and in thin fibrous cap atheromas.

specimens with SFC with sensitivity 83% and specificity 86%.

JACC March 19, 2003

The primary end point was thus achieved in 53.8% of acolysis and 73.1% of abciximab.

cardial Infarction was also higher in patients treated with acolysis (5.4% vs 2.2%, p=NS).

patients (p=O.O14) due mainly to a greater frequency of non-Q-wave myocardial infarction

(19.6% vs 7.9%, p=O.O3) in patients treated with acolysis. The incidence of Q-wave myocardial infarction was also higher in patients treated with acolysis (5.4% vs 2.2%, p=NS).

The 30-day composite rate of adverse events. X-SIZER use does, however, reduce procedural complications as evidenced by less need for bail-out GP IIb/llla inhibitors, and enhances 30-day survival free from large MI.

Conclusions. FIRE is the first completed large-scale randomized trial comparing filter-
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**


**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. Joseph’s 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=0.90). 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 (86% 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)**

<table>
<thead>
<tr>
<th></th>
<th>ISJ</th>
<th>SMH</th>
<th>Bootstrapped 95% CI (mean)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room and</td>
<td>$2422</td>
<td>$2341</td>
<td>(-183, 346)</td>
<td>0.64</td>
</tr>
<tr>
<td>Room</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications</td>
<td>$2062</td>
<td>$1147</td>
<td>(1299, 1610)</td>
<td>&lt;0.000</td>
</tr>
<tr>
<td>Laboratory</td>
<td>$1731</td>
<td>$1401</td>
<td>(164, 446)</td>
<td>0.0009</td>
</tr>
<tr>
<td>Supplies</td>
<td>$5013</td>
<td>$3861</td>
<td>(698, 1654)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Length of Stay</td>
<td>2.34 days</td>
<td>2.23 days</td>
<td>(-0.173, 0.378)</td>
<td>0.49</td>
</tr>
</tbody>
</table>

3:15 p.m.

**820-6 Genetic Risk Diagnosis System for Restenosis After Percutaneous Coronary Intervention**

*Hideo Tsubaki*, Yoshiji Yamada, Hideki Horibe, Tomoko Kato, Sakohoko Ichihara, Fumimaro Takatsu, Toshiaki Murakura, Mitsuhiro Yokota, Nagoya University Graduate School of Medicine, Nagoya, Japan, &If" International lnstit& 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 risk condition remain to be definitively identified. 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 patients at St Marys Hospital (SMH) for 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 1 gene with 440 patients with myocardial infarction and 440 controls, were determined in men and women, respectively, with a fluorescence- or calorimetry-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 in men and women, respectively, with a fluorescence- or calorimetry-based allele-specific DNA primer-probe assay system.

**Conclusions:** A genetic risk diagnosis system was expected to contribute to the prediction of restenosis after PCI.

**1:00 p.m.**

**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**

Emeron C. Bates, Hans F. Dohmann, Redovan Bonjovic, Andre Luis S. Sousa, Hans J. Dohmann, Antonio C. Carvalho, Yong J. Geng, Guilherme V. Silva, Fernando Rangel, Suzara 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 (87.2 ± 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. serial marrow mononuclear cell and BMNCs were isolated. TE injections were performed using the Myo-Star catheter (NOGVO, Biosense) to target hibernating myocardium in 10 pts. Four pts were followed without cell implants as a control group.

**Results:** 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 BMNC group included 1 pt that had NSTEMI at 7 days. In the Control group 1 pt died at 8 wks. Non-invasive FU: In the BMNC group NYHA functional class decreased from 2.2±0.8 to 1.6±0.4 compared to an increase 2±0.8 to 2.5±0.6 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 4.2±0.20 in the control group. SPECT results will be presented.

**Conclusions:** Preliminary results suggest that TE delivery of BMNCS is safe and feasible. Further studies and follow-up are needed.

**2:15 p.m.**

**823-2 Glycoprotein Ila PIA Polymorphism and Early Outcome After Coronary Stenting in Patients With Adjunctive Abciximab Therapy**

Nicolai von Beckerath, Olga Gorchekova, Werner Koch, Julinda Mehlli, Petra Hoppmann, Adrian Kasrati, Albert Schomig, Munich, Germany

**Background:** PII* polymorphism of glycoprotein (GP) IIa has been intensively investigated. We and others have reported that homoscygous PII* IIa 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 PI A2 allele after coronary stenting persists in the presence of recent abciximab therapy with abciximab. The second purpose was to test whether PII* polymorphism that underlies most cases of alloimmunethrombocytopenia occurring in caucasians is associated with thrombocytopenia in response to abciximab.

**Methods:** Consecutive patients (n=2288) undergoing coronary stent implantation with adjunctive abciximab therapy were included in the study. Serial platelet counts were obtained (baseline, 8, 16, 24, 72 h post intervention and before discharge) and in case of a platelet count < 100 000 /µL pseudothrombocytopenia was excluded or confirmed. GP IIa PI genotype was determined 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 2.6% PI A2/A2, 26.7% PI A2/A1 and 70.5% PI A1/A1. Early thrombotic events were observed in 4.8% of PI A2/A2, 5.0% of PI A2/A1 and 5.4% of PI A1/A1 patients (P<0.006). Acute profound thrombocytopenia developed in 14 patients (1 PI A2/A2, 7 PI A2/A1 and 6 PI A1/A1). Thus, carrying PI A2/A2 was associated with a three-fold increase of the risk to develop acute profound thrombocytopenia (OR 3.2 [95% CI, 1.1-9.3]).

**Conclusions:** Adjunctive abciximab therapy appears to eliminate the previously described prothrombotic influence of the PI A2 allele in the setting of coronary stenting. PI A2 carriers, though, have an increased risk to develop acute profound thrombocytopenia in response to this therapy.