

TCT-50

Influence of Age on Clinical Outcomes in Patients with NSTEMI Undergoing Treatment with Abciximab plus Unfractionated Heparin vs. Bivalirudin: Analysis of the ISAR React 4 StudyLamin King¹, Lamin King¹, Oltjon Albajrami², Robert Byrne³, Salvatore Cassese⁴, Tomohisa Tada⁵, Julinda Mehilli³, Adnan Kastrati³¹Deutsches Herzzentrum, Munich, Munich, Germany, ²Deutsches Herzzentrum, Munich, Munich, Bavaria, ³Deutsches Herzzentrum Munich, Munich, Germany, ⁴Deutsches Herzzentrum, Munich, BAVARIA, ⁵Deutsches Herzzentrum Munich, Munich, Bayern

Background: In the ISAR-REACT 4 clinical trial in 1721 randomized patients undergoing percutaneous coronary angioplasty for non-ST elevation myocardial infarction, treatment with abciximab and heparin demonstrated an increased risk of bleeding in comparison to bivalirudin. However the results were not analyzed with respect to the age of the patients and it was not clear if this excess bleeding risk occurred in any particular sub-group.

Methods: In this study, the patients from the ISAR REACT study were organized into four quartile groups according to age, and the outcomes analyzed with respect to treatment with abciximab and heparin or bivalirudin. The primary endpoint was the composite of death, large myocardial infarction, urgent target vessel revascularization or major bleeding within 30 days. The secondary endpoints were death, myocardial infarction or target vessel revascularization (efficacy endpoint) and major bleeding (safety endpoint) at 30 days.

Results: A total of 1721 patients entered the study. The primary endpoint occurred in 11.8% vs. 11.6% in Q1, 10.2% vs. 9.8% in Q2, 10.7% vs. 10.3% in Q3 and 11.0% vs. 12.4% in Q4 in patients treated with abciximab and heparin or bivalirudin respectively. There was no overall interaction between age and occurrence of the primary endpoint (PINTERACTION =0.81). There were no differences within the age quartile groups and no interaction between age and clinical outcome for the secondary efficacy endpoint (PINTERACTION=0.84) or for the primary safety endpoint (PINTERACTION=0.59)

Conclusions: In patients undergoing treatment for non-ST elevation myocardial infarction and stratified by age, there were no differences in clinical outcome, safety or efficacy between those receiving abciximab and those receiving bivalirudin. This finding was consistent across a variety of key risk sub-groups.

TCT-51

Comparison of Clopidogrel and Prasugrel in Patients with Unprotected Left main Disease Treated with Everolimus-Eluting Stents: Insight From the Florence Left Main-PCI RegistryRenato Valentini¹, Angela Migliorini¹, Guido Parodi¹, Ruben Vergara¹, Nazario Carrabba¹, Emilio Vincenzo Dovellini¹, David Antonucci¹¹Careggi Hospital, Florence, Italy

Background: Randomized trials and registries have shown that everolimus-eluting stent (EES) performs better than first generation drug-eluting stent (DES). Prasugrel as compared to clopidogrel in acute coronary syndromes treated invasively is associated with improved clinical outcome and decreased risk of stent thrombosis. No data exist about prasugrel as compared to clopidogrel in patients with unprotected left main disease (ULMD) treated with EES. The aim of the study was to compare clinical outcome in patients receiving Clopidogrel or Prasugrel who underwent ULMD-PCI with EES.

Methods: From the prospective Florence LM-PCI registry, consecutive patients receiving EES were included in the analysis. Antiplatelet treatment included clopidogrel until March 2010, while prasugrel was routinely used from April 2010. The end points of the study were cardiac mortality and stent thrombosis at 1 year of follow-up. Definite, probable and possible stent thromboses were defined according to the Academic Research Consortium criteria.

Results: From January 2004 to 2011, 192 patients underwent EES implantation for ULMD. Out of these 94 pts received clopidogrel and 98 received prasugrel. Patients on prasugrel therapy had a worse baseline risk profile than patients on clopidogrel, but these differences did not reach statistical significance: mean age 70 ± 10 vs. 71 ± 11 yrs, male 78% vs. 75%, diabetes 28% vs. 21%, acute myocardial infarction 15% vs. 8%, left ventricular ejection fraction <0.40 40% vs. 32%, renal insufficiency (creatinine > 1.5 mg/dL) 15% vs. 8%, 3-vessel disease vs 35% vs 30%, EuroSCORE ≥13 31% vs. 21%. Procedural characteristics were similar in prasugrel group and clopidogrel group: LM stenting of both branches 30% vs. 28%, respectively, mean stent length (mm) 24 ± 12 vs. 21 ± 10, IVUS guidance 58% vs 56%. One-year clinical outcome was significantly better in the prasugrel group as compared to clopidogrel group: cardiac mortality rate 2.0% and 8.5%, respectively (p=0.044), stent thrombosis rate 0 vs. 4.3% (p=0.039).

Conclusions: As compared to clopidogrel, prasugrel improves clinical outcome in all comers patients with ULMD receiving EES.

