TCT-184

Immobilized recombinant human troponilasin on a plasma-activated coating dramatically enhances biocompatibility of metal alloys: implications for coronary stents

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Background: Metallic endovascular stents have suboptimal biocompatibility reducing their clinical efficacy. We sought to develop a unique non-thrombogenic metal/protein interface to covalently bind proteins in their bioactive state to metallic surfaces, to achieve vascular biointegration of stents. We then bound recombinant human troponilasin TE (TRE), a major regulator of vascular cell function and investigated the biocompatibility of TRE-coated metal compared to 316L stainless steel (SS).

Methods: A pulsed plasma deposition system was developed to deposit a plasma-activated coating (PAC), a carbon-based surface capable of covalent protein binding, on 316L stainless steel sheets or on slotted tube stents. Horseradish peroxidase and human recombinant TE were bound to PAC. PAC surfaces were characterized for 1) coating durability, 2) immobilized protein adhesion, activity and stability, 3) cellular interactions and 4) thrombogenicity.

Results: PAC is extremely smooth (1-2nm rms roughness), is wear resistant using a 3 week pulse flow of 500ml/min. 100μl/ml clotting is prevented after stent expansion. Horseradish peroxidase activity (a probe for retention of protein conformation) remained higher after 10 days when bound to PAC vs SS. TE remained attached to PAC despite SDS washing, and incubation with supraphysiological serum enzymes, indicating covalent binding. PAC+TE coating dramatically enhanced endothelial cell attachment and proliferation by 86.3±10.5% (p<0.01) & 76.9±6.4% (p<0.001 vs Control) respectively. Moreover, thrombus weight was reduced on PAC & PAC+TE by 94.0±9.0% and 93±1.2% respectively (p<0.001 vs Control) in a model of angioplasty loop, and time to clot formation was reduced 3-fold. Serum soluble P-selectin was reduced by 25.3±8.7% and 24.5±8.7% on PAC and PAC+TE respectively, p<0.05.

Conclusion: PAC is durable, non-thrombogenic metal coating that enables covalent binding of bioactive proteins to stents. PAC+TE enhanced endothelialisation and remained non-thrombogenic. This has profound potential to improve stent efficacy.

TCT-185

Comparison of bivalirudin versus heparin during PCI in patients receiving prasugrel M Hamon, S Marso, SV Rao, M Valgimigli, F Verheugt, A Gershlick, Y Wang, YG Steg, D Elinier

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Background: Antiplatelet agents are used as adjunctive agents with BIV or unfractionated or low molecular weight heparin (HEP) a glycoprotein IIb/IIIa inhibitor (GPI) in PCI. Prasugrel (PRAS) is a recently introduced agent and thus little data is available regarding the use of PRAS with BIV.

Methods: Using the Premier Perspective database, 6986 patients who underwent elective, urgent, or primary PCI between Q3 2009 and Q4 2010 from 166 US hospitals were identified. Patients were treated with either BIV (n=3377) or HEP GPI (n=3609) on the day of PCI and given PRAS before or on the day of PCI. Outcomes of interest included bleeding, transfusion, death, and hospital length of stay. To control for patient and hospital level characteristics, propensity score matching analyses were performed.

Results: 13 patients met the above criteria. All patients received: clopidogrel 600mg pre-procedure; prasugrel 60mg, 15 patients met the above criteria. All patients received: clopidogrel 600mg pre-procedure; prasugrel 60mg, 15 patients met the above criteria. All patients received: clopidogrel 600mg pre-procedure; prasugrel 60mg, 15 patients met the above criteria. All patients received: clopidogrel 600mg pre-procedure; prasugrel 60mg, 15 patients met the above criteria. All patients received: clopidogrel 600mg pre-procedure; prasugrel 60mg. They were admitted for acute coronary syndrome procedure lasting 5.5 hours. None received pretreatment with antihistamines or rescue medications. Each patient received PRBC infusion for procedure duration; abc 0.25mg/kg bolus IA via T6, divided if multiple dwellers, & 10mg/kg/min IV for 12 hours; t-PA 10mg/kg of T6 catheter with 10min dwell, 53% required 2 dwells for lesions >50cm. Age 72±9.3; Male 53% 31±11cm. The majority of the thrombus was lysed in all cases; adjunctive thrombolytic use was seen in 53% of the cases to clean up minor residual thrombus. Pre Hg 13.0±1.9/dL. Post Hg 10.9±2.2/dL. A closure device was used in all cases. Bleeding complications: 1 pt had a GI bleed, 3 pts had >4cm groin hematoma, 5 pts had significant in argument on >30cm in vivo, and 5 pts had clinically significant late embolic tx despite primary PCI. Pre Hg 13.0±1.9/dL. Post Hg 10.9±2.2/dL. A closure device was used in all cases. Bleeding complications: 1 pt had a GI bleed, 3 pts had >4cm groin hematoma, 5 pts had significant in argument on >30cm in vivo, and 5 pts had clinically significant late embolic tx despite primary PCI.

