAL TRIAL REGISTRATION INFORMATION: URL www.clinicaltrials.gov; Unique identifier NCT00735280.