**ABSTRACTS - Angiography & Interventional Cardiology 67A**

**1101-46** First Human Experience With the ABT-578 Eluting Phosphorylcholine Polymer Stent: A Serial Volumetric Intravascular Ultrasound Analysis From the PREFER Trial

Pyrota Sakurai, Yoichiro Hongo, John Ormiston, Robert J. Whitbourn, Ian Meredith, Yasuhiro Honda, Paul G. Yock, Peter J. Fitzgerald, The PREFER Trial Investigators, Stanford University, Stanford, CA, Green Lane Hospital, Auckland, New Zealand

**Background:** ABT-578, an analog of rapamycin, is an anti-proliferative agent with promising preclinical study results. PREFER is a multicenter, non-randomized, single-arm, feasibility trial of the ABT-578 eluting phosphorylcholine-coated BiodivYsio® (Abbott Vascular Devices, Redwood City, CA, stent which enrolled 11 cases with de novo human coronary lesions. The aim of this substudy was to evaluate the impact of this new drug-eluting stent on both stented segment and stent edges.

**Methods:** Serial 3-D IVUS analysis (baseline and 3-month follow-up) was available in 9 out of 11 patients (one case was excluded due to low IVUS image quality; the other due to additional dilatation with a non-study stent). Minimum lumen area (LA) and mean areas for lumen, plaque (PA), stent (SA), vessel (VA) and neointima (NI) were measured over the stented segment and the stent edge (both 5 mm proximal and distal adjacent to the stent) segments.

**Results:** At baseline, neither significant plaque protrusion / thrombus nor edge dissection was detected. At follow-up, no late incomplete stent apposition was observed. Mean NIA was 0.17 ± 0.32 mm², and %NIA (100*mean NIA/mean SA) was 2.11 ± 3.96%. Table shows serial changes in quantitative IVUS parameters.

**Conclusion:** Preliminary analysis of the initial human experience with the ABT-578 eluting phosphorylcholine-coated stent showed no apparent adverse vessel response. The amount of neointimal proliferation was minimum. Further studies will be needed to confirm these favorable observations.

<table>
<thead>
<tr>
<th>Stent</th>
<th>Segment</th>
<th>Proximal</th>
<th>Distal</th>
<th>Edge</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Follow-up</td>
<td>P-Value</td>
<td>Baseline</td>
<td>Follow-up</td>
<td>P-Value</td>
</tr>
<tr>
<td>Minimum LA (mm²)</td>
<td>6.20</td>
<td>6.09</td>
<td>NS</td>
<td>6.42</td>
<td>6.83</td>
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<tr>
<td>Mean LA (mm²)</td>
<td>7.34</td>
<td>6.55</td>
<td>NS</td>
<td>8.35</td>
<td>8.40</td>
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<tr>
<td>Mean PA (mm²)</td>
<td>7.74</td>
<td>7.30</td>
<td>NS</td>
<td>6.30</td>
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<td>Mean SA (mm²)</td>
<td>7.34</td>
<td>7.12</td>
<td>NS</td>
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<tr>
<td>Mean VA (mm²)</td>
<td>14.75</td>
<td>14.42</td>
<td>NS</td>
<td>14.65</td>
<td>14.46</td>
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</table>

**1101-64** Six-Month Intracoronary Ultrasound Findings Following Sirolimus-Eluting Stents for the Treatment of Restenosis-Prone Coronary Lesions

José Suárez de Lezo, Alfonso Medina, Miguel Romero, Manuel Pan, José Segura, Antonio Delgado, Djordje Pavlovic, Isabel Ureña, Enrique Hernández, Juan Herrador, Federico Segura, Francisco Melián, Reina Sofia Hospital, Córdoba, Spain, Dr. Negrín Hospital, Las Palmas de Gran Canaria, Spain

**Background:** Drug-eluting stents are promising. However, follow-up information is still limited. Intravascular ultrasound (IVUS) is a unique tool is evaluating in situ late results.

**Methods:** We describe the follow-up IVUS findings obtained from 102 patients with coronary lesions prone to restenosis who had been treated with sirolimus-eluting stents (SES). Lesions were considered at risk for restenosis because of the following reasons: in-stent restenosis, major bifurcation lesion, long-diffuse stenosis, or chronic total occlusion. Sixty-two patients had more than 1 risk condition for restenosis. The mean age was 60±10 years. All patients had six-month angiographic and IVUS evaluation. Motorized IVUS pull-back study of the treated segment was always performed. Proximal and distal references were interrogated at 1 cm from the stent borders. Intra-lesion IVUS-measurements were also performed. Results: Qualitatively, we observed focal non-stent apposition in 11 patients and a bulge or minor aneurysm formation in 2. Eleven patients (11%) showed focal restenosis. In the remaining 91 patients, the stent was covered with a fine lining. In addition, the intima was thicker at the edges showing compensatory vessel enlargement. The table summarizes the quantitative results.