Conclusion: The utility and safety of Bivlaridurin in the Out-patient Peripheral Procedures

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Background: According to recent studies Bivalirudin, in comparison to heparin, provides reduced clinical event rates after percutaneous coronary interventions. In peripheral interventions it is even more important to obtain a predictable and reliable anticoagulation level because of the higher risk of the vascular and bleeding complications. Therefore, and in the light of increasing demands for health care cost reduction, we believe that by combining Bivalirudin with Vascular Closure Device (VCD), we can safely discharge patients within 5 hours after the procedure. The aim of this study was to evaluate the incidence of early and late complication rates after the same-day discharge peripheral interventional use with the use of Bivalirudin as the procedural anticoagulant.

Methods: Between January 2008 and May 2011, in San Antonio Endovascular & Heart Institute 409 peripheral interventional procedures were performed in 188 consecutive patients. Patients received Bivalirudin in accordance with the standard protocol. Hemostasis was obtained with Mynx VCD. Primary end point (Major Vascular Complications): retroperitoneal bleeding, urgent hospitalization, hematoma>5cm and pseudoaneurysms. Secondary end point (Minor Vascular Complications): ecchymosis, hematoma<5cm and adjunctive manual compression. Follow up was performed three times: before discharge, next day and 30±5 days after the procedure.

Results: 168 procedures (41.1%) were performed with antegrade approach. Hemostasis was achieved after 409 (100%) procedures. Mean times to hemostasis and ambulation were 2.5±3.9 min and 3±1.2±2.8 hours, respectively. All patients were discharged on the day of intervention. Primary end points noted in 16 cases (3.9%) included 7 hematoma>5cm, 3 retroperitoneal bleedings, 2 pseudoaneurysms and 4 hospitalizations. Secondary end point was observed after 61 (14.9%) procedures (19 hematoma>5cm, 4 adjunctive manual compressions, 38 ecchymosis>20cm).

Conclusion: Bivalirudin, thanks to favorable pharmacokinetics and pharmacodynamics, is an attractive alternative to heparin in Peripheral Interventions and seems to ensure safe discharge 5 hours after the procedure.

TCT-186

Combination Abciximab and t-PA Use with the Trellis™-6 Peripheral Infusion System for Thrombotic Occlusion of the Superficial Femoral and Popliteal Arteries

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Background: The Trellis™-6 (T6) catheter (Covidien, Mansfield, MA, USA) has proximal and distal occlusion balloons with drug infusion holes inbetween and mechanical drug dispersion capabilities allowing mechanical pharmacological thrombolysis of the superficial femoral (SFA) and popliteal (POP) arteries. Yet, the optimal dose of lytics and ideal dwell time of the T6 catheter are unknown. We report our experience with the combination abciximab (abc), t-PA and T6 in the SPA-Pop.

Conclusion: In this analysis of real world data, patients receiving BIV and PRAS had less bleeding than with HEP+GPI and required less transfusion.

TCT-188

Long Term Outcomes in Patients with Acetylsalicylic Acid Sensitivity Undergoing a Novel Desensitization Protocol

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Background: Patients with aspirin sensitivity (2.5%) have an increased risk of cardiovascular events. Undergoing a Novel Desensitization Protocol

Methods: During a 2 year period, 111 patients were enrolled in a desensitization protocol. Undergoing a Novel Desensitization Protocol

Results: Of the 380 pts undergoing coronary angiography, seventy-seven had a history of aspirin sensitivity (2.5%). They were admitted for acute coronary syndrome (67.2%) or stable angina (32.4%). A history of cutaneous reactions was reported in 76% of pts, respiratory sensitivity in 21.5%, whereas 2.5% had a history of anaphylactic shock. All pts underwent the desensitization procedure: six sequential doses of aspirin (1, 5, 10, 20, 40, and 100 mg) administered orally at predefined intervals, with the procedure lasting 5.5 hours. None received pretreatment with antihistamines or corticosteroids, and beta-blockers were withheld 24 hours before desensitization. Blood
pressure, pulse, cutaneous, nasoocular, or pulmonary reactions were monitored until 4 hours after the procedure. Pts were followed-up for 18 ± 6.3 months. Major adverse cardiac events (MACE), defined as death, repeat revascularization and stroke were recorded.

