

based distal protection to balloon occlusion and aspiration during PCI of diseased saphenous vein grafts. The principle safety and efficacy data will be unblinded for presentation in March 2003.

3:00 p.m.

820-5

### Economic and Clinical Analysis of Elective Percutaneous Coronary Intervention Without On-Site Cardiac Surgery

Kirsten Hall Long, Henry H. Ting, Erin K. Mc Murtry, Aaron S. Terry, Thomas H. Tiggelaar, Ryan J. Lennon, Kirk N. Garratt, Mandeep Singh, Charanjit S. Rihal, Douglas L. Wood, David R. Holmes, Mayo Clinic, Rochester, MN

**Background:** Elective percutaneous coronary interventions (PCI) are routinely performed at hospitals with on-site cardiac surgery (CS). Since 1999, elective PCI has been performed at Immanuel St. Josephs Hospital (ISJ), a community hospital without on-site CS, with telemedicine support from Saint Marys Hospital (SMH).

**Methods:** 215 PCI patients at ISJ were matched on clinical and lesion criteria to 430 PCI patients at SMH. Clinical outcomes assessed included procedural success (<20% residual stenosis and without in-hospital death, myocardial infarction, coronary bypass surgery, or repeat PCI), and target vessel failure rates at 1 year (any death, myocardial infarction, or target vessel revascularization). Economic outcomes included billed charges for room and board, medications, supplies, laboratory, and hospital length of stay.

**Results:** Procedural success rates were similar between groups (ISJ 99.0%; SMH 97%). Target vessel failure rates were also similar between groups at 1 year follow-up (ISJ 16%; SMH 16%, P=0.80). Results of the economic comparison are shown in the table. Patients undergoing PCI at ISJ had significantly higher charges for medication and supplies reflecting higher utilization of stents (93% versus 86%) and glycoprotein IIb/IIIa inhibitors (88% versus 57%).

**Conclusions:** Favorable clinical outcomes can be achieved at a hospital without on-site CS at additional cost. Economic analyses are ongoing to assess the relative cost-effectiveness of providing PCI without on-site CS.

Economic Endpoints (2000 Constant Dollars)

	ISJ (mean)	SMH (mean)	Bootstrapped 95% CI (mean difference)	P-value
Room and Board	\$2422	\$2341	(-183, 346)	0.64
Medications	\$2602	\$1147	(1299, 1610)	<0.0001
Laboratory	\$1731	\$1401	(164, 486)	0.0009
Supplies	\$5013	\$3861	(698, 1564)	0.0001
Length of Stay	2.34 days	2.23 days	(-0.173, 0.378)	0.49

3:15 p.m.

820-6

### Genetic Risk Diagnosis System for Restenosis After Percutaneous Coronary Intervention

Hideo Izawa, Yoshiji Yamada, Hideki Horibe, Tomoko Kato, Sahoko Ichihara, Fumimaro Takatsu, Toyooki Murohara, Mitsuhiro Yokota, Nagoya University Graduate School of Medicine, Nagoya, Japan, Gifu International Institute of Biotechnology, Mitake, Japan

**Background:** Although genetic epidemiological studies have suggested that several genetic variants increase the risk for restenosis after percutaneous coronary intervention (PCI), the genes that contribute to this condition remain to be identified definitively. Our aim was to develop a reliable system for genetic risk diagnosis of restenosis after either plain old balloon angioplasty (POBA) or stent implantation separately.

**Methods:** Restenosis was evaluated for 1390 (910 in men, 480 in women) and 1001 (710 in men, 291 in women) coronary lesions 6 months after successful POBA or stent implantation, respectively. The genotypes for 19 or 18 single nucleotide polymorphisms (SNPs), which we previously identified in an association study of 112 polymorphisms in 71 genes with 445 patients with myocardial infarction and 464 controls, were determined in men and women, respectively, with a fluorescence- or colorimetry-based allele-specific DNA primer-probe assay system.

**Results:** Multivariate logistic regression analysis with adjustment for age, body mass index, and the prevalence of smoking, hypertension, diabetes mellitus, hypercholesterolemia, and hyperuricemia revealed that six and five SNPs were associated with restenosis after POBA or stent implantation, respectively, both in men and in women. Combined genotype analysis yielded maximal odds ratios of 15.09 and 44.54 for restenosis after POBA and of 6.64 and 117.83 for in-stent restenosis in men and women, respectively.

**Conclusions:** Ten and seven genes are susceptibility loci for restenosis after PCI in Japanese men and women, respectively, and the corresponding combined genotypes may prove reliable for determination of genetic risk for restenosis after POBA or stent implantation. This genetic risk diagnosis system is thus expected to contribute to the prediction of restenosis after PCI.

## ORAL CONTRIBUTIONS

## 823 Percutaneous Intervention: Highlighted Biologic and Pharmacologic Adjuncts

Monday, March 31, 2003, 2:00 p.m.-3:30 p.m.  
McCormick Place, Room S402

2:00 p.m.

