

clinical, angiographic, treatment factors

Conclusion: For single vessel disease, increasing DES length appears to be associated with adverse clinical outcomes. This should be considered when selecting strategies for revascularization.

TCT-436

Development of DES with a Biodegradable Polymer Matrix

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Background: Drug delivery from drug eluting stents is presently achieved through bio-stable polymeric coatings; these remain in the body following drug release. Development of a polymeric coating that is biodegradable offers the advantage that after polymer degradation is complete, a bare metal stent remains, eliminating concerns about reactions resulting from residual polymer.

Methods: Novel biodegradable co-polymers were developed, built around materials with similar chemistry to poly-lactic acid (PLA); PLA is used to good effect in medical implants, such as absorbable sutures. By varying polymer composition (both type of component and component ratio) and polymer molecular weight (MW), we control drug elution and polymer degradation rates. Targeting performance criteria important to a DES product we identified candidate formulations for use in animal tests. Two animal models were employed: a rat model used to evaluate polymer degradation, and a pig model used to evaluate safety and biocompatibility. Stents coated with four candidate polymers containing 0.8Mg/mm² of Zotarolimus were implanted into porcine coronaries and sampled at 28, 90 and 180 days. The assessment panel included histopathology, polymer degradation and elution.

Results: Polymer composition and MW could be adjusted to control drug elution and polymer degradation rates; this was confirmed in-vivo. A typical elution curve has a short time frame "burst" of ~40% of the drug and complete elution by 28 days, but by varying the polymer composition, the burst ranged from 20 - 60% and elution to exhaustion could range from less than 10 days to more than 60 days. Histological performance of the polymers showed comparable performance to bare metal stent controls measured by low inflammation scores and percent area of stenosis. In addition, we saw peri-strut fibrin at day 28 indicating presence of active drug in tissue. In-vivo degradation correlated with bench top testing. In the rat model, polymer degradation times ranged from 100 days to more than 180 days.

Conclusion: These studies have demonstrated that the biodegradable polymers we have developed offer potential as a carrier material for a drug eluting stent.

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Supralimus™ Bioabsorbable Sirolimus-Eluting Stent Technology in Diabetic Pts Undergoing Percutaneous Coronary Intervention (PCI): Preliminary Findings from the Prospective, International, Multicenter E-SERIES Registry

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Background: Diabetes mellitus (DM) is a well recognized predictor for adverse events following PCI. Despite the undeniable clinical efficacy of 1st generation DES with durable polymers, concerns regarding their long-term safety have been raised, especially in more complex subsets. The Supralimus™ stent (SS,

Sahajanand Med, India) uses a stainless steel platform with a bioabsorbable polymer loaded with sirolimus. We sought to determine the safety and clinical effectiveness of this new generation DES in diabetic pts.

Methods: The E-SERIES Registry is an open-labeled, non-randomized study with consecutive enrollment (ongoing) of pts all-comers for PCI with SS implantation. All clinical, procedural, and follow-up (FU) information were collected and analyzed by an independent organization, and all adverse events were independently adjudicated.

Results: Since July/07, 423 pts were included and completed 6 months FU (170 DM; 253 non-DM). Compared to non-DM, pts with DM were older (67±10 vs. 62±11 years, p<0.0001), had more hypertension (91.6 vs. 72.5%, p=0.002), and chronic renal failure (8.4 vs. 2%, p=0.005). Baseline angiographic characteristics were similar among groups: mean vessel size and lesion length were 2.5±0.5mm and 24.0±10.8mm, respectively, and 80.5% of lesions were type B2/C. Procedural success was >98% (p=NS). Clinical outcomes at 6 months are shown in the table.

	Diabetics (n=170)	Non-diabetics (n= 253)	p
MACE	5,9% (10)	5,5% (14)	0,61
Cardiac death	2,9% (5)	1,6% (4)	0,49
MI	2,9% (5)	4% (10)	0,77
TLR	0,5% (1)	1,8% (5)	0,24
Stent thrombosis, definite/probable	0,6% (1)	0,4% (1)	0,99

MI-myocardial infarction, TLR-target-lesion revascularization

Conclusions: The novel Supralimus™ DES demonstrated excellent performance and safety profile in unselected diabetic pts. At 6 months FU, clinical outcomes were comparable in diabetics vs. non-diabetics, including overall MACE <6% and TLR <2%. Complete 1 year clinical FU will be presented at the meeting.

TCT-438

Common Site of Stent Fracture after Sirolimus-eluting stent -Unique Distribution at Native Coronary Artery-

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Background: Stent fracture after drug-eluting stent has been reported to occur more frequently at RCA than other native coronary arteries. However, further information of common sites of stent fracture remains unclear. In this study, we evaluated the fracture site according to the branches of each coronary vessel after sirolimus-eluting stent (SES).

Methods: Between November 2002, and December 2006, a total of 2417 consecutive patients with 3888 lesions underwent stenting with SES. Of these, 2291 patients with 3621 lesions were treated with SES successfully and exclusively. A total of 1979 patients with 3086 lesions which were followed by angiography constituted the study population for evaluation of stent fracture. Angiographic stent fracture was defined as apparent complete separation of stent segments at any view of angiogram. Fluoroscopy with focusing on stent without contrast medium or inverse image analysis of routine angiography was used in selected cases in which stent fracture was suspected by routine angiography. Stent fracture at ostial or proximal site of RCA was also evaluated using left oblique view of LVG in addition to routine coronary angiogram. Angiographic stent fractures were observed at 154 lesions (total number of stent fractures was 180). Prevalence of stent fracture of RCA, left main trunk LMT, LAD, LCX, SVG and IMA were 7.6% (92/1205 lesions), 2.8% (4/142 lesions), 2.8% (29/1030 lesions), 3.1% (21/687 lesions), 25% (5/20) and 0% (0/2 lesions) respectively. Prevalence of stent fracture at various branches of native coronary artery was shown in the Figure.