**Conclusion:** These findings show that adequate healing of restenosis-prone lesions occurs in most patients. However, focal restenosis may develop. A favorable remodeling is observed at the edges.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Intimal thickening (mm)</th>
<th>Intimal area (mm²)</th>
<th>Lumen area (mm²)</th>
<th>Stent area (mm²)</th>
<th>External elastic laminae (mm²)</th>
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</thead>
<tbody>
<tr>
<td>Proximal reference</td>
<td>0.5±0.2</td>
<td>6±3</td>
<td>11±5</td>
<td>--</td>
<td>19±7</td>
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<tr>
<td>Proximal edge</td>
<td>0.8±0.3</td>
<td>8±4</td>
<td>9±4</td>
<td>--</td>
<td>20±7</td>
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<tr>
<td>Maximal stent diameter</td>
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<td>0.8±0.9</td>
<td>6.9±2.2</td>
<td>7.7±2.5</td>
<td>19±5</td>
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<tr>
<td>Minimal lumen diameter</td>
<td>0.2±0.2</td>
<td>1.0±1.4</td>
<td>4.7±2.2</td>
<td>6±3</td>
<td>17±6</td>
</tr>
<tr>
<td>Distal edge</td>
<td>0±0.3</td>
<td>5±3</td>
<td>7±4</td>
<td>--</td>
<td>14±6</td>
</tr>
<tr>
<td>Distal reference</td>
<td>0±0.2</td>
<td>5±3</td>
<td>7±3</td>
<td>--</td>
<td>13±6</td>
</tr>
</tbody>
</table>

**1101-83** Impact of Preinterventional Lesion Calcification on Neointimal Hyperplasia Following Sirolimus-Eluting Stent Implantation: An Intravascular Ultrasound Analysis

Hideaki Kaneda, Tomomi Koizumi, Junya Ako, Yasuhiro Honda, Mitsuyasu Terashima, Yoshisasa Shimada, Yoshihiro Morino, Paul G. Yock, Martin B. Leon, Jeffrey W. Moses, Peter J. Fitzgerald, The SIRIUS Investigators, Stanford University, Stanford, CA, Lenox Hill Hospital, New York, NY

**Background:** Although the negative impact of lesion calcification on stent expansion is well known, the effect of calcification on neointimal hyperplasia (IH) following sirolimus-eluting stent (SES) implantation is not well characterized.

**Methods:** Eighty-two patients who underwent SES (n=45) or bare metal stent (n=37) implantation and preinterventional IVUS were enrolled in this substudy from the overall SIRIUS population. Lesions were divided into calcified (defined as calcific deposits at minimum lumen area cross section), or non-calcified. Stent, lumen, IH (stent-lumen) area were measured at baseline and 8 month follow-up.

**Results:** Overall, acute lumen area gain tended to be less in calcified lesion (5.19±2.38 vs. 6.06±2.43mm², P=0.13), resulting in smaller stent area (7.90±2.66 vs 8.70±2.56mm², P=0.19). There was a significant interaction between calcification and stent type on IH suppression (Figure). However, multiple logistic regression analysis including stent type, stent area at baseline, and plaque type showed that stent type was the only predictor for target lesion revascularization or binary angiographic restenosis.

**Conclusion:** The treatment effect between sirolimus and control in reducing restenosis remained constant, irrespective of lesion characteristics. Despite less optimal acute results in calcified lesions, SES suppressed IH effectively.

**1101-85** Predictors of Edge Stenosis Following Sirolimus-Eluting Stent Deployment: A Quantitative Intravascular Ultrasound Analysis From the SIRIUS Trial

Pyrota Sakurai, Junya Ako, Shinjo Soroda, Hideaki Kaneda, Yoshihiro Morino, Mitsuyasu Terashima, Ali Hassan, Paul G. Yock, Martin B. Leon, Jeffrey W. Moses, Peter J. Fitzgerald, Yasuhiro Honda, Stanford University, Stanford, CA

**Background:** While sirolimus-eluting stents (SES) have substantially reduced instant restenosis, less efficacy at stent edges has been reported in the SIRIUS trial, a multicenter, randomized, prospective clinical trial comparing the sirolimus-eluting Bx VELOCITY™ stent to bare metal stents.

