stratified according to planned GPIIb/IIIa inhibitor(GP) use. Bolus Dalt. or UFH were administered via arterial sheath (100 units/kg alone or 70units/kg with planned GP) immediately prior to PCI. The primary endpoint was death, myocardial infarction (defined as CK-MB ≥2XULN), urgent CABG/PCI or need for bail-out GP) up to 24 hours post-procedure.

Results: A total of 321 (Dalt. 160 (51 planned GP) vs UFH 161 (50 planned GP) patients were randomized. All randomized patients received the assigned drug and underwent PCI. Overall baseline characteristics were as follows: mean age 62.9 yrs, male gender 70.4%, diabetes 25.5%, PCI post acute coronary syndrome 50.5%, stent 88.2%, multivessel 11.5%, ad-hoc PCI 27.1%, clopidogrel pre-treatment 87%. The primary endpoint was reached in 21(13.1%) Dalt. and 22(13.7%) UFH patients (p=ns). There was one death in the Dalt. group due to guider dissection. Angiographic complications (abrupt closure or new thrombus) occurred in 6 (3.8%) Dalt. vs 4(2.5%) UFH patients. There were two major bleeds, both in the UFH group. The primary composite plus re-hospitalization at 30 days was 18.1% vs 16.1%, Dalt. vs UFH patients. Mean activated clotting time at 30 minutes post bolus was 239s for Dalt. vs 345s for UFH. Mean anti-factor Xa levels were Dalt. 1.1 *u*/mLvs UFH 0.8 *u*/mLat 30 minutes and Dalt.0.6 *u*/mL vs UFH 0.2 *u*/mL at 4 hours post PCI. Conclusions: Dalt. appears to be a safe and effective alternative to UFH during PCI, either alone or in combination with IV GPIIb/IIIa inhibitors. Despite elevated anti-factor Xa levels at 4 hours, bleeding complications were not increased in the Dalt. group.

1176-202

Tissue Factor Predicts Long-Term Outcome After Percutaneous Coronary Revascularization

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Background:Tissue factor (TF) induced upon inflammatory stimuli including C-reactive protein (CRP) could participate in the thrombus progression associated with plaque rupture.

The aim of this study was to determine the predictive value of plasma levels of TF measured immediately before percutaneous coronary revascularization (PCR).

Methods:Plasma TF and hs CRP were prospectively measured in 175 consecutive patients before PCR. Patients with 1.5 ng/mL were excluded. The primary endpoint was the composite of death, myocardial infarction and hospitalization for unstable angina at one year. Multivariate correlates of events were analyzed with the use of Cox's proportional hazard model. Risk factors such as age, gender, diabetes, smoking status, family history of CAD, hypertension, hyperlypidemia, unstable angina, left ventricular ejection fraction, hs CRP and plasma TF were included in the analysis.

Results: The mean +/- SD TF level was 205 +/- 169 pg/mL and the mean +/- SD hs CRP level was 0.8+/- 1.6 mg/dL. The actuarial rate of events was 9.7% at 1 year. Tertiles of TF were predictors of cardiac events at 1 year (see Table).

Three independent predictors were found in this population: diabetes (p=0.007), hs CRP (p=0.01) and plasma TF (p=0.02).

Conclusion: Plasma TF measured immediately before PCR is an independent predictor of cardiac events at 1 year. This suggests that measurement of TF may help to select patients at high risk of events following PCR.

	n	events (%)	
tertile 1 (<130 pg/mL)	60	1.7%	
tertile 2	59	8.5%	0.005
tertile 3 (>200pg/mL)	56	19.6%	

ORAL CONTRIBUTIONS

850 Brachytherapy Update

Tuesday, April 01, 2003, 2:00 p.m.-3:30 p.m.
McCormick Place, Grand Ballroom S100 A

2:00 p.m.

