the NO-releasing compound sodium nitroprusside (SNP; NO donor)/silicone mixture containing 54.5 pg SNP were tested. In vivo measurable levels of NO were detected and poisoning vascular smooth muscle cell proliferation. We hypothesized that releasing NO from a stent would reduce neointimal hyperplasia after vascular intervention without drug toxicity was observed. Morphometric measurements indicated that the injury score needed to determine the persistence of this effect on neointimal suppression.

Methods and Results: We compared PLA polymer containing 160 or 220 ug of Everolimus(E), 180 ug Sirolimus(S), and bare metal stent. 40 stents were deployed in coronary arteries of 19 pigs with sacrifice at 28 days. Endpoints were assessed by quantitative coronary angiography (QCA), histomorphometry, and histology at 28 and 90 days. There was a significant reduction of intimal hyperplasia as assessed by QCA and histomorphometry by both E and S (Table 1). At both 28 and 90 days, there was complete endothelialization and no difference in inflammation or fibrin between the bare stent and drug-polymer groups.

Conclusion: Everolimus and Sirolimus delivered via stent and thin layer biodegradable polymer are equally effective at inhibition of intimal hyperplasia. At follow-up evaluation, complete healing without foamy or inflammatory reaction was seen. A clinical trial to determine safety and efficacy of the Everolimus coated stent has commenced.

Reducing Neointimal Proliferation by a Stent-Based Delivery of Nitric Oxide in a Porcine Carotid Overstretch Injury 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 SNP as a NO donor via SNPlsilicone mixture stents in reducing neointimal hyperplasia at 28 days in a porcine carotid overstretch injury model. Long-term follow-up is needed to determine the persistence of this effect on neointimal suppression.

Methods: The FUTURE trial, which has started in May 2002, is a prospective, randomized, single blinded study including a clinical follow-up at 30 days and 12 months post procedure. Patients with restenosis after stent implantation with remarkable improvement of patient outcome. Background: Sirolimus and Paclitaxel eluting stents have shown significant reduction of restenosis after stent implantation with remarkable improvement of patient outcome. 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, TGF-β, and EGF. BiodivYsio DD Polylactic acid (PLA) coated stent shows promising results for local anti-proliferative agents to the coronary artery. Objective: To evaluate the feasibility, safety and impact on tissue growth of Angiopeptin-eluting BiodivYsio DD PC stent in humans native de novo coronary lesions. Method: 13 patients (14 lesions) underwent intravascular ultrasound(IUSV/IVUS)-guided Angiopeptin-eluting stent implantation. The primary endpoint is to compare clinical performance of the Everolimus coated and one with 126 microgram. No major adverse cardiac events had occurred. Off-line quantitative coronary angiography(QCA) showed pre-procedural mean reference diameter of 3.23±0.72mm. Minimal luminal diameter(MLD) improved from 0.69±0.26mm to 3.19±0.60mm. Mean lesion length was 12.82±0.24mm. 8 consecutive patients (9 stents with 22 microgram Angiopeptin) underwent 6-month angiographic and volumetric IVUS follow-up. Late loss was 0.55±0.36mm and late loss index was 0.23±0.13 by QCA. Binary restenosis was 0%. Follow-up stent vessel by IVUS was 195±62.13mm2 and percentage neointimal hyperplasia vessel was 20.7±28.5%. There was no edge effect and late stent mal-aposition. Conclusion: Angiopeptin-eluting BiodivYsio DD PC stent appears to be feasible and safe in treating native de novo coronary lesions. Procedural success rate of 100%. No in-hospital MACE were reported. At 30-day clinical follow-up period was 28.9±6.8 weeks. Coronary arteries between 3.0 and 4.0mm in diameter and lesion length>10mm were included. 8 patients were treated with 10 w/mm2 of Angiopeptin and the encouraging preliminary results warrant further confirmation by randomized controlled trial.

First Human Experience Using a New Everolimus Stent Coating: Procedural and Six-Month Follow-Up Results of the FUTURE Trial

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Background: Sirolimus and Paclitaxel eluting stents have shown significant reduction of restenosis after stent implantation with remarkable improvement of patient outcome. Everolimus is a new anti-proliferative agent binding to cytosolic immunophyllin FKBP12 and reduces cell proliferation with dramatic reduction in animal models. Methods: The FUTURE trial, which has started in May 2002, is a prospective, randomized, single blinded study including a clinical follow-up at 30 days and 12 months post procedure and a 6 month angiographic and IVUS follow-up, to evaluate acute gain and late clinical outcomes due to neointimal suppression. The primary endpoint is MACE at 30 days. The secondary endpoint is to compare the clinical performance of the Everolimus coated stent (Challenge-Stent) as compared to the control bare metal S-Stent with regards to device success, MACE, and restenosis rate at 6-month follow-up. In this randomized, unbalanced 2:1 ratio, 24 and 12 patients are allocated to the drug and control groups respectively. De novo coronary lesions with a reference diameter between 2.75-4.0mm and lesion length>10mm were enrolled with mandatory predilatation. Results: To date, the patient enrollment has been completed including 36 patients with a procedural success rate of 100%. No in-hospital MACE were reported. At 30-day clinical...