Effects of the QUADD-PQ2 Drug-Eluting Stent Extend Beyond the Targeted Area Into Adjacent Nonstenosed Zones: Results of the SCORE Trial

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Background: The QUADD-Q2 stent, a 2.16 stainless steel stent that delivers QP2 (an antiproliferative taxane derivative) from polymer sleeves, was shown to reduce restenosis (RS) compared to placebo in the SCRE trial (RS includes thrombosis cases). Whether high doses of QP2 (4000 ug), delivered through a high capacity polymer membrane, as used in transgenic mice to achieve less than 10 nm vessel target area is not known. Methods: We performed QCA on the first 260 randomized pts treated for de novo native lesions (134 bare metal vs 126 QP2 stents). Follow-up QCA (MEDIUS), available in 77% (N=202), was performed with systematic analysis of the QP2 stent area as a 3-mm proximal and distal non-stented segment. Results: Baseline lesion characteristics were similar in both groups, including ACC/AHA class >B1 (32%) mean vessel size 7.14 mm, lesion length 11.8 mm, and final results (final stent DS 5.8%). Follow-up restenosis was reduced by 72% within the QP2 stent, 67% proximal and 65% distal to the stent (see table). Conclusion: High dose QP2 delivered via a high capacity polymer on the QP2 stent demonstrated striking reductions in RS within the targeted stent zone, with equal efficacy extending at least 3 mm proximally and distally beyond the confines of the target stent, likely representing elution of QP2 into adjacent non-stented vessel areas. Whether positive remodeling is the mechanism of luminal improvement at the edges will be determined by IVUS.

Table 1. Baseline Lesion Characteristics

<table>
<thead>
<tr>
<th>Quadd ST (n=134)</th>
<th>QP2 (n=126)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restenosis Stent (%)</td>
<td>10.8%</td>
<td>39.5%</td>
</tr>
<tr>
<td>FU Proximal Edge %</td>
<td>24.0%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Restenosis Prox Edge %</td>
<td>3.0%</td>
<td>20.5%</td>
</tr>
<tr>
<td>FU Distal Edge %</td>
<td>16.5%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Restenosis Distal Edge (%)</td>
<td>3.5%</td>
<td>14.7%</td>
</tr>
</tbody>
</table>

1078-20 Comparison of a Novel Polymer (PLLg-PEG) With Gold-Coated and Stainless Steel Stents for Prevention of Neointimal Hyperplasia


Background: Stent coating aims to reduce neointimal hyperplasia. The purpose of this study was to investigate the effect of a novel polymer (poly-L-lysine with polyethylene-glycol-PLLg-PEG) on neointimal hyperplasia and to compare it with gold-coated and stainless steel stents in porcine restenosis models.

Methods: Three different (NIR) stents were implanted each in a total of 13 pigs: (1) an PLLg-PEG dip coated on a bare NIR stent), and (3) a gold-coated stent (NIR Royal). Coated and stainless steel stents were implanted in the proximal vessel. Histological evaluation of intimal thickness and luminal diameter measured 5 mm proximal and distal to the light source did not change at follow-up. Conclusion: In-stent binary restenosis was 38.5% in Group I and 26.3% in Group II. Lumen changes at the proximal (0.17±0.06 mm) or distal (0.04±0.01 mm) end were not consistent with an "edge effect." Conclusion: Treatment with MIU in patients undergoing stent implantation resulted in no deleterious luminal changes at the edge of the treatment zone (i.e., no "edge effect"). Neointima was primarily located within the axial stent length and indicated an early dose and light response in its effect on restenosis. Further analysis of the potential biologic activity of MIU on the lighted but unirradiated atherosclerotic region is ongoing.