823-1

### Improvement in Symptoms and Exercise Capacity at Eight Weeks in a Controlled Study of Autologous Bone Marrow Cell Transplant in Humans With Severe Ischemic Heart Failure

Emerson C. Perin, Hans F. Dohmann, Radovan Borojevic, Andre Luiz S. Sousa, Hans J. Dohmann, Antonio C. Carvalho, Yong J. Geng, Guilherme V. Silva, Fernando Rangel, Suzana A. Silva, Roberto Esporcatte, James T. Willerson, Texas Heart Institute, Houston, TX, Hospital ProCardiaco, Rio de Janeiro, Brazil

**Background:** Relatively limited treatment options exist for pts with severe ischemic heart failure (HF). We evaluated the safety and efficacy of transcatheter (TE) delivery of bone marrow mononuclear cells (BMNC) to treat pts with severe HF.

**Methods:** Fourteen pts (57.2 ± 10.5 yrs, 11 males) with severe LV dysfunction by echo (EF 27 ± 8 %) and severe CAD not amenable to revascularization were included. Pts were evaluated by exercise stress tests before and 8 wks after the procedure. Bone marrow (50ml) was aspirated from the iliac crests and BMNCs were isolated. TE injections were performed using the Myo-Star catheter (NOGA, Biosense) to target hibernating myocardium in 10 pts. Four pts were followed without cell implants as a control group.

**Results: Events:** There were no major in-hospital events. Minor events included transient hypotension with pulmonary congestion (n=1) and PVCs (n=1) on day 1. CK-MB levels did not increase in 24h. Late events in the BMSC group included 1 pt that had NSTMI at 7 days. In the Control group 1 pt died at 8 wks. **Non-invasive F/U:** In the BMNC group NYHA functional class decreased from 2.2±0.8 to 1.2±0.4 compared to an increase 2.3± to 2.5± in the control group (p<0.0004). Exercise times increased from 7.45 ± 1.97 to 9.00± 0.2 min.in the treatment group vs. 7.42±0.48 to 4.26±2.00 in the control group. SPECT results will be presented.

**Conclusion:** Preliminary results suggest that TE delivery of BMNCs is safe and feasible. In this high risk and small group of pts we have observed symptomatic benefit and improvement in treadmill exercise time. Further studies and follow-up are needed.

2:15 p.m.

823-2

### Glycoprotein IIIa PIA Polymorphism and Early Outcome After Coronary Stenting in Patients With Adjunctive Abciximab Therapy

Nicolas von Beckerath, Olga Gorchakova, Werner Koch, Julinda Mehilli, Petra Hoppmann, Adnan Kastrati, Albert Schomig, TU München, Munich, Germany

**Background:** P<sup>a</sup> polymorphism of glycoprotein (GP) IIIa has been intensively investigated. We and others have reported that homozygous P<sup>a</sup> carriage is associated with an increased risk of early thrombotic events following coronary artery stenting. In those studies only few or no patients had received abciximab. One purpose of this study was to test if the prothrombotic influence of the P<sup>a</sup> allele after coronary stenting persists in the presence of potent antiplatelet therapy with abciximab. The second purpose was to test whether P<sup>a</sup> polymorphism that underlies most cases of alloimmunethrombocytopenia occurring in caucasians is associated with thrombocytopenia in response to abciximab.

**Methods:** Consecutive patients (n=2265) undergoing coronary stent implantation with adjunctive abciximab therapy were included in the study. Serial platelet counts were obtained (baseline, 8, 16, 24, 72h post intervention and before discharge) and in case of a platelet count < 100 000/μl pseudothrombocytopenia was excluded or confirmed. GP IIIa P<sup>a</sup> genotyping was performed with a TaqMan assay. Thrombotic events (death, myocardial infarction and stent thrombosis) were recorded during the first 30 days following stent implantation. Acute profound thrombocytopenia was defined as a true drop in platelet count to < 20 000/μl within 24h.

**Results:** The overall genotype distribution was 2.8% P<sup>a</sup>2/A<sup>a</sup>2, 26.7% P<sup>a</sup>2/A<sup>a</sup>1 and 70.5% P<sup>a</sup>1/A<sup>a</sup>1. Early thrombotic events were observed in 4.8% of P<sup>a</sup>2/A<sup>a</sup>2, 5.0% of P<sup>a</sup>2/A<sup>a</sup>1 and 5.4% of P<sup>a</sup>1/A<sup>a</sup>1 patients (P=0.88). Acute profound thrombocytopenia developed in 14 patients (1 P<sup>a</sup>2/A<sup>a</sup>2, 7 P<sup>a</sup>2/A<sup>a</sup>1 and 6 P<sup>a</sup>1/A<sup>a</sup>1). Thus, carrying P<sup>a</sup>2 was afflicted with a three-fold increase of the risk to develop acute profound thrombocytopenia (OR 3.2 [95% CI, 1.11-9.30]).

**Conclusions:** Adjunctive abciximab therapy appears to eliminate the previously described prothrombotic influence of the P<sup>a</sup>2 allele in the setting of coronary stenting. P<sup>a</sup>2 carriers, though, have an increased risk to develop acute profound thrombocytopenia in response to this therapy.