TCT-52

Bivalirudin reduces cardiac mortality in patients with and without major bleeding: The HORIZONS-AMI trialGregg Stone¹, Tim Clayton², Roxana Mehran³, Makis Deligiannis⁴, Jayne Prats⁴, Stuart Pocock⁵¹Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY, ²London School of Hygiene and Tropical Medicine, London, United Kingdom, ³Mount Sinai Hospital, New York, USA, ⁴The Medicines Company, Parsippany, NJ, ⁵London School of Hygiene and Tropical Medicine, London, United Kingdom

Background: In HORIZONS-AMI, bivalirudin (Biv) compared to heparin + a GPIIb/IIIa inhibitor (H+GPI) in pts with STEMI undergoing primary PCI resulted in reduced rates of major bleeding and cardiac mortality. Whether the reduction in mortality with Biv can be fully ascribed to reduced bleeding is unknown.

Methods: We examined the rates of cardiac mortality among pts randomized to Biv vs H+GPI in those with and w/o non-CABG major bleeding during 3 yr follow-up in a time- and covariate-adjusted multivariable model.

Results: The 3 yr rates of non-CABG major bleeding (6.7% vs 10.3%, P=0.0007) and cardiac mortality (2.8% vs 4.9%, P=0.001) were lower in pts randomized to Biv vs H+GPI. Among 306 pts with major bleeding, cardiac mortality at 3 yrs occurred in 7/121 (5.8%) and 27/185 (14.6%) pts assigned to Biv vs H+GPI, respectively, HR[95%CI]= 0.39 [0.17-0.89], P=0.02. Among 3296 pts w/o bleeding, 3 yr cardiac mortality occurred in 43/1679 (2.6%) and 61/1617 (3.8%) pts assigned to Biv vs H+GPI, respectively, HR[95%CI]= 0.67 [0.46-1.00], P=0.046. Thus 20 fewer deaths occurred in Biv treated patients with a major bleed compared to 18 fewer deaths in Biv treated patients w/o a major bleed. In the fully adjusted model Biv treatment was associated with reduced cardiac mortality both in pts with (HR[95%CI]= 0.32 [0.14,0.78], P=0.01) and w/o (HR[95%CI]= 0.65 [0.44,0.97], P=0.03) major bleeding. Among pts w/o bleeding fewer pts treated with Biv developed new thrombocytopenia (147/1625 (9.0%) vs 180/1546 (11.6%), p=0.02). In pts w/o bleeding the adjusted HR [95%CI] for 3 yr cardiac mortality with Biv vs H+GPI was 0.22 [0.06,0.84], p=0.01 vs 0.78 [0.49,1.24], p=0.29 in those with vs. w/o acquired thrombocytopenia

Conclusions: In pts with STEMI undergoing primary PCI, procedural anticoagulation with Biv rather than H+GPI is associated with reduced cardiac mortality among pts with as well as those w/o major bleeding, a benefit which may be attributed to prevention of thrombocytopenia.

TCT-53

Assessment of 30-Day Rehospitalization For Acute Myocardial Infarction In Patients With Acute Coronary Syndrome Who Received Percutaneous Coronary Intervention: A Comparative Effectiveness Study Of Clopidogrel And PrasugrelJay Bae¹, Douglas Faries¹, Frank Ernst², Craig Lipkin², Zhenxiang Zhao¹, Chad Moretz²¹Eli Lilly and Company, Indianapolis, IN, ²Premier Research Services, Charlotte, NC

Background: A 30-day rehospitalization rate for acute myocardial infarction (AMI) following hospital discharge among patients with acute coronary syndrome (ACS) who have received percutaneous coronary intervention (PCI) has been adopted as a hospital quality and performance measure. This study sought to compare 30- and 90-day AMI-related rehospitalization rates between ACS-PCI patients receiving clopidogrel versus those receiving prasugrel.

Methods: The study endpoint was pre-specified, and analysis was done under blinding. Using a large geographically diverse US database maintained by PREMIER, the study analyzed AMI-related rehospitalizations among ACS-PCI patients receiving either clopidogrel or prasugrel between July 2009 and June 2011. Analysis included patients treated with prasugrel who were on-label and clopidogrel-treated patients who would have been eligible for prasugrel treatment per the label. Treatment differences in rehospitalization rate at 30 and 90 days were analyzed. Unadjusted comparisons used chi-square tests. Multivariate logistic regression analyses adjusted for baseline patient differences using propensity score stratification.

Results: Data were available for 83,576 patients, of which 74,163 received clopidogrel and 9,403 received prasugrel. For clopidogrel and prasugrel, respectively, the observed AMI-related rehospitalization rates were 4.74% and 3.85% at 30 days (P=0.0001) and 6.27% and 5.13% at 90 days (P<0.0001). Prasugrel was associated with approximately 10% lower odds of AMI-related rehospitalization (Odds ratio=0.892 at 30 days [95% CI: 0.798-0.998]; Odds ratio=0.901 at 90 days [95% CI: 0.817-0.994]).

Conclusions: Compared to clopidogrel-treated patients, prasugrel-treated patients experienced fewer rehospitalizations for AMI at 30 days and 90 days following ACS-PCI discharge. Similar results were obtained after adjusting for patient demographics and clinical characteristics. The potential for unmeasured confounder bias is a limitation in this real-world observational research.