Biolimus A9: A New Generation Rapamycin Analogue

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Background: Biolimus A9 is a novel, rapamycin analogue especially designed for drug eluting stent application. Biolimus A9 is developed with the intent of optimizing release kinetics and tissue partitioning while maintaining the inhibitory properties of sirolimus on smooth muscle cells.

Methods: Nineteen male rats and 9 Biolimus A9(B9) stents were evaluated in 28 day on-stent porcine model. The drug delivery polymer was thin layer bio-resorbable Poly-lactic-acid. The average balloon artery ratio was 1.18±0.3. At sacrifice coronary angiography and histologic analysis was performed for each stented vessel.

Results: The results are tabulated in Table 1. There was no difference of injury in both groups. There was 50% reduction of area stenosis by the B9 coated stent(0.001). Histology, showed near complete endothelialization in both control and A9 groups with a only a slight increase in fibrin content in the B9 group. Conclusions: Biolimus A9 delivered via bioresorbable polymer coated stent inhibits intimal hyperplasia in a porcine model. There is normal healing of treated arteries at 28days and no inflammation as compared to controls.A first-in-man clinical trial has been initiated.

Histomorphometric Analysis of the Bare and Biolimus A9 stents

| Injury Score | 0.30±0.10 | 0.30±0.12 | NS |
| Intimal Hyperplasia(Lmm) | 238±24 | 152±14 | 0.004 |
| Area Stenosis(%) | 38 | 20 | 0.001 |

The Long-Term Clinical Results of a Platelet Glycoprotein Ib/IIb Receptor Blocker (Abciximab; Reopro®) Coated Stent in Patients With Coronary Artery Disease

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Background: Previously we reported the inhibition of coronary restenosis with Abciximab(Reopro®)-coated stent in a porcine model. RePro® inhibits platelet aggregation, the proliferation of vascular smooth muscle cells and inflammatory reaction.

Methods: We performed a prospective randomized trial to compare two types of stents for the revascularization in native coronary artery. The primary effective end points were major adverse coronary events (MACE): cardiac death, acute myocardial infarction, target vessel revascularization (TVR), restenosis at 6-month clinical and angiographic follow-up.

Results: One hundred fifty-five patients were enrolled between Aug, 2001 and Jun, 2003. Mean ages (56±10 vs. 56±10 years), baseline diameter stenosis and minimal luminal diameter were not different between the two groups. There was one myocardial infarction and revascularization during hospital stay in control stent group. During clinical follow-up, there were two myocardial infarctions in control group. Follow-up coronary angiogram was done 62.3% (48/77) in coated and 65.4% (51/78) in control groups. Diameter stenosis and late loss were significantly less in the RePro®-coated stent group compared with controls (16±5.8% vs. 34±6.5% p=0.009; and 0.33±0.28 mm vs. 0.88±0.41 mm; p=0.002). The restenosis and TVR rates of RePro®-coated stent were relatively lower compared with control stent (14%/7/48) vs. 29%/15/51, p=0.062; and 9.2%/7/76 vs. 14.7%/11/75; p=0.327.

Conclusion: A RePro®-coated stent is safe and may be effective in the prevention of coronary restenosis.

Impact of Stent Implantation Techniques on Stent Edge Neointimal Hyperplasia Following Sirolimus-Eluting Stenting

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Background: IVUS substudy of the SIRIUS trial showed a tendency for neointimal hyperplasia (NI) to develop at stent edges after sirolimus-eluting Bx VELOCITY stent (SES) implantation. However, predictors for this phenomenon have not been clarified. In this study, we examined the potential risk factors including procedural demographics for stent