T139-61

Is the Sirolimus Drug Eluting Stent Better Than Paclitaxel Coated Stent in "Real Life" Environment?

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Background: Active stents seems to improve the outcome after percutaneous intervention (PCI) in reducing MACE at 9 months. However no prospective data comparing various devices are available.

Method: Since March 2003, all patients suitable for stent implantation were randomized to receive either a sirolimus eluting stent (SES) or a paclitaxel active stent (PAS). Standard procedures were performed. Aspirin and clopidogrel were initiated for at least one year. Clinical outcome (MACE incidence at 9 months) is the primary end-point. Control angiography was performed only when clinically driven.

Results: A total of 102 pts were included (mean age 66±11), (24 female), received a 54 month clinical and angiographic evaluation. Demographic data were comparable with a proportion of 8 pts with unstable angina. Diabetes was present in 7 pts in the SES group and in 6 pts in the PAS group. Baseline data and follow-up at 3 months are presented in the table below. The incidence of MACE did not differ after a mean follow-up of 3±4 months between the 2 groups. Particularly no pt died in either group. MI did not occur either. Only sub-acute thrombosis was documented in 2 pts in the PAS group. TLR and TVR were required in 0 pts in the SES group versus 2 pts in the PAS group.

Conclusion: There was no significant difference in the incidence of MACE between sirolimus and paclixtalex during this short follow-up. Nine-month follow-up will be available at time of presentation.

T139-62

Sirolimus Coated Stent Implantation Versus Intracoronary Beta-irradiation for the Treatment of De Novo Lesions

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Introduction: Antiproliferative strategies for the reduction of restenosis such as vascular brachytherapy (VBT) and drug-eluting Stents have proven to be safe and highly effective. While VBT is effective for the treatment of in-stent restenosis, the data for the treatment of de-novo lesions are less convincing. This study aimed to compare the safety and efficacy of VBT and Sirolimus-eluting Stents (Cypher) for the treatment of de-novo lesions.

Methods: 53 individuals with de-novo lesions were treated with PTCA and Cypher-Stent Implantation. Matching was performed with the cohort of patients with de-novo lesions from the European RENO registry. This registry included the first 1098 patients treated with intracoronary beta-irradiation (Sr90) in Europe. 123 patients met the matching criteria. Angiographic results and MACE rates (death, MI, TLR, TVR) were compared after 6 months.

Results: There were more diabetics in the Cypher-Stent group (32.1 vs. 19.5%: p=0.07) and more patients with multivessel disease (83.0 vs. 56.1%; p<0.001). Lesion length (13.3±4.1 vs. 13.2±3.9 mm) and reference diameter (3.1±0.5 vs. 3.0±0.5 mm) were comparable. Mean radiation dose in the RENO patients was 18.2±3.1 Gy geographic dose occurred in 6.5%. New Stents were implanted in 94 RENO patients (76.4%). After 6 months the overall MACE (21.1% vs. 7.5%; p=0.03) and binary restenosis rates (30.7 vs. 11.8; p=0.01) were significantly higher in the RENO group when compared with the Cypher patients. This was irrespective whether a new-stent was implanted or not.

Conclusion: The use of vascular brachytherapy for the treatment of de-novo lesions cannot be recommended. In these cases, the implantation of drug-eluting stents is clearly favourable.

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Drug-Eluting Stents: Randomized Trials

Tuesday, March 09, 2004, 2:00 p.m.-3:30 p.m.

Morial Convention Center, La Nouvelle C

843-1

REDOX Trial - Reduced Sirolimus Doses on the Bx VELOCITY™ Stent Four-Month Results


Background: The Cypher™ Sirolimus-eluting Coronary Stent has demonstrated a significant reduction in late loss and restenosis in four randomized trials. The next generation of drug-eluting stents are being developed with new materials which have potentially less surface area. For this reason there is a need to understand the effect of reducing the amount of drug on the stent. A trial was conducted to assess the safety and efficacy of two reduced sirolimus doses on the Bx VELOCITY™ stent, in patients with de novo native coronary artery lesions.

Method: A double blind, randomized study of the sirolimus-eluting Bx VELOCITY™ stent containing 45% or 70% of the current sirolimus dose (140 mcg/mm²) was conducted in 60 patients (40 non-diabetic/20 diabetic) with de novo native coronary artery lesions < 18mm in length and in vessels ≥0.9mm to ≤3.5mm in diameter. Four month angiography and IVUS were performed.

Results: The 4-month follow-up TVF, TLR and MACE were zero for both groups. The table is a comparison of the angiographic results from the FIM and REDOX trials.

Angiographic - 4 Month Follow-up

<table>
<thead>
<tr>
<th></th>
<th>FIM – Slow Release</th>
<th>45% Sirolimus Dose</th>
<th>70% Sirolimus Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-stent MLD, mm</td>
<td>2.85±0.46</td>
<td>2.74±0.39</td>
<td>2.65±0.48</td>
</tr>
<tr>
<td>In-stent DS, %</td>
<td>5.0±6.7</td>
<td>3.4±9.0</td>
<td>7.7±13.5</td>
</tr>
<tr>
<td>In-stent late loss, mm</td>
<td>0.09±0.25</td>
<td>0.10±0.31</td>
<td>0.10±0.35</td>
</tr>
<tr>
<td>In-stent binary restenosis, %</td>
<td>0.0</td>
<td>0.0</td>
<td>3.6 (1)</td>
</tr>
</tbody>
</table>

Conclusion: The results of the two reduced doses of sirolimus on the Bx VELOCITY™ stent are the same and are similar to those of the Cypher stent used in the FIM trial. These data suggest efficacy is maintained when reducing the total sirolimus dose on the Bx VELOCITY™.

2:15 p.m.

843-2

Everolimus-Eluting Stents for the Prevention of Restenosis: Results of the FUTURE II Trial

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In the first-in-man experience, the everolimus-eluting stent (EES) demonstrated safety, feasibility and effectiveness to inhibit neointimal proliferation in human coronary arteries. The FUTURE II trial is a larger, prospective, randomized, blinded multicenter study of the EES (with a bioabsorbable polymer coating) vs. metallic stent (MS). We report the 6-month clinical and angiographic results.

Methods and Results: 64 patients (65 lesions) were randomized in a 1:2 ratio to EES (n=21) vs. MS (n=43). Baseline clinical and angiographic characteristics were similar in both groups, with 26.6% diabetics, mean vessel size of 2.95±0.48mm and lesion length of 11.43±3.44mm. Final and 6-month angiographic and clinical results are shown in the Table. Conclusion: The expanded FUTURE II trial confirmed the efficacy demonstrated in the FUTURE I trial with a significant 85.9% reduction in neointimal proliferation (in-stent late loss) with EES compared to the bare metal stent. There was no exaggerated hyperplasia at the proximal and/or distal edges of the stent in the everolimus group.