878-2
Oral Rapamycin in Patients Undergoing Coronary Stent Therapy: Final Results of the ORAR Study (Oral Rapamycin in Argentina)
Alfredo E. Rodriguez, Maximo Rodriguez Alemprate, Carlos Fernandez Pereira, César F. Vigo, Claudio Laubach, Miguel A. Pozo, David Vethcer, Otamendi Hospital, Buenos Aires, Argentina, Argentine Society for Cardiac Intervention, Buenos Aires, Argentina

Background: We previously reported (ACC03) preliminary findings of this study suggesting that high concentration of rapamycin blood level (>8ng/ml) is associated with a trend to low late loss and restenosis rate in patients(pts) undergoing coronary stent therapy.

Methods: From December 2001 to February 2003, 76 pts with 103 arteries treated with stents were included in phase I (34 pts/49 arteries) and phase II (42 pts/54 arteries) of the ORAR study. A loading dose of 6 mg of oral rapamycin was administered immediately after stent deployment in all pts. In Phase I, 2 mg of oral rapamycin was given daily during 28 days. In Phase II 3 mg daily of rapamycin was given plus 160 mg of diltiazem during 28 days. Rapamycin blood levels were measured at third week in all pts. Cholesterol and triglycerides were evaluated before and after one month of treatment. Stains were given as well clopidogrel in all pts during six months. Angiographic binary restenosis, late loss, target lesion revascularization, treatment compliance, side effects and optimal concentration of the drug were analyzed. At the present time 6 month angiographic follow up data were available in 82.5% of the arteries.

Results: Baseline clinical characteristics showed diabetes 25.2%, type B1, B2 and C lesions in 81%, reference vessel size -2.9 mm in 37% and with a length of 11.2 ± 0.8 mm. Minor side effects were present in 25% of the patients but only 3% discontinue the treatment (4%). Follow up quantitative angiographic data showed that pts having > 8 ng/ml compared with those having < 4 ng/ml had lower late loss (0.65 mm vs. 1.11 mm respectively p < 0.033), binary in stent restenosis (6.2% vs. 23% respectively p < 0.039) and better MLD (2.16 mm vs.1.71 respectively p < 0.054). Pearson test showed strong correlation between blood level of the drug and the late loss (r = 0.0001). Minor adverse side effects had a trend to increased with high blood concentration of the drug (p = 0.083).

Conclusions: Oral rapamycin after coronary stent deployment in those pts who reached high concentration of the drug are associated with low late loss, binary restenosis and better MLD in the follow up angiogram. A randomized drug / placebo study is ongoing (ORAR II).

878-3
Subgroup Analysis of the Impact of the Glycoprotein Iib/IIa Inhibitor Abciximab in Patients Undergoing Elective Stent Placement >2 Hours After Treatment With a 600 Milligram Loading Dose of Clopidogrel: Results From the ISAR REACT Trial

ISAR REACT was designed to evaluate whether the glycoprotein Iib/IIa inhibitor abciximab is beneficial in low and intermediate risk patients undergoing elective percutaneous coronary intervention (PCI) with a stent after maximal inhibition of aggregation had been achieved after pretreatment with a high, 600 mg loading dose of clopidogrel. The frequency of events among subgroups, including the 20% of pts with non-insulin dependent diabetes (n=441), has not been reported. (See figure for results)

Conclusion: In these subgroups of varying risk among the low to intermediate risk patients who undergo elective PCI after pretreatment with a high loading dose of clopidogrel, the results suggest that, as in the entire trial glycoprotein Iib/IIa inhibitor abciximab is associated with no clinically measurable benefit within the first 30 days.

878-4
Qualitative and Quantitative Analysis of Saphenous Vein Graft Platelet Debris Within the MedNova CardioShield™ Embolic Capture Device
David R. Holmes, Jr., on behalf of the CAPTIVE Pivotal Study Investigators, Deena Weber, Frank Kolodgie, Renu Virmani, Mayo Clinic, Rochester, MN, Armed Forces Institute of Pathology, Washington, DC

Background: There is limited information on the composition of atherothrombotic debris released during stent treatment of diseased aorto-coronary bypass saphenous vein grafts (SVG). Intravascular filtration systems provide a unique opportunity to analyze plaque debris captured following SVG intervention.

Device Description: The CardioShield embolic capture device consists of a polyurethane membrane having 140 micron distal perfusion holes, two proximal entry ports, and an internal self-expanding nitinol support system. The filter is delivered over a pre- placed 0.014” filter delivery wire, allowing independent wire movement, and is deployed distal to the SVG lesion. Following stenting, the filter is removed using a retrieval catheter system.

Methods: One-hundred sixteen (116) filter devices utilized during stent treatment of 113 SVG lesions were submitted for histologic and morphometric analysis. Filter contents were removed, embedded, and microscopically evaluated to establish a profile of the contained embolic debris.