1078-22 A Quantitative Assessment of Regional Changes In Lumen Diameter After Photodynamic Therapy With Moxetaxin Luteinum In Patients Undergoing Stent Implantation

Jeffrey J. Poppino, Nicholas Cox, Dennis Wahl, Howard Herrmann, Daniel I. Simon, Campbell D. Rogers, Paul Kramer, Wendy Sheer, Kendrick Shunk, Alan Yeung, Ross Pippic, Daniel Adelman, Dean Kereiakes, Brigham and Women’s Hospital, Boston, Massachusetts.

Background: Moxetaxin luteinum (MIU, Antrin® injection) is a synthetic expanded porphyrin-photosensitizing agent that localizes in atherosclerome. Upon activation of MIU with intra-arterial 732 nm light, singlet oxygen is produced and apoptosis of inflammatory cells occurs. Preliminary data suggests a potential benefit of MIU for restenosis, but its effects at the light therapy edges are unknown. Methods: We quantitatively analyzed angiograms obtained from 59 patients who underwent stent placement and were enrolled in a phase 1 drug and light escalation study. Group I: MIU dose range: 0.04-0.6 mg/kg; light range: 100-200 J/mm². Group II: MIU dose 2.0-3.0 mg/kg; light range: 200-600 J/mm². Image frames were compared before (DL) and just after endovascular illumination, and 6 months (FU) after. Analysis zones included the stent, injured segment, lighted segment, and 5 mm segment proximal and distal to the light source. Results: Histologic analysis measured a 5% (p=0.03) increase in MIU vs Control. MIU % restenosis was 46% patients presented at the follow-up with percent diameter stenosis of 5% or less, compared to only 9% in the control group (p<0.001). There were no late thrombotic events. Conclusion: The photaxilix-eluting stent is capable of extraordinary inhibition of neointimal proliferation. This inhibition most likely does not occur at the cost of impaired vessel healing and reendothelialization since it was not associated with late thrombotic events. This pattern of minimal neointimal stent "paving" is fundamentally different from the wicker ring of neointimal growth almost invariably induced by conventional metallic stents.

POSTER SESSION

1079 Optimizing the Selection and Use of GPIIb/IIIa Agents

Monday, March 18, 2002, 9:00 a.m.-11:00 a.m.
Georgia World Congress Center, Hall G
Presentation Hour: 9:00 a.m.-10:00 a.m.

1079.0 Unfractionated Heparin Reduces the Antplatelet Effects of Abciximab but Not Eptifibatide During Coronary Interventions

Ettymos N. Delaerys, Laura G. Metton, Cheryl Thompson, Melissa Fowler, Don A. Gabriels, Gregeny J. Dehmer, University of North Carolina, Chapel Hill, North Carolina, Wake Forest University School of Medicine, Winston-Salem, North Carolina.

Background: Abciximab (AB) and Eptifibatide (EP) are both effective during PCI, however only EP has proven beneficial as an adjuvant medical treatment for ACS. We hypothesized that the concomitant use of unfractionated heparin (UH) may differentially effect the degree of platelet inhibition produced by AB and EP. Methods: We randomized AB pts before (n=20) and immediately after (n=20) UFH (70 U/kg bolus) activation (TRAP) platelet aggregation and calculated based on the baseline values. All received aspirin and 300 mg of dipropylate. Results: Mean % inhibition was higher in EP pts compared with AB pts both before (96 vs 85% [ADP]; 89 vs 63% [TRAP], p=0.001 for both) and after UH (96 vs 79% [ADP]; 81 vs 52% [TRAP], p=0.001 for both). As well from baseline to 10 min after standard weight-based AB (n=14) or double-bolus EP (n=14) and 5 min after UH (70 U/kg bolus). Percent inhibition of platelet aggregation was assayed after both AB and EP and the addition of UH significantly reduced platelet aggregation in AB pts (95 vs 79% [ADP]; 86 vs 52% [TRAP], p=0.05 for both) but not in EP pts (96 vs 96% [ADP]; 89 vs 81% [TRAP], p=ns for both). Following addition of UH none of AB pts achieved the "optimal" >90% inhibition of platelet aggregation (Figure). Conclusion: With standard dosing, EP...