Results: The desensitization procedure was successful in 71 pts (92.2%). No serious adverse reactions occurred: 3 pts with history of idiopathic urticaria developed cutaneous reaction, 2 pts (with frequent asthma attacks) experienced shortness of breath associated with bronchospasm, and 1 pt had shortness of breath without bronchospasm. All reactions were immediately resolved with corticosteroids and antihistamines. The mean time from desensitization to coronary angiography was 35.6 ± 33.3 hours. All pts but 15 (19.4%) underwent PCI (1.8 stent/pat, DES 75.5%, multivessel PCI 31.4%) and were discharged on dual platelet therapy. At follow-up, aspirin was maintained in 92.9% pts. None of the discontinuations were due to allergic reaction. The incidence of MACE was 6.5% (1 non-cardiac death and 4 repeat revascularizations). None of the pts experienced stent thrombosis.

Conclusion: This novel desensitization procedure seems to be safe and effective in the vast majority of pts with cutaneous or respiratory aspirin sensitivity. Complex PCI procedures can be performed also in such pts, without increasing the risk of stent thrombosis.

Bioabsorbable, Drug-Eluting, and Bare Metal Stent Studies

TCT-192
Two-Year Patient Outcomes with the Resolute Zolotrolimus-Eluting Stent: Results of the RESOLUTE International Registry

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Background: The Resolute stent (R-ZES) is a new-generation zotarolimus-eluting stent that utilizes the BioLinx polymer, a proprietary tri-polymer coating that provides gradual drug elution out to 180 days while maintaining biocompatibility to allow for noninvasive healing. The RESOLUTE International study showed optimal 1-year performance of the R-ZES for treatment of coronary artery disease, however, longer follow-up is required for a full comprehension of its clinical safety and efficacy.

Methods: RESOLUTE International is part of the Global RESOLUTE Clinical Trial Program, and is a prospective, multi-center, observational registry, which enrolled 2349 patients with symptomatic coronary artery disease from 88 centers worldwide. The trial had minimal eligibility criteria to reflect routine clinical practice, and the primary endpoint was cardiac death and target-vessel myocardial infarction (CD-TV-MI) at 1 year. This trial was harmonized with the rest of the Global RESOLUTE Clinical Program from an adjudication point of view. Enhanced edit checks to detect unreported procedural MIs, and full monitoring of all patient consents and 25% monitoring of patient source files were also per performed. We will report the overall 2-year clinical outcomes, and comparisons between unmonitored (75%) and source file monitored (25%) patient cohorts.

Results: Patients were enrolled between 29 August 2008 and 19 March 2009, and 97.4% of patients completed 1-year follow-up. At baseline, 78% were male, 31% had diabetes mellitus, 46% with acute coronary syndrome, and 67.5% had at least 1 complex clinical/lesion characteristic. Clinical outcomes at 1 year were: CD-TV-MI, 4.2%; TVR, 3.4%; definite/probable ST, 0.9%. There were no significant differences in 1-year outcomes between monitored and unmonitored patients, reflecting the robustness of the trial data.

Conclusion: We will report the overall 2-year clinical outcomes with special emphasis on safety endpoints at the time of the meeting.

TCT-193
Outcomes After Revascularization with Everolimus- and Sirolimus Eluting Stents in Patients with Acute Coronary Syndromes: A Substudy of the SORT OUT IV Trial

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Background: Randomized trials comparing outcomes after implantation of first generation drug-eluting stents (DES) versus second generation DESs in patients with acute coronary syndromes (ACS) are limited. In this study of the SORT OUT IV trial, we compared the clinical outcome among patients with ACS and stable angina pectoris (SAP) treated with everolimus-eluting stents (EES) or sirolimus-eluting stents (SES).

Methods: Of 2,705 patients treated for ACS or SAP, 1,178 (43.5%) patients had ACS and were treated with EES (n=1,353, ACS: n=580) or SES (n=1,352, ACS: n=598). The primary composite endpoint, major adverse cardiac events (MACE), was defined as a composite of cardiac death, myocardial infarction (MI), stent thrombosis, or target vessel revascularization (TVR) within 18 months.

Results: 18-month MACE was higher among ACS patients compared to patients with SAP: 8.1% vs. 6.7%, Hazard Ratio (HR) 1.23, 95% confidence interval (CI) 0.93-1.62. In ACS patients, clinical outcome in EES treated patients did not differ significantly to SES treated patients at 18 months; MACE 7.3% vs. 8.9% (HR 0.81, 95% CI 0.54-1.22), cardiac death 2.8% vs. 2.0% (HR 1.39, 95% CI 0.66-2.93), MI 2.1% vs. 2.3% (HR 0.88, 95% CI 0.41-1.91), stent thrombosis 0.5% vs. 0.7% (HR 0.77, 95% CI 0.17-3.45) and TVR 4.3% vs. 5.9% (HR 0.73, 95% CI 0.44-1.12). Also in the group with SAP, the clinical outcome did not differ significantly between EES- and SES-treated patients.

Conclusion: EES and SES appear similar with respect to MACE in patients with ACS.