Results: Atherothrombotic debris was collected in 95% (92%) of the 116 devices. In the devices containing debris, 72 (76%) demonstrated macrophage foam cells, 46 (48%) had smooth muscle cells, and 85 (90%) had necrotic core. Other identified debris included platelets/fibrin in 89 (94%), cholesterol clefts in 56 (59%), and collagen/elastin in 51 (54%). Use of a platelet glycoprotein IIb/IIIa inhibitor did not affect a difference in frequency, amount or composition of embolic debris. Morphometric measurements on 1,193 particles yielded an average particle size of 0.11 mm2 and minimal/maximal areas of 0.02 mm2 and 0.50 mm2, respectively. The area of the largest particle was 3.47 mm2. The majority of devices contained particles <0.1 mm2.

Conclusions: During treatment of SVG disease, embolic debris is frequently liberated and seen in the majority of patients. The debris typically consists of necrotic core, macrophage foam cells, and platelet/fibrin aggregates. This filter system is effective at capturing released embolic particles of variable size and composition.

878-5
Provisional Versus Systematic T Stenting: Insights From a Large Prospective Single-Center Database
André Kojis, Gunasekaran Senguttuvan, Thierry Lefèvre, Samer Mansour, Yves Lounaud, Pierre Dumais, Christophe Loubeyre, Marie-Claude Morice, Institut Cardiovasculaire Paris Sud, Massy, France

Background: Although numerous studies on PCI in bifurcation lesions are available, the superiority of either provisional or systematic T stenting has not been conclusively proven. Our registry is a large, single centre database on patients undergoing PCI in coronary bifurcations and will give insights on this issue.

Methods: Our registry of PCI in bifurcation lesions started in November 1995 including patients who underwent treatment for true and false bifurcation lesions. We compared from this prospective database the in-hospital and 6 months outcome following systematic versus provisional T stenting for bifurcation lesions.

Results: Of the 1149 patients, provisional T stenting strategy was the most commonly adopted strategy with 837 patients. In the provisional T stenting group, 25.6% patients also required a stent in the side branch. 297 received systematic T stenting which was performed using Type A treatment (Systematic T stenting of the side branch first) 33%, Type C treatment (Culotte) in 1.9% and Type D treatment (V stenting) in 6%. Baseline characteristics were similar in both groups. The angiographic success (residual stenosis < 50 %) was 93.6 % vs 91.8% in the main branch and 90.6 % vs 84.8% in the side branch in the systematic versus provisional T stenting group. In the provisional T stenting group compared to systematic T stenting group all measured parameters were significantly lower: in-hospital MACE (3.2% vs 7.4%, p = 0.008), in- hospital death (0.1% vs 1.3%, p = 0.02), sub-acute thrombosis (0.1% vs 1.7%, p = 0.007), need for urgent
repeated-PCI (1% vs 2.7%, p = 0.005), need for urgent CABG (0.1% vs 1.3%, p = 0.03), seven months MACE (1% vs 3.1%, p = 0.029), seven months TVR (11% vs 19.9%, p = 0.001), combined MACE/BVR at seven months (14.2% vs 26.9%, p = 0.001) and death at seven months (1% vs 3.1%, p = 0.029).

Conclusion: Analysis of our large database of bifurcation lesions shows that provisional T stenting is the sole modifiable predictor associated with a reduction in target vessel revascularization as well as MACE and should be the preferred strategy for coronary bifurcation lesion PCI.

ORAL CONTRIBUTIONS

880 Intracoronary Brachytherapy Wednesday, March 10, 2004, 10:30 a.m.-Noon Morial Convention Center, Hall E-1

10:30 a.m.

POST-T Repeat Intracoronary Gamma Radiation for Patients With In-Stent Restenosis Who Failed Radiation Therapy: Results From the Re-WRIST Clinical Trial
Ron Waksman, Andrew E. Ajani, Rebecca Torgeson, Donna J. Whitman, Daniel A. Canos, Regina Debbie, Lowell F. Satler, William O. Suddath, Augusto D. Pichard, Kenneth M. Kent, Joseph Lindsay, Washington Hospital Center, Washington, DC

Background: Intracoronary radiation (IR) is an effective therapy for preventing the recurrence of in-stent restenosis (ISR). However, nearly 20% of patients enrolled in radiation studies required repeat revascularization to the irradiated site. Re-WRIST is a registry evaluating the safety and efficacy of retreatment with IR.

Methods: Thirty pts (31 lesions) with ISR at the previously irradiated segment and who failed a subsequent angioplasty without radiation were eligible for retreatment with IR. The treatment protocol consisted of using Ir-192 seeds at the proximal stent and repeat radiation was performed at 6 months. The primary endpoint was the occurrence of a major adverse cardiac event (MACE) during follow-up.

Results: 18 patients were included: male 14, age 62 (13) year. The LAD/diag bifurcation was the target lesion in 17/18. Post-IR, and at follow-up, IVUS was performed in MB and SB using a 30 MHz catheter and automated pull-back.

