**Safety of Bivalirudin as a Single Antithrombotic Agent in Patients Undergoing Percutaneous Coronary Intervention and Vascular Brachytherapy With Gamma and Beta Emitters**

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**Background:** Bivalirudin (Angiomax) has proven to be a valuable alternative to heparin in percutaneous coronary intervention (PCI). The aim of this study is to assess the efficacy and clinical safety of bivalirudin administration in patients undergoing PCI and vascular brachytherapy (VBT) with γ; and β; radiation.

**Methods:** A total of 100 patients who were included in the BRAVES (Brachytherapy and Bivalirudin Evaluation Study) trial at the Washington Hospital Center, and who underwent PCI and VBT with either γ (192)Ir or β (90)Sr or (90)Y radiation were investigated for procedural, in-hospital and 30-day clinical outcomes. All patients were treated with bivalirudin as a single antithrombotic agent during PCI.

**Results:** Baseline clinical and angiographic characteristics were similar between the two groups. In-hospital events showed a higher prevalence of early thrombotic occlusions in patients treated with γ radiation (25% vs 11%, p = 0.02) Thirty-day outcomes were comparable in both groups.

**Conclusions:** The use of bivalirudin as an antithrombotic agent during PCI and vascular brachytherapy was safe only with β radiation, and should not be used in the setting of PCI and γ radiation due to high incidence of intraprocedural thrombosis.

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**Coronary Blood Flow Velocity and Myocardial Perfusion With Balloon Occlusion and Filter-Based Distal Protection Devices in Saphenous Vein Graft Stenting: Early Experience of Two Centers**

Gora Weisz, Amir Hakim, Costantino O. Costantini, Issan Micheov, Arlene Reyes, Issam Moussa, Zoran Lasic, Tudor Vageoescu, Vladimir Ilic, Martin B. Leon, Antonio Colombo, Jeffrey W. Moses, Lenox Hill Heart and Vascular Institute, and Cardiovascular Research Foundation, New York, NY

**Background:** Distal emboli following saphenous vein grafts (SVG) stenting results in high rates of peri-procedural events. Distal protection devices (DPD) were shown to be associated with improved outcomes. We compared the effect of balloon vs. filter devices on blood flow (frame count) and myocardial perfusion (blush).

**Methods:** In two institutions, the first 57 consecutive pts that had filter-DPD SVG-stenting of de novo lesions were compared to 57 consecutive pts in whom balloon - DPD was used, in the same period of time. Measurements were done before placement of the DPD, and post retrieval. Cathangiographic frames were counted from ostium of graft to distal anastomosis (TFCg), anastomosis to a standardized distal landmark (TFCn), and combined (TFCh). Myocardial blush was graded 0-3 using the Zwirel/CRF methodology.

**Results:** The two groups were balanced in demographics, risk factors, and clinical presentation. TIMI flows, frame counts, and blush are shown in Table. In-hospital non Q-wave MI occurred in 5 pts in the filter group, and 1 in the balloon group (p=ns). There were no Q-wave MIs, urgent revascularizations, or mortality in either group.

**Conclusions:** This early world experience in SVG’s treatment suggests that balloon occlusion and aspiration DPD enhance immediate post procedure coronary flow (especially in the native coronary segment) and myocardial perfusion compared to filter-based DPDs. Whether this is due to learning curve with filters, or has clinical relevance deserves further study.
Arterial Closure Device Decreases Vascular Complications After Percutaneous Coronary Interventions

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Background: Vascular complication is an important determinant of patient satisfaction after Percutaneous Coronary Intervention (PCI). Many studies have shown that use of closure devices (CD) had lower vascular complications after PCI, but some studies have not.

Methods: We analyzed patients who had PCI from July 1999 to March 2003: 2,033 patients had attempted closure devices (61% Perclose, 27% Angioloop, 6% Vasoseal, 3% Duett, 2% unsuccessful), and 4,419 patients had manual compression.

Results: Using intention to treat analysis, the use of closure device compared to manual compression (MC) resulted in decrease in overall vascular complication (1.4% vs. 2.6%, p=0.0008), specifically, in moderate to large hematomas, or retroperitoneal bleeding (p=0.0062), pseudoaneurysm (p=0.003), but not in vascular surgery (p=0.7). Successful deployment of the device had a very low vascular complication rate (1.2%). The predictors for CD deployment failure(2% of all devices used) were: Month of July (8.4% vs. 1.7%, p=0.0001) and increasing body weight (p=0.03). After successful deployment of CD, the predictors for significant vascular complications included July month, the use of Duett or Vasoseal (7.7% vs. 1.1% in Perclose or Angioloop, p=0.0001), female sex (2.2% vs. 0.8%, p=0.0001), CHF NYHA class (p=0.0034), age (p=0.001), and the use of post-procedural heparin (3.4% vs. 1.1%, p=0.04), but not the use of glycoprotein IIb/IIIa (p=0.8). Weight and ACTmax were not predictors for vascular complication after successful deployment of device. If the device fails to deploy, the risk of vascular complication was much higher (18% vs. 1.2%, p=0.0001), especially if glycoprotein IIb/IIIa had been used (21% vs. 0%, p=0.04), mostly moderate or large hematoma. Vascular complication was a significant predictor for in-hospital death (p<0.0001), though the successful or unsuccessful use of CD had no significant statistical impact on survival. Length of stay was significantly lower in CD (19±3.1 day vs. 26±5.0 days) p<0.0001).

