Conclusions: In this large pilot experience, rates of ischemic and bleeding events trended lower with bivalirudin than with heparin during contemporary PCI. Bivalirudin may be the first antithrombotic agent to uncouple suppression of ischemic events from hemorrhagic risk.

1053-4   Reduction in Percutaneous Coronary Intervention-Related Bleeding With Bivalirudin Is Particularly Striking in Women

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Background: Female gender is a known potent risk factor for post-procedural bleeding among patients undergoing percutaneous coronary intervention (PCI).
Methods: Within a randomized clinical trial of coronary angioplasty comparing bivalirudin to unfractionated heparin (the Bivalirudin Angioplasty Trial), rates of ischemic events and major hemorrhage were stratified by gender.
Results: Of the 4312 patients enrolled, 1387 (32.2%) patients were women. Compared to males, female gender was associated with a 2.3-fold increased risk of major hemorrhage - males: 131/2925 (4.5%) vs females: 144/1387 (10.4%) ($p<0.0001$). When stratified by treatment arm, bivalirudin was associated with a significant reduction in bleeding regardless of gender. However, this effect was most striking among female patients (Table). Considering a combined safety and efficacy endpoint of death, MI, revascularization, and major hemorrhage, bivalirudin was associated with a 50% relative risk reduction in adverse events in women - 141/690 (20.4%) vs 69/697 (9.9%) ($p<0.0001$), and a 35% relative risk reduction in men - 171/1461 (11.7%) vs 111/1464 (7.6%) ($p<0.0001$).
Conclusions: Bivalirudin is associated with a substantial reduction in bleeding and ischemic events in both men and women, but the improved safety profile is especially prominent among women. Such patients with an increased risk of bleeding during PCI may benefit if bivalirudin is used in place of unfractionated heparin.

Major Hemorrhage

	Heparin	Bivalirudin	P Value
Women	(107/690) 15.5%	(37/697) 5.3%	<0.0001
Men	(92/1461) 6.3%	(39/1464) 2.7%	<0.0001

1053-5   A New Rapid Ecarin Clotting Time Assay but Not Activated Clotting Time Strongly Correlates With Bivalirudin Concentration: A Percutaneous Coronary Intervention Study

Leslie Cho, Joel Reginelli, A. Michael Lincoff, Marco Roffi, Teresa Kaldus, Kandice Kottke-Marchant, Patrick D. Mize, David J. Moliterno, *The Cleveland Clinic Foundation, Cleveland, Ohio, Pharmanetics Inc, Chapel Hill, Ohio.*

Background: Recently, direct thrombin inhibitors (DTI) have been approved for anticoagulation in percutaneous coronary interventions (PCI). The accuracy of the activated clotting time (ACT), used for monitoring heparin, is uncertain for patients receiving DTI. A new point-of-care assay has been developed based on the ecarin clotting time (ECT), which specifically measures the activity of direct thrombin inhibitors. No prior study has evaluated the correlation of ECT and ACT to the direct measurement of anti Factor IIa activity duirng PCI. **Methods:** To test the accuracy of available ACT assays (Hemochron and Pro-DM) and the rapid ECT assay (Pharmanetics), we enrolled 64 consecutive PCI patients receiving the DTI bivalirudin at The Cleveland Clinic. We compared point of care ACT and ECT to central laboratory anti Factor IIa activity levels. Anti Factor IIa activity is a direct measurement of bivalirudin concentration in body. Samples were tested in both citrated and non-citrated blood. Correlation coefficient was calculated by the Spearman test. **Results:** Bivalirudin concentration correlated well with ECT sample (r=0.78, p<0.001). In contrast, there was relatively poor correlation between bivalirudin concentration and Hemochron ACT (r=0.26, p=0.05) or pro-DM ACT (r=0.41, p<0.001). There was also poor correlation between ECT and Hemochron ACT (r=0.27, p=0.04) and ECT with pro-DM ACT (r=0.52, p<0.001). There was poor correlation between pro-DM ACT and Hemochron ACT (r=0.40, p=0.002). **Conclusion:** ECT is a reliable measurement of anticoagulation in patients receiving bivalirudin, while ACT has poor correlation with bivalirudin concentration. Additionally there is poor correlation between ACT and ECT in such patients. These findings have important implications for guiding the extent of anticoagulation during PCI with DTI.

POSTER SESSION

1054   Vulnerable Plaque: Acute Ischemic Syndromes

Sunday, March 17, 2002, 3:00 p.m.-5:00 p.m.
Georgia World Congress Center, Hall G
Presentation Hour: 3:00 p.m.-4:00 p.m.

