1121-60 **Sirolimus Drug-Eluting Stent for the Treatment of In-Stent Restenosis (I-SR) With a Clinical and Angiographical Follow-Up Over Six Months**

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Introduction: I-SR still is a major challenge in interventional cardiology. Sirolimus Drug Eluting Stents (DES) have been successfully implanted in patients with de-novo stenosis in the Ravel and Sirius trial with low restenosis rates. The aim of this registry was to determin whether patients with I-SR can successfully be treated with the DES
Patients and Methods: During the time from May 2002 till April 2003 we collected data from 60 (48 male; aged 62 years) consecutive patients with I-SR who were treated with DES. (LAD 34, CX 12, RCA 7, vein graft 7). 28 patients had a history of MI and 10 patients of bypass surgery. Diabetes was present in 11 patients (64% IDDM). Angiographical and clinical follow up were scheduled 6 months after index procedurer. The grade of the stenosis at implantation and at follow up was assessed by QCA. A diameter stenosis more then 50% was considered relevant. Values are given as mean ± standard deviation.
Results: The implantation of DES in the treatment of I-SR was successful in all patients, in 53 after predialtation and in 7 patients direct stenting was achieved. The mean implantation pressure was 16,7 bar. At the time of this report 48 patients had clinical and angiographic follow up (5,96±1,01 months).
Before stent implantation we found a MLD of 0,84±0,38mm and after the stent implantation a MLD of 2,32±0,36mm with an acute lumen gain of 1,48±0,45mm. After 6 months the MLD was 2,26±0,48mm, resulting in a late lumen loss of 0,06±0,33mm. Binary restenosis rate was 4%.Clinically 44 patients were asymptomatic, 4 patients suffered from angina pectoris CCS class 3 or 4. In 11 patients a reintervention was performed based on angiographical data, but only 2 of them had target lesion restenosis over 50%. One of these patients received bypass surgery the other had an aditional stent implantation. 9 patients had an intervention in an other segment of the coronaries.
Conclusion: Data of our registry implicate that I-SR can be treated with the DES very effectively.

1121-61 **Characterization of Neointimal Hyperplasia After Sirolimus-Eluting Stent Implantation in Patients With Previous Brachytherapy Failure: Insights From the SECURE Study**

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Background: The patterns of neointimal hyperplasia (NIH) after drug-eluting stent (DES) implantation in patients with de novo coronary lesions have been reported. The aim of this study was to determine the pattern of NIH after the implantation of sirolimus eluting stents in patients who have failed brachtherapy and other revascularization procedures using 3D IVUS
Methods: The compassionate use of Sirolimus Drug Eluting Stents (SECURE) trial was conducted in 5 US sites. All patients with failed brachytherapy had mandated 8-month angiographic and IVUS followup. Volumetric 3D IVUS data was analyzed by an independent core lab. Significant NIH was defined as >10% lumen obstruction. Focal IH was defined as <10mm in length or <25% of total stent length. The location of obstruction was defined as proximal, mid or distal portion of the stent. Results: To date 252 patients have enrolled in the SECURE trial and 39 brachy failure patients have completed 8 month IVUS follow-up. Mean age was 60 years, 42% diabetics, and 16% with SVG lesions. Mean stent length was 27.4 mm. Twenty-eight patients had minimal or no NIH throughout the stent segment. Significant NIH was found in 11 patients, with a mean NIH length of 10.55mm. Average NIH volume was 57mm^3 with 27% lumen volume obstruction. NIH was focal in 8 patients. The focal stenoses were located mainly in mid portion of the stent (n=5) versus proximal (n=1) and distal (n=2) edges. One patient had multifocal NIH located in proximal and mid portions of the stent, and 2 patients had a diffuse pattern. Echolucent tissue (black hole) was found in 6 of 11 patients with significant NIH and 3 patients with minimal NIH. Black hole was the predominant in-stent tissue observed in 5 patients.
More data will be available at time of presentation.
Conclusions: Preliminary IVUS data confirm the focal pattern of NIH, even in patients with previous PCI and failed brachytherapy treated with long/multiple overlapping DES. In contrast to previous DES studies in de novo lesions, NIH was located mainly the mid portion of the stent. Black hole was frequently observed in patients with significant NIH.