**Methods:** Angiographic and IVUS data were obtained from SIRIUS. To investigate possible determinants of peri-stent edge stenosis (defined as diameter stenosis greater than 50% either proximal or distal to the stent) at follow-up, baseline IVUS parameters were analyzed in 172 edges of 92 SES.

**Results:** Of these, 6 edges in 6 SES had edge stenosis at 8-month follow-up. Quantitative IVUS results are shown in the table.

**Conclusion:** The IVUS measurements of maximum stent area (SA) and edge SA compared to reference suggest that oversizing (not detected by angi balloon / artery
Intimal Hyperplasia Thickness Is Independent of Stent Size in Paclitaxel-Coated Stents: A Serial Intravascular Ultrasound Analysis From the Asian Paclitaxel-Eluting Stent Clinical Trial


Background. Intravascular ultrasound (IVUS) studies have shown that IH thickness is independent of bare metal stent size. This study determined whether intimal hyperplasia (IH) thickness within nonpolymeric paclitaxel-coated stents is dependent on stent size.

Methods. IVUS was performed post-stent implantation and at 6-months follow-up in 81 patients, 55 of which were randomized to the nonpolymeric paclitaxel-coated stent: 27 to 3.1 mm, 28 to 4.0 mm, and 26 to 4.5 mm. IH thickness was measured every 1 mm over the length of the stent for a total of 810 slices. Maximum IH CSA and thickness and mean IH CSA and thickness over the length of the stent were calculated.

Results. Overall, maximum IH CSA measured 2.15±1.58 mm², mean IH CSA measured 0.59±0.31 mm², mean IH thickness measured 0.45±0.33 mm, and mean IH thickness measured 0.33±0.21 mm. There was a weak correlation between IH CSA vs stent CSA (r=0.196, p<0.0001), but no correlation between IH thickness vs stent CSA (r=0.052, p=0.138) on a per slice basis or between maximum IH thickness vs stent CSA (r=0.252, p=0.0013) or maximum IH thickness vs stent CSA (r=0.07, p=0.6) on a per stent basis. The results were similar when high and low dose patients were analyzed separately on a per slice basis: (1) IH CSA vs Stent CSA (r=0.252, p<0.0001, and r=0.153, p=0.0013) and (2) IH thickness vs Stent CSA (r=0.126, p=0.015, and r=0.02, p=0.96).

Conclusions. IH thickness is independent of stent size in drug-eluting stents, similar to bare metal stents.

Poster Session

1102

Restenosis: Basic Research I

Monday, March 08, 2004, 3:00 p.m.-5:00 p.m.
Morial Convention Center, Hall G
Presentation Hour: 3:00 p.m.-4:00 p.m.

1102-47

Important Species Differences of Sirolimus, Paclitaxel, and Tacrolimus on Porcine and Human Coronary Smooth Muscle and Endothelial Cells

Kai Pinkernell, Christian Valina, Eckhard Alt, Tulane University, School of Medicine, New Orleans, LA

Background: Implantation of drug coated stents shows clinical efficacy for the prevention of restenosis, but large animal studies have not shown any long term benefit with the use of Sirolimus (SIR) and Paclitaxel (PAC). Despite this the possible interspecies differences have not been investigated. Methods: Porcine (p) and human (h) smooth muscle (SMC) and endothelial cells (EC) were serum deprived for 48h until addition of drugs. Cells were counted after 72h of treatment to SIR, PAC or Tacrolimus (TAC) by means of a CASY cell counter on the basis of the resistance measurement principle. Cell viability and size was determined simultaneously. Results: hSMC and hEC were generally more susceptible to growth inhibition than porcine cells (maximum differences seen with SMC). More than a 90% reduction in cell due to cytotoxicity could be seen for hSMC at 10µM for SIR and PAC compared to 75µM TAC. pSMC showed only a 80% reduction at 75µM for SIR and PAC and a 40% reduction with TAC. Sirolimus showed the most pronounced effect with 99% reduction in cell count starting at 50µM compared to 100µM for PAC.

Conclusion: Cytotoxicity and cell growth inhibition shows remarkable species differences at concentrations which are easily exceeded in the stent viciuity in vivo (100 µM). This partially explains the different results of re-endothelialization and reduction of in-stent restenosis with drug coated stents in swine and humans and shows the problems regarding the prediction of outcomes in human trials on the basis of animal data.