1054-13   Smoking, Thrombus, and Plaque in the Culprit Vessel in Patients With Acute Myocardial Infarction: Angioscopic Findings

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Backgrounds, Habitual smoking is paradoxically associated with good prognosis in patients with acute myocardial infarction (AMI), and results in the higher successful thrombolytic therapy. Therefore, we investigated the hypothesis that smoking status is closely associated with amount of thrombus culprit lesion. **Methods,** The prevalence of plaques and amount of thrombus in the major coronary arteries were successfully evaluated in 62 patients (male: 55, mean age: 60.2). All patients were underwent percutaneous coronary intervention (PCI), and the residual amount of thrombus after PCI were semi-quantatively divided into 2 groups (massive: n=33 or little: n=29) by angioscopy. Furthermore, we analyzed the color of plaque on culprit lesion (4 grades from white to yellow), and the number of plaque in infarct related artery (IRA). **Results,** 65% of the enrolled patients were current smokers. Although baseline TIMI grade was not significantly changed, prevalence of collateral vessels to infarcted related artery was higher in smoking patients, compared with non- smoking patients (45% vs. 17%, p=0.09). The massive thrombus was higher prevalence in smoking patients, compared with non-smoking patients (65% vs. 22%, p<0.01). The number of plaque in IRA (3.0±2.0 vs. 3.3±1.8), max plaque score (2.7±0.9 vs. 2.7±0.9) and the color of plaque in culprit lesion (2.7±0.9 vs. 2.6±1.1) were not significantly affected by smoking status. As coronary risk factors, Total cholesterol (205 vs. 180 mg/dl, p<0.05) and triglycelide (138 vs. 114 mg/dl, p<0.05) were significantly higher, and the prevalence of hypertension (50% vs. 35, p<0.1) was significantly lower in smoking patients. **Conclusion.** This is first evidence to assess the association of smoking status and the amount of thrombus in culprit lesion directly, and also these findings may provide the explanation of the smoker's paradox.

1054-14   Possible Mechanism of Coronary Thrombosis Caused by Vasospasm in Angiographically Nearly Normal Coronary Artery: Evaluation by Plaque Appearance and Malondialdehyde-Modified Oxidized LDL

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Background: Investigators have that demonstrated focal vasospasm has a high incidence of acute coronary syndrome(ACS) compared with diffuse vasospasm. Recently circulating malondialdehyde-modified oxidized LDL(MDA-LDL) was reported to activate thrombus formation .Therefore we investigated the differences in plaque appearance and plasma MDA-LDL between two patterns of vasospasm .Methods and Results: Blood samples were collected from aortic root(Ao) and coronary sinus(CS) before provocation of left coronary spasm . After relief of spasm, IVUS study was performed and volumetric analyses of spasm lesions were evaluated with Netra-3D IVUS system. More abundant soft plaque was localized just at the lesion with focal vasospasm even in the absence of significant angiographic disease, whereas in diffuse vasospasm, intimal thickness existed diffusely along the coronary arteries. Data is presented in Table.Conclusions: Plasma MDA-LDL levels associated with triggering thrombosis were significantly elevated in the coronary circulation in focal vasospasm. Under this condition, dramatically increased % plaque volume during focal vasoconstriction might play an important role in the mechanism of thrombogenicity leading to ACS .

	Diffuse n=20	Focal n=15	p value
Cs-Ao difference of MDA-LDL (U/L)	-6.9+/-9.0	12+/-14.9	<0.05
Vessel volume(mm3)	127.7+/-39.1	134.4+/-44.0	ns
Lumen volume(mm3)	91.3+/-11.2	79.5+/-10.8	ns
Plaque volume(mm3)	30.6+/-10.2	55.2+/-10.3	<0.05
% plaque volume(plaque volume/vessel volume)	23.9+/-9.2	40.2+/-9.6	<0.05

1054-15   Insulin Resistance as an Independent Predictor of Acute Coronary Syndrome: An Intravascular Ultrasound Study With Clinical Correlations

Takashi Yoshitama, Masato Nakamura, Taro Tsunoda, Yoko Kitagawa, Masanori Shiba, Suguru Yajima, Masamichi Wada, Raisuke Iijima, Rintaro Nakajima, Takuro Takagi, Hitoshi Anzai, Takahiro Nishida, Tetsu Yamaguchi, *Ohashi Hospital, Toho University, Tokyo, Japan.*

Background: Insulin resistance has been implicated as an important initiating factor in coronary atherosclerosis. However, associations between insulin resistance and acute coronary syndrome (ACS) remain unclear.
Methods: Before intervention, 75 patients with 85 culprit lesions underwent intravascular ultrasound (IVUS) examination by which cross-sectional area (CSA) within the external elastic membrane (EEM), lumen CSA, and plaque CSA were evaluated. Positive remod-