1121-62 **Pattern of Brachytherapy Failure in Unselected Patients Treated With Gamma and Beta Radiation for Saphenous Vein Graft In-Stent Restenosis**

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It is postulated that failure would be high with vascular brachytherapy (VBT) in saphenous vein grafts (SVG) for unselected patients treated outside of clinical trials.We studied 36 consecutive patients undergoing treatment for SVG in-stent restenosis (ISR) at our institution (8.7% of VBT cases). Four patients received multi-SVG VBT. Beta radiation using a Sr/Y-90 source train was used in 30 (73%), 8 (20%) were treated using a P-32 source train, and 5(12%) were treated with gamma radiation using the IR-92 wire. RESULTS: Baseline demographics showed a mean age of 64±11 years with 16 (44%) diabetics, and 31 (86%) patients were men. Mean reference diameter was 3.0± 0.59 mm, and the minimum lumen diameter was 0.65± 0.64 mm with an acute gain of 1.9± 0.87 mm. Mean lesion length was 22.5 mm±21.2 requiring stepped therapy in 16(39%) of cases. The in-hospital major adverse cardiac events rate was 5.7%. During a median follow-up of 166 days, target lesion revascularization occurred in 9 patients (3 due to geographic miss and 6 due to brachytherapy failure at the target lesion); 6 additional patients underwent non-target lesion revascularization . Freedom from any revascularization was 80% at 90 days and only 55% at 180 days. CONCLUSION: VBT in SVG is feasible and safe with both gamma and beta radiation, but repeat revascularization procedures are extremely common, and result from a combination of brachytherapy failure, geographic miss, and non-target lesion revascularization in this cohort with long lesions, larger vessels, and a high prevalence of diabetes.

POSTER SESSION

1138

Miscellaneous Interventional Topics

Tuesday, March 09, 2004, Noon-2:00 p.m.
Morial Convention Center, Hall G
Presentation Hour: 1:00 p.m.-2:00 p.m.

1138-41 **Impact of Obesity on Cardiovascular Outcomes in Patients Undergoing Percutaneous Coronary Intervention: Is There Really a Paradox?**

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Background:
Obese adults are at increased risk for cardiovascular morbidity and mortality, however a higher body mass index (BMI=wt/ht^2) of patients undergoing PCI is associated with a paradoxically better outcome as suggested by recent studies. These studies were limited by small sample size.
Hypothesis:
The purpose of our study was to examine the relationship of BMI to cardiovascular outcomes following PCI.
Methods:
Between Jan 1, 2001 and Mar 31, 2003, data on 278,105 consecutive PCI procedures was submitted to the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR). Five BMI categories were compared. Complications and risk of mortality using a validated risk model were calculated for each category.
Results:
The table summarizes complications and the predicted mortality:

	Low weight BMI _ 18.5	Normal BMI 18.6 to 24.9	Overweight BMI 25.0 to 29.9	Obese BMI 30.0 to 35.0	Very Obese BMI > 35.0	p-Value
N	2,181	55,623	103,568	66,557	45,423	**<0.0001**
In-hospital Death	3.7%	2.0%	1.3%	0.9%	0.9%	**<0.0001**
Post PCI MI	1.6%	1.3%	1.1%	1.1%	0.9%	**<0.0001**
Unplanned CABG	1.0%	0.8%	0.7%	0.7%	0.7%	**<0.0001**
Vascular Bleeding	2.8%	2.1%	1.6%	1.4%	1.9%	**<0.0001**
Predicted Mortality	2.3%	1.7%	1.2%	0.9%	0.9%	**<0.0001**

Further analysis of risk model factors demonstrated that compared with very obese patients, the low weight group had more patients with age greater than 80 (24.7% vs. 5.7%) and more often were females (60.3% vs. 31.3%) more likely to have chronic lung disease (32.9% vs. 16.4%) and LV Ejection fraction < 35% (12.4% vs. 7.1%) p<0.00001.
Conclusions:
Analyses of data from the ACC-NCDR confirm the observation of paradoxically better outcome for obese patients undergoing PCI, but demonstrate that this phenomenon is primarily due to the differences in PCI risk that is associated with different comorbidities.

1138-42 **13-Year Follow-Up of the German Angioplasty Surgery Investigation**

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Background: The German Angioplasty Bypass Surgery Investigation (GABI) was designed to compare symptomatic efficacy and safety of percutaneous coronary angioplasty (PTCA) and coronary artery bypass surgery (CABG) in patients with symptomatic multivessel disease. This follow-up was performed to determine the long-term outcome of patients undergoing these interventions.
Methods: From 1986 to 1991, 359 patients with angina CCS class II-IV, age below 75 years and coronary multivessel disease requiring revascularisation of at least 2 major coronary vessels were recruited at 8 German centers and randomized to PCI or CABG. Exclusion criteria were complete occlusion, lesion length of >20 mm, recent myocardial infarction and left main coronary artery stenosis > 30%.