Conclusion: While this study failed to demonstrate any difference in target vessel revascularization or a major adverse cardiac event compared to the RA group, this study may be limited by the small sample size and the short follow-up period.

880A Randomized Comparison of Rotational Atherectomy and Cutting Balloon Angioplasty Followed by Radiation Therapy With a 188Re-MAG3-Filled Balloon in the Treatment of Diffuse In-Stent Restenosis
Seong-Wook Park, Seung-Whan Lee, Young-Hak Kim, Ki-Hoon Han, Cheol Whan Lee, Myeong-Ki Hong, Jae-Joong Kim, Seung-Jung Park, Asan Medical Center, Seoul, South Korea

Background: Randomized comparison of rotational atherectomy (RA) and cutting balloon (CB) followed by beta-radiation for in-stent restenosis (ISR) has not been published.

Methods: This randomized controlled study was conducted to compare the efficacy of RA (n=58) with CB (n=50) prior to beta-radiation therapy with a thium-188-mercaptoacetyltriglycine (188Re-MAG3)-filled balloon for diffuse in-stent restenosis (ISR). The radiation dose was 18 Gy at a depth of 1.0 mm into the vessel wall.

Results: The baseline clinical and angiographic characteristics were similar between the two groups. The lesions were 21.0±11.2 mm in the RA group and 20.8±10.2 mm in the CB group (p=0.77). The delivered dose was successfully delivered to all patients. Adverse events including myocardial infarction, death, or stent thrombosis did not occur during the 9-month follow-up period. Six months angiographic follow-up was obtained in 88 patients (78%) and the rates of angiographic restenosis was not statistically different between the RA group (13%, 6/44) and the CB group (12%, 5/42)(p=0.87). The risk of a target lesion revascularization or a major adverse cardiac event was similar between two groups (RA group vs CB group: 3.4% vs 3.6%, p=0.94) during 9-month follow-up period.

Conclusions: Concomitant treatment of RA or CB with beta-radiation using a 188Re-MAG3-filled balloon for diffuse ISR was safe and had a similarly favorable angiographic and clinical outcomes.

MDL: minimal lumen diameter

ABSTRACTS - Angiography & Interventional Cardiology

10A

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<tr>
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<th>Baseline (post procedure)</th>
<th>Follow up (9 months)</th>
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<tbody>
<tr>
<td>RV0 mm</td>
<td>2.66±0.57</td>
<td>2.62±0.58</td>
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<tr>
<td>MLD mm</td>
<td>2.07±0.66</td>
<td>1.61±0.98</td>
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<tr>
<td>DS %</td>
<td>23.5±10.5</td>
<td>38.4±36.3</td>
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<tr>
<td>In-stent MLD mm</td>
<td>1.95±0.56</td>
<td>1.23±0.76</td>
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<tr>
<td>In-stent DS %</td>
<td>27.75±8.48</td>
<td>51.66±33.2</td>
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<tr>
<td>In lesion late loss, mm</td>
<td>0.51±0.99</td>
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<td>Binary Restenosis, %</td>
<td>35</td>
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880Y Histopathological Characteristics of Edge Restenosis After Intracoronary Brachytherapy for In-Stent Restenosis
Masaeharu Okada, Hideo Tamae, Eisho Kyo, Kunihiko Kosuga, Tatsuhiko Hata, Takui Nakamura, Shinya Fujita, Takafumi Tsuji, Shinshaku Takeda, Nobutoyo Masunaga, Katsuyuki Hasegawa, Seiichiro Motohara, Hiromu Uehata, Shinsaku Takeda, Katsuji Hasegawa, Satoru Motora, Hiroto Uehara, Shiga Medical Center for Adults, Morayama, Japan

Background: Histopathology of edge restenosis following intracoronary brachytherapy (BT) has not been fully evaluated in humans. The purpose of this study was to clarify the histopathological characteristics of edge restenosis following BT by examining the specimens obtained from directional coronary arterectomy (DCA). Methods: Eight edge restenosis lesions which developed in native coronary arteries after BT with the beta-emitting 32P source wire were obtained by DCA and were compared with the restenosis lesion which developed after ordinary balloon angioplasty without BT (R, 6 lesions). Edge restenosis was defined as a lesion which developed 5 mm proximal or distal to either edge of the 32P source wire. Mean interval from BT to edge restenosis was 242±28 days. Specimens retrieved by DCA were immediately placed in 10% buffered formalin, processed for paraffin embedding and stained with hematoxylin and eosin. To assess the proliferation of myofibroblast, we categorized the severity as grade 0, 1, 2, and 3 by estimating the cell density and analyzed by Mann-Whitney U test. Results: 1) Invasion of inflammatory cells and evidence of vasculitis were not apparent in any of the edge restenosis lesions or R lesions. 2) In edge restenosis lesions, myofibroblasts were more scarce and active proliferating...