TCT-749

Heparin Versus Bivalirudin– In-hospital And 30 Day MACE In Patients Having DES Implantation

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Background: Bivalirudin(B) and heparin(H) are the most common drugs used to prevent acute stent thrombosis during drug-eluting stent (DES) deployment. Prior studies comparing B to H with a IIB/IIIA agent have shown similar rates of stent thrombosis but decreased bleeding and mortality with B. With improved stent design, routine post-stent high pressure balloon inflation and IVUS guided therapy, acute complications of stent procedures other than bleeding have been reduced. We examined whether heparin given without a IIB/IIIA agent and bivalrudin would have similar rates of major adverse cardiac events (MACE) with DES.
Methods: DES implants performed between 01/01/2007 and 01/01/2012 at St. Francis Hospital were reviewed using data reported to the New York State Department of Health. Clinical presentations, in-hospital and 30 day mortality, in hospital stent thrombosis and transfusion were assessed. Due to data element limitations and lags in Social Security Death Index reporting, full clinical presentation data and 30 day vital status were available in 76% and 77.9% respectively.
Results: In 10,486 DES implantations a bolus of 7000U heparin(H, 5525) alone or a bolus and/or infusion of bivalrudin(B, 4875) was administered. Overall in-hospital mortality was 0.38%(H) versus 0.41%(B) p=0.55 and 30 day mortality was 0.76%(H) versus 0.81%(B), p=0.77. However in a very small subset with a diagnosis of acute myocardial infarction(AMI) mortality was increased on H(B 1.3%,n=233, vs H 7.0%, n=133, p=0.0036). Inpatient stent thrombosis was present in 0.09% on B compared to 0.08%on H, p=0.90, while 3.0% of patients on B required transfusion as compared to 2.9% on H, p=0.65. The frequency of all ACS at presentation was similar for H(93.6%) and B (93.2.%)(p=0.54).
Conclusions: In patients undergoing DES implantation, bivalirudin reduced mortality only in patients with acute myocardial infarction. There were no differences in MACE between patients receiving bivalirudin and those receiving heparin without a IIB/IIIA inhibitor if AMI was absent. Given the marked cost differential between these agents, further studies to confirm our results in non- AMI patients would be appropriate.

TCT-750

Can the Rate of Acute Stent Thrombosis with Bivalirudin Anticoagulation During Primary PCI in STEMI be Reduced with Modified Pharmacologic Regimens?

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Background: In the HORIZONS-AMI (HZN) trial, among STEMI patients undergoing primary PCI after aspirin and clopidogrel loading, anticoagulation with bivalirudin (BIV) (in most patients terminated at end of the PCI procedure)reduced major bleeding, thrombocytopenia and mortality compared to unfractionated heparin plus gpIIb/IIIa inhibitor, albeit with an increased risk of acute (≤24 hours) stent thrombosis (AST). Whether more potent antiplatelet agents or a prolonged BIV infusion may safely reduce this acute stent thrombosis risk is unknown.
Methods: We identified 5 contemporary STEMI registries and randomized clinical trials (Post-HZN-5 group) with a total of 1993 patients and evaluated baseline and treatment characteristics together with 30-day outcomes and compared with the HZN trial. The analysis focused on AST rates and major bleeding as well as rates of alternative treatment strategies from HZN such as the use of a prolonged BIV infusion for 2-4 hours post PCI and/or an oral faster acting P2Y12 inhibitor (prasugrel).
Results: Baseline characteristics were comparable between HZN and the P-HZN-5. Treatment characteristics and AST rates of the P-HZN-5 studies and HZN are summarized in Table 1. The AST rate was significantly lower in the P-HZN-5 studies compared to HZN (0.15% (3/1993) vs. 1.34% (21/1571), p<0.0001). There was no increase in major bleeding reported with prolonged BIV infusion and/or prasugrel.