850-1

Angiographic In-Stent Restenosis Patten Predicts Outcome After Gamma Vascular Brachytherapy

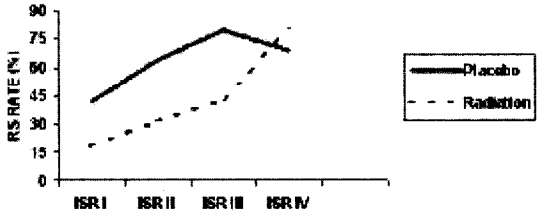
Costantino O. Costantini, Alexandra J. Lansky, Roxana Mehran, Kazuyuki Shirai, Maria Corral, Moses Tarawali, Teraza Conway, Brian Proctor, Ecaterina Cristea, George Dangas, Gregg W. Stone, Martin Leon, Cardiovascular Research Foundation, New York, NY

Background: Angiographic in-stent pattern (ISRP) is an important predictor of RS after conventional PCI. The prognostic value of ISRP after gamma VBT has not been defined.

Methods : From a pooled data set of gamma VBT for ISR trials, the ISRP was assessed in 531 pts. Placebo (N=206) and radiated (N=327) pts were compared for angiographic recurrence based on the ISRP. The patterns are defined as focal (I), diffuse in stent (II), diffuse proliferative (III) or total occlusion (IV).

Results: Demographics were well matched between groups. Mean reference diameter (2.66±0.6 vs 2.67±0.5), lesion length (22.7±11.8 vs 21.2±11) and final MLD (1.99±0.4 vs 1.95± 0.3) were similar (p=NS) between placebo and radiated patients. Angiographic RS rate increased with higher ISRP class for placebo (42.2%, 63.6%, 79.3%, 69.2%, p=0.002) and radiated pts (18.7%, 31.6%, 43.1%, 80%, p<0.001) from I to IV, respectively (graphic). A treatment effect was maintained with Gamma VBT except for ISRP IV, where RS rate was not significantly different compared to placebo. By multivariable regression analysis, ISRP was an independent predictor of treated segment RS in both treatment groups.

Conclusions : Angiographic classification of ISR is prognostically important independent of the treatment applied. Although a treatment effect is observed in class I, II and III, gamma radiation does not improve angiographic outcome in pattern IV compared to placebo. ISRP continues to identify pts with higher probability of recurrence even after Gamma VBT.



2:15 p.m.

850-2

Five-Year Follow-Up After Intracoronary Gamma Radiation Therapy for In-Stent Restenosis: Results From a Randomized Clinical Trial

Ron Waksman, Andrew E. Ajani, Larry R. White, Edouard F. Cheneau, Augusto D. Pichard, Lowell F. Satler, Kenneth M. Kent, Regina Deible, Verne Mattox, Ellen Pinnow, Peter Iloanya, Joseph Lindsay, Washington Hospital Center, Washington, DC

Background: The Washington Radiation for In-Stent Restenosis Trial (WRIST) is a double-blinded randomized study evaluating the effects of intracoronary radiation therapy (IRT) in patients (pts) with in-stent restenosis (ISR).

Methods: One hundred and thirty pts with ISR (100 native coronary and 30 vein grafts) underwent PTCA, laser ablation, rotational atherectomy, and/or additional stenting (36% of lesions). Pts were randomized to either ^{192}Ir IRT, with a prescribed dose of 15 Gy to a 2 mm radial distance from the center of the source or to placebo.

Results: Angiographic restenosis (27% vs. 56%, p=0.002) and target vessel revascularization [TVR, (26% vs. 66%, p<0.001)] were dramatically reduced at 6 months in IRT pts. Between 6 and 60 months, IRT pts compared to placebo had more target lesion revascularization (IRT=20% vs. placebo=1.5%, p=0.001) and TVR (IRT=20% vs. placebo=3%, p=0.003). At 60 months clinical follow-up, pts receiving IRT continued to have markedly lower MACE (TLR) rates when compared with placebo: 51% vs.71%, p=0.02 (see Figure).

Conclusions: In WRIST, pts with ISR treated with IRT using ^{192}Ir had a marked reduction in the need for repeat target lesion and vessel revascularization at 6 months. Although more events were recorded in the irradiated group at the follow-up 6-60 months, the clinical benefit was maintained at five years without adverse events related to the radiation therapy.