

5:00 p.m.

ORAL CONTRIBUTIONS

822-5

**Impact of Radiation Dose on Outcomes in Diabetic Patients: Results From the SCRIPPS IV Trial**

Paul S. Teirstein, Jeffrey Moses, Martin Leon, Michael Collins, Roxanna Mehran, Eve Montang, Manuela Neogota, Huan Giap, Ray Lin, Shirish Jani, Stephen Balter, Jack Dalton, Roberto Lipsztein, Matthew J. Price, Prabhakar Tripuraneni, ScrippsClinic Research Foundation, La Jolla, CA, Lennox Hill Hospital, New York, NY

**Background:** The Scripps IV trial investigated the safety and efficacy of 14 Gy vs 17 Gy of gamma intracoronary radiation for the treatment of in-stent restenosis (ISR). Patients (pts) with diabetes mellitus (DM) are at particularly high risk for developing recurrent ISR and may benefit from the higher dosing regimen.

**Methods:** 358 patients with native or vein graft ISR  $\leq$  80 mm in length and diameter between 2.75 and 4 mm were randomized in a double-blind fashion to 14 or 17 Gy at 2mm from the radiation source. Angiography was obtained at 8 months.

**Results:** Baseline characteristics were equivalent between the 14 Gy and 17 Gy groups for the DM and non-DM pts, except more males in the DM group received 17 Gy. Mean lesion length was 22mm and mean vessel diameter was 0.75mm. At 8 months, DM pts who received 17 Gy had a 57% reduction in MACE (death, MI, or target lesion revascularization,  $p=0.003$ ), 63% reduction in target lesion revascularization (TLR) ( $p<0.002$ ), and a 61% reduction in target vessel revascularization (TVR) ( $p<0.001$ ) compared to DM pts receiving 14 Gy. In contrast, higher dosing did not significantly impact MACE in the non-DM pts (22.4% vs 16.3%,  $p=ns$ ). There were no differences in stent thrombosis between treatment groups in DM or non-DM pts.

**Conclusions:** In diabetics, a dosing regimen of 17 Gy, instead of the recommended 14 Gy, of gamma radiation at 2 mm from the source is safe and results in significantly less MACE, TLR, and TVR at 8 months. Higher dosing of gamma radiation should be considered when treating diabetic pts.

Diabetes	14 Gy (n=50)	17 Gy (n=64)	p value	No Diabetes	14 Gy (n=116)	17 Gy (n=98)	p value
MACE (Death/MI/TLR)	44.0%	18.8%	0.003	MACE (Death/MI/TLR)	22.4%	16.3%	NS
Death	2.0%	4.7%	NS	Death	0.9%	1.0%	NS
TLR	42.0%	15.6%	<0.002	TLR	20.7%	15.3%	NS
TVR	48.0%	18.8%	<0.001	TVR	26.7%	23.5%	NS
MI	2.0%	3.1%	NS	MI	0.9%	1.0%	NS
Acute Stent Thrombosis	0%	0%	NS	Acute Stent Thrombosis	0%	0%	
Late Stent Thrombosis	0%	3.1%	NS	Late Stent Thrombosis	1.7%	0%	

5:15 p.m.

822-6

**Restenosis After Sirolimus-Eluting Stent Implantation: Long-Term Evaluation Following Repeat Percutaneous Intervention**

Pedro A. Lemos, Chourmouzos A. Arampatzis, Angela Hoye, Joost Daemen, Francesco Saia, Andrew T L Ong, Georgios Sianos, Jiro Aoki, Pieter C. Smits, Willem J. van der Giessen, Pim de Feyter, Eugenne McFadden, Sjoerd H. Hofma, Ron T. van Domburg, Patrick W. Serruys, Erasmus University Medical Center, Rotterdam, The Netherlands

**Background:** Restenosis after sirolimus-eluting stent (SES) implantation has been shown to occur in a small but sizeable proportion of cases. Currently, the best management of patients with post-SES restenosis remains undefined.

**Study Population:** From April 2002, drug-eluting stent implantation has been adopted as the default strategy in our institution, without clinical or anatomical restrictions. During 6 months enrollment, a total of 631 patients received at least one SES. From these, 22 consecutive patients have undergone subsequent repeat percutaneous intervention to treat post-SES restenosis. The long-term outcomes after the re-treatment are reported.

**Results:** Patients with post-SES restenosis treated with repeat percutaneous intervention were frequently diabetics (46%). Re-treatment was performed after a median time of 204 days from the index procedure. Most patients were re-treated with implantation of another drug-eluting stent at the restenotic site: new SES implantation in 10 patients (46%), and paclitaxel-eluting stent implantation (46%). The remaining 2 patients were treated with plain balloon dilatation and bare stent implantation respectively. After a median follow-up of 131 days, the incidence of death, myocardial infarction, or re-intervention was zero. One-year follow-up will be available at the presentation. **Conclusions:** Percutaneous re-treatment of post-SES restenosis utilizing repeat drug-eluting stent implantation as the strategy of choice appears to be safe and associated with very low incidence of recurrence at medium-term follow-up.