Study	Total N	Prasugrel	Pre Heparin	Prolonged Bivalirudin >2hrs	Major Bleeding	Acute Stent Thrombosis
INFUSE-AMI	452	125 (27.7%)	287 (63.5%)	0%	19 (4.2%)	0 (0%)
PROBI VIRI 2	172	0 (0%)	0 (0%)	86 (50%)	0 (0%)	0 (0%)
UVM-Registry	346	36 (10.4%)	207 (59.8%)	283 (81.8%)	15 (4.3%)	3 (0.9%)
Bristol-Registry	345	345 (100%)	7 (2.0%)	0%	5 (1.4%)	0 (0%)
EUROVISION	678	87 (12.8%)	300 (44.2%)	208 (30.7%)	10 (1.5 %)	0 (0%)
Combined	**1993**	**593 (29.8%)**	**801 (40.2%)**	**577 (29.0%)**	**49 (2.4%)**	**0.15%**
HORIZONS-AMI	1571	0%	65.40%	<12%	5.10%	1.30%

Conclusions: Among patients with STEMI undergoing primary PCI with BIV anticoagulation, use of faster and more potent P2Y12 inhibitors and/or a prolonged BIV infusion may reduce the rate of acute stent thrombosis compared to an abbreviated procedural-only BIV regimen in combination with clopidogrel. Randomized studies are warranted to determine whether these strategies improve clinical outcomes without adversely affecting the safety profile of the currently recommended abbreviated bivalirudin infusion.

TCT-751

Novel oral anticoagulants in patients with acute coronary syndromes: meta-analysis of randomized controlled trials

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Background: Patients with acute coronary syndromes (ACS) remain at significant risk for thrombotic events despite double antiplatelet therapy. The role of oral activated factor X antagonists (anti-Xa) and direct thrombin inhibitors (DTI) are debated in this setting. We aimed to evaluate the safety and efficacy of new-generation oral anticoagulants as compared to placebo in patients receiving antiplatelet therapy after ACS.
Methods: Electronic databases were searched to find prospective, randomized, placebo-controlled clinical trials (RCT) that evaluated the clinical impact of anti-Xa or DTI treatment in patients receiving antiplatelet therapy after ACS. Efficacy measures included overall mortality, stent thrombosis and a composite endpoint of major ischemic events, while TIMI-defined major bleeding events were used as safety endpoint. Net clinical benefit was calculated as a sum of composite ischemic events and major bleeding.
Results: Between January 2000 and December 2011, seven RCTs comprising 31,286 patients were identified. Based on the pooled results, the use of novel oral anticoagulants in addition to antiplatelet therapy was associated with a dramatic increase in bleeding events (OR: 3.03; 95%CI: 2.20-4.16; p<0.000001). Significant, yet moderate reductions in the risk of stent thrombosis and composite ischemic events were observed without a significant effect on mortality. Regarding net clinical benefit, oral anticoagulant treatment provided no advantage over placebo (OR: 0.98 95% CI 0.9-1.06; p=0.57).
Conclusions: Anti-Xa and DTI agents are associated with a dramatic increase in major bleeding events that might offset all ischemic benefits in patients receiving antiplatelet treatment after ACS.

TCT-752

Ecarin Clotting Time (ECT) more accurately reflects bivalirudin concentration than Activated Clotting Time (ACT) in patients undergoing Percutaneous Coronary Intervention using bivalirudin anticoagulation

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Background: Bivalirudin is increasingly the anticoagulant of choice for PCI.The degree of anticoagulation with direct thrombin inhibtors(DTI)has been measured with activated clotting time (ACT).This is hampered by the absence of a linear dose-response.Ecarin clotting time(ECT) however,has a linear dose response over a wide range of DTI concentrations.We aim to assess the correlation of both ACT and a point-of-care ECT assay with bivalirudin concentrations in an elective PCI patient population.
Methods: A multi-center study of 150 patients undergoing elective coronary intervention with bivalirudin anticoagulation was performed.Citrated ECT,ACT,and anti-factor IIa activity were measured at baseline,10 minutes after bivalirudin bolus,and at the end of the procedure,producing 450 individual ECT,ACT,and anti factor IIa assays.Correlation and linear regression analysis of both ACT and ECT compared to bivalirudin concentration were performed.
Results: Mean Age 66(+/−11.6).68% were male.Mean eGFR was 88(+/−37.4).40% of procedures were for unstable angina, 18% were performed for AMI.Median LOS 1 day.5 bleeding complications occurred.1 acute stent thrombosis occurred.No in-hospital deaths

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