Conclusion: Use of vascular closure devices after PCI resulted in significantly lower vascular complications and a significantly lower length of stay.

ORAL CONTRIBUTIONS

ABSTRACTS - Angiography & Interventional Cardiology 53A

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Restenosis: Basic Research I

Monday, March 08, 2004, 9:15 a.m.-10:30 a.m.
Morial Convention Center, Hall E-2

9:15 a.m.

803-1

The Number and Adhesive Properties of Circulating Endothelial Progenitor Cells in Patients With In-Stent Restenosis

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Background: Endothelialization is essential to facilitate vessel healing after stent deployment to prevent restenosis. Circulating endothelial progenitor cells (EPC) are present in the peripheral blood and display endothelial functional properties along with ability to home to damaged vasculature. Prolifer in-stent intimal growth may be related to impaired endothelialization resulting from a reduced number or dysfunction of circulating EPC.

Methods: 27 patients (pts) after stent deployment had recurrent unstable angina and underwent coronary angiography. In 16 pts in-stent restenosis was demonstrated (group A), in 6 focal and in 10 diffuse. 11 had patent stents (group B). Both groups were similar with respect to drug usage and risk factors. Circulating EPC number was initially determined by the colony-forming unit assay and their phenotype was characterized by endothelial- cell markers. Adhesiveness of EPC from both groups to extra-cellular matrix and to endothelial cells was also assayed.

Results: Pts in both groups with in-stent restenosis and with patent stents displayed a similar number of circulating EPC (26.5±2.6 vs. 25.3±4.8). Pts with diffuse in-stent restenosis exhibited reduced numbers of EPC (24.0±3.9) as compared with patients with focal restenosis (30.7±1.7; p<0.05). Fibronectin-binding was compromised in pts in group A as compared to pts of group B (9.2±2.5 vs. 15.3±3.2 cells/field; p=0.01)

Conclusions: Reduced numbers of circulating EPC in pts with diffuse in-stent restenosis and impaired adhesion of EPC from patients with restenosis provides a potential mechanism mediating the exuberant proliferative process of restenosis. These markers, if further validated, could provide means of risk stratifying patients for the likelihood of developing in-stent restenosis.

3:30 p.m.

803-2

Genetic Predictive Factors for Restenosis After Percutaneous Transluminal Coronary Angioplasty

Pascale S. Monraats, Willem R.P. Agema, Aaiilo H. Zwintderman, Robbert J. de Winter, Rene A. Tio, Pieter A.F.M. Doevendans, Harry J.G.M. Crinjs, Moniek P.M. de Maat, Douwe E. Altsma, Arnoo van der Laarse, Ernst E. van der Wall, J.Wouter Jukema, Leiden University Medical Center, Leiden, The Netherlands

Background: Percutaneous transluminal coronary angioplasty (PTCA) is still limited by the recurrence of luminal stenosis. The underlying mechanisms are not fully understood. Stratifying patients at risk based upon clinical factors has proven difficult so far. However evidence exists that gene polymorphisms may play a role in the restenotic process. The aim of this study was to evaluate if various gene polymorphisms can predict clinically important restenosis after PTCA in an unselected patient population and thereby influence the choice of therapy.

Methods: The GENetic DETerminants of Restenosis (GENDER) project was a multicenter prospective cohort study, which included 3,146 patients after successful PTCA. Patients with acute myocardial infarction (MI) were excluded. Genotyping was performed for different polymorphisms in several candidate genes.

Results: A total of 3,146 patients (age 62.1±10.7 yrs) were followed for 10±3 months. Of the patients 2,250 (71.5%) were male, 459 (14.6%) had diabetes and 1,459 (46.4%) had multivessel disease. The majority was treated for stable angina. Stenting was performed in 2,340 (74.4%) patients. Target vessel revascularisation (TVR) after the first month of follow-up by either CABG or PTCA was necessary in 304 patients (9.7%). So far we identified an association between three polymorphism and TVR.

Conclusions: Reduced numbers of circulating EPC in pts with diffuse in-stent restenosis and impaired adhesion of EPC from patients with restenosis provides a potential mechanism mediating the exuberant proliferative process of restenosis. These markers, if further validated, could provide means of risk stratifying patients for the likelihood of developing in-stent restenosis.

9:30 a.m.