Stents Coated With the Lipophilic Compound A24 Profoundly Inhibit Neointimal Formation in the Porcine Coronary Model
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Background: Stent-based immunosuppressive therapy reduces restenosis by impairing vascular smooth muscle cell proliferation and mitigating the inflammatory response to the prosthesis.

Methods: We evaluated the feasibility and efficacy of A24 eluting stents in a porcine coronary model. Stainless steel balloon expandable stents were coated with a non-erodible polymer or polymer with A24 (10.0 µg/mm²). Fifteen pigs underwent placement of overvized bare metal (n = 12), polymer (n = 5), and A24 (n = 9) stents in the coronary artery.

Results: At 28-days, histology demonstrated similar mean injury scores for the control, polymer and A24 coated stents. The mean neointimal area (mm²) was significantly reduced with A24 (1.70 ± 0.47) compared with polymer (2.12 ± 0.24), and control (3.90 ± 1.91) stents (p < 0.005). The 40% reduction in neointimal area resulted in significantly less mean percent diameter stenosis for A24 (19.4 ± 4.0 %) as compared with polymer (30.3 ± 12.1 %), and control (29.4 ± 15.5 %) stents (p < 0.001). Twelve of the 45 bare metal stent cross sections exhibited a giant cell reaction while none of the 26 sections from the A24 stents had a giant cell response.

Conclusions: Stent-based delivery of A24 inhibits neointimal formation and the inflammatory response to the prosthesis in the porcine coronary model. Further study is necessary to determine the dose-response and long-term effects A24 eluting stents in the porcine coronary model.

6A-181
First-In-Human Study of Angiopeptin-Euting Stents: A Quantitative Coronary Angiography and Volumetric Intravascular Ultrasound Study
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Background: Angiopeptin, a somatostatin analogue, has been shown to reduce neointimal hyperplasia after stenting in various animal models. Angiopeptin inhibits smooth muscle cell proliferation through attenuating the production and release of several growth factors including PDGF, b-FGF, IGF-1 and EGF. BiodivYsio DD Phosphorylcholine (PC) coated stent provides a viable platform for local delivery of anti-proliferative agents to the coronary artery. Objective: To evaluate the feasibility, safety and impact on tissue growth of Angiopeptin-eluting BiodivVso DD PC stents in human native de novo coronary lesions. Method: 13 patients (14 lesions) underwent intravascular ultrasound (IVUS)/quantitative coronary angiography (QCA) of Angiopeptin-eluting Biodivysio DD PC stents in human native de novo coronary lesions. Results: 13 patients (14 lesions) underwent intravascular ultrasound (IVUS)/quantitative coronary angiography (QCA) of Angiopeptin-eluting Biodivysio DD PC stents in human native de novo coronary lesions. Sixteen (80%) of the stents were deployed with complete procedural success rate of 100%. No in-hospital MACE were reported. At 30-day clinical follow up, there were 3 target vessel revascularizations, which included 1 target lesion revascularization (TMR) and 2 target vessel revascularizations (TVR). All patients were enrolled in the trial with escalating doses of Angiopeptin and the encouraging preliminary results warrant further confirmation by randomized controlled trial.

6A-182
Reducing Neointimal Proliferation by a Stent-Based Delivery of Nitric Oxide in a Porcine Carotid Overstretch Model
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Background: Nitric oxide (NO) is a potent vasodilator and anti-platelet agent that suppresses vascular smooth muscle cell proliferation. We hypothesized that releasing NO from a stent would reduce neointimal hyperplasia after vascular intervention without affecting systemic hemodynamics. The present study was designed to test the efficacy of an NO eluting stent in a porcine carotid overstretch injury model.

Methods and Results: ePTFE-covered stents (aSpireS Vascular Architects, Inc) with the NO-releasing compound sodium nitroprusside (SNP, NO donor)/silicone mixture con-
follow-up, all patients in each study arm remained free of any cardiac events. There were no target lesion revascularisations reported so far. 6 month follow-up examinations are expected to start in September 2002. At time of presentation, we will present the complete 6 month follow-up angiographic and IVUS data.

Conclusions: The FUTURE trial represents a pioneer experience demonstrating safety of the new Everolimus coated Challenge-Stent with a 100% procedural success rate and an complete 6 month follow-up angiographic and IVUS data.