830

**Distal Embolic Protection**

Tuesday, March 09, 2004, 8:30 a.m.-10:00 a.m.  
Morial Convention Center, Hall E-1

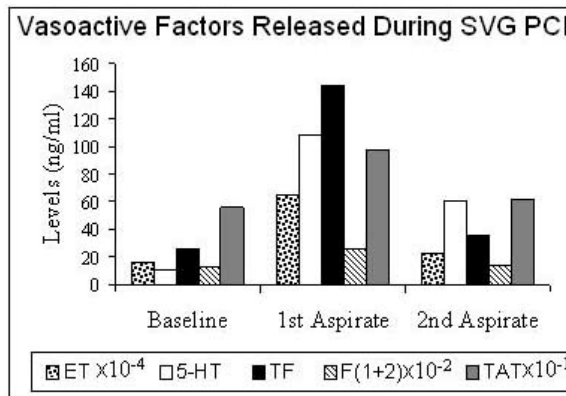
8:30 a.m.

830-1

**Elimination of Soluble Vasoactive Factors by the PercuSurge GuardWire Distal Protection Device During Percutaneous Coronary Intervention of Saphenous Vein Graft**

Joseph Salloum, Bhagat Reddy, Douglas E. Vaughan, David X. Zhao, Vanderbilt University Medical Center, Nashville, TN

**Background:** Embolization, vasoconstriction, and *in situ* thrombosis are potential mechanisms of no-reflow during SVG PCI. While most distal protection devices trap debris, only distal occlusion and aspiration systems such as PercuSurge Guardwire (GW) eliminate soluble factors that can lead to vasoconstriction and *in situ* thrombosis. **Methods:** We tested the hypothesis that soluble vasoactive factors were released during PCI and removed by GW in 35 consecutive patients underwent SVG PCI using GW. Blood was taken prior to PCI for baseline measurement of vasoconstrictors: endothelin (ET), serotonin (5-HT), and components of coagulation: tissue factor (TF), plasminogen activator inhibitor 1 (PAI-1), prothrombin fragment 1+2 (F1+2), and thrombin-antithrombin complex (TAT). After stenting and before deflating the distal protection balloon, two aspiration runs were performed with the export catheter and sent for analysis. **Results:** Levels of vasoactive factors were substantially higher in the first post-intervention aspirate as compared to baseline: ET (300% increase,  $p=0.001$ ), 5-HT (970%,  $p=0.031$ ), TF (450%,  $p=0.005$ ), F1+2 (95%,  $p=0.04$ ), and TAT (76%,  $p=0.05$ ). Levels were significantly lower in the second aspirate, indicating clearing of these vasoactive factors. **Conclusions:** Vasoactive factors are released during SVG PCI. GW effectively removes debris and soluble factors, which may translate clinically in a more effective distal protection as compared to filter devices.



8:45 a.m.

830-2

**Platelet Glycoprotein IIb/IIIa Receptor Inhibition as Adjunctive Treatment During Saphenous Vein Graft Stenting: Differential Effects After Randomization to Occlusion or Filter-Based Embolic Protection**

Michael Jonas, Gregg W. Stone, James Hermiller, Robert Feldman, Patrick Hall, Robert Haber, Zaki Masud, Patrick Cambier, Ron P. Caputo, Mark Turco, Richard Kovach, Bruce Brodie, Howard C. Hermann, David Cox, Roxana Mehran, Campbell Rogers, Brigham and Women's Hospital, Boston, MA, Cardiovascular Research Foundation, New York, NY

**Background:** Embolic protection devices (EPD) reduce complications during saphenous vein graft (SVG) PCI. However, periprocedural adverse events occur in >10% of patients. IIb/IIIa inhibitors (IIb/IIIa) have not been proven effective during SVG PCI, although adjunctive use with certain EPD's may improve outcomes.

**Methods:** In the prospective, multicenter FIRE trial, 651 pts undergoing SVG stenting were randomized to either the FilterWire EX or the balloon occlusion/aspiration GuardWire EPD. IIb/IIIa use was at the discretion of the investigator, but randomization was stratified by intended use. Data regarding IIb/IIIa treatment was available in 646 pts.

**Results:** In FIRE, IIb/IIIa were used in 345 (51.5%) FilterWire EX and 301 (53.3%) GuardWire pts ( $p=0.65$ ). Patients preselected for IIb/IIIa use had higher baseline risk: more angina/recent MI (93.9% vs 89.0%  $p=0.03$ ), lower rate of TIMI 3 flow (77.3% vs 87.1%  $p=0.001$ ), tighter diameter stenosis (68.6 vs 64.7%  $p=0.002$ ), and higher SVG degeneration score. They also had a higher incidence of 30d MACE (12.8% vs 8.0%  $p=0.05$ ).

Although overall success rates and 30d outcomes were similar with both EPD's, marked differences were noted in IIb/IIIa effect between the FilterWire and GuardWire. As opposed to the GuardWire population (MACE with IIb/IIIa 15.5%, without IIb/IIIa 6.3%