1006-184 Evaluation of a Tacrolimus-Eluting Coronary Stent With Nanoporous Ceramic Coating in Treatment of Native Coronary Artery Lesions: Phase I and II of the PRESENT Study

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Background: Drug eluting stents (DES)has recently emerged as one of the most promising techniques for interventional treatment of coronary lesions. Tacrolimus is an antiproliferative and antinflammatory agent with proven efficacy in other therapeutic areas (transplant medication). The antiproliferative effect in coronary applications is selectively focused on smooth muscle cell activities rather than inhibition of endothelial cell proliferation. To evaluate both safety and feasibility of a Tacrolimus eluting stent, which utilizes a nanoporous aluminium oxide ceramic as drug carrier, the PRESENT study have been conducted. Methods: Results: The PRESENT Study is a prospective study, evaluating the ceramic coated coronary stent with and without arocinain in treatment of native coronary de-novo lesions with 30 patients in each arm. Primary endpoint was 30-day safety defined as absence of MACE. Angiographic and IVUS follow-up was scheduled at 1 month and 6 month after procedure. To evaluate antiproliferative effect assessment of stent and vessel scores were calculated. At 6 month follow-up the net contrast area stenosis was not significantly different (4.6 ± 4.3 vs. 4.4 ± 3.8). The stent proximal in-stent in-stent re-restenosis was not significantly different (4.9 vs. 4.9%). Further analysis of in-stent and late loss were also not signsifying any differences. Conclusion: The PRESENT trial demonstrates safety and feasibility of a new ceramic coated coronary stent with and without elution of Tacrolimus. The need of target vessel revascularizations in the long run seems to be similar to other drug eluting stents. The current 6 month follow-up data will be presented.

1007 Intravascular Ultrasound and Cardiovascular Disease

Sunday, March 30, 2003, 9:00 a.m.-11:00 a.m.
McCormick Place, Hall A

Presentation Hour: 9:00 a.m.-10:00 a.m.

1007-173 Incidence of Renal Artery Stenosis in 2,111 Patients Undergoing Coronary Angiography: A Model of Predictive Risk of Renal Artery Stenosis

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Background: Renal artery stenosis (RAS) is an important cause of hypertension and ischemic renal disease and should be identified in patients (pts) where possible. Data on the predictive risk of RAS at the time of coronary angiography for different patient profiles is lacking. Our aim was to determine the incidence of RAS in a large group of pts undergoing coronary angiography and to develop a model to determine the risk of RAS for any subgroup of pts. Methods: A total of 5111 consecutive pts were screened for RAS with a contrast injection in the descending aorta after the angiographic run. Multiple risk factors were assessed. Results: RAS was present in 1% of pts without CAD and in 13% of pts with CAD. Independent risk factors for RAS in pts with CAD were age [Odds ratio (OR) 1.05/year, p<0.001], female sex (OR 1.91, p<0.001), peripheral vascular disease (PVD) (OR 2.32, p<0.001), cerebrovascular disease (CVD) (OR 1.60, p<0.05), 3 vessel disease (OR 3.14, p<0.001) and hypertension (OR 1.58, p<0.01). A model was developed utilizing these risk factors which enables the prediction of RAS in different patient profiles. An example is shown for males aged 60 with hypertension and CAD. Conclusions: RAS was rare in pts without CAD. In pts with CAD, there was a relatively high incidence of unsuspected RAS (13%). In pts with CAD and RAS there was a high incidence of other vascular disease. The incidence of RAS in pts with CAD can be predicted using the model developed and may aid in determining which pts should be screened.

ABSTRACTS - Angiography & Interventional Cardiology 7A

1006-186 Titanium Nitride-Oxide Coated Stent: Six-Month Angiographic and Intravascular Ultrasound Follow-Up

Christophe Lassus, Marie-Jeanne Arbel, Meyer Cebal, Mamie Hamon, Ulyses Uron, Philippe Combeau, Bernard Lancelin, C.C. Marie Lannelouge, Le Plessis Robinson, France

Titanium nitride oxide (TiNO) is biologically inert and has an excellent biocompatibility as well as good mechanical properties. Though it is not possible to encapsulate an antiproliferative drug by this means, the TiNO coating (without active drug) has less favorable results. As the restenosis rate for the Biolinx stent (TiNO coated phospholipid coated stent) was 4.9% in the pilot study, it is necessary to account for when designing and interpreting studies with this kind of coating.

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