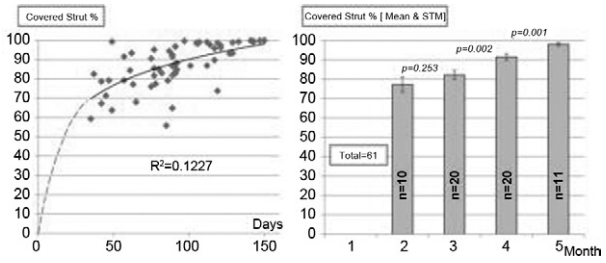

TCT-293

Neointimal Tissue Characteristics Based on Optical Coherence Tomography Analysis Following Paclitaxel Coated Balloon Treatment in a Porcine Iliofemoral Vascular Territory

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Background: The optical coherence tomography (OCT) characteristics of in-stent neointimal tissue have been associated with histological markers of healing. We aimed to investigate the differences in neointimal characteristics based on OCT analysis of Paclitaxel coated balloon (PCB) treatment versus POBA in the Iliofemoral territory of the familial hypercholesterolemic swine model (FHS).
Methods: 14 Iliofemoral arterial segments of 7 FHS were balloon injured followed by a BMS placement. At 14 days, the injured sites were treated with either a PCB or POBA (control). OCT images, acquired at 28 days post inflation, were classified at every 2mm according to previously published classification of neointimal types (homogeneous, heterogeneous and layered). Quantitative morphometric evaluation of vessel, stent, microvessel and peristrut low intensity areas (PLI) presence was also performed. A multivariable logistic regression model was performed dividing the neointima into homogeneous and non-homogeneous.
Results: AA total of 150 OCT cross sections were included in the final analysis. PCB resulted in a reduction of percent area stenosis (%AS) by 50% (PCB: 34±18% versus POBA 68±21%, p<0.05). The homogeneous pattern was more frequent in PCB (25%) than in the POBA group (3%, p<0.001). Conversely, the layered pattern was more prevalent in the POBA group (50.7% versus 4%, p<0.001). The homogeneous pattern correlated with less degree of neointimal formation [%AS: 16.68±5.3%, p<0.001) than the non-homogeneous group (heterogeneous: 49.01±24.9% and layered: 67.29±15.6%). The presence of micro vessels (89% versus 58%, p<0.001) and PLI (39% versus 24%, p=0.1) were more frequently found in the POBA group than in the PCB group. The only independent predictor of non-homogeneous patterns was the %AS [OR (95% CI)] = [3.98(1.21-13.09)].
Conclusions: In vivo OCT analysis suggests that the biological effect of Paclitaxel delivered via DCB frequently results in the homogeneous development of neointimal formation and lower frequency of PLI and micro-vessels compared to a POBA control. These in vivo findings support the biological efficacy observed in clinical trials using this technology.

TCT-294

Temporal Course of Vessel Healing after Everolimus-eluting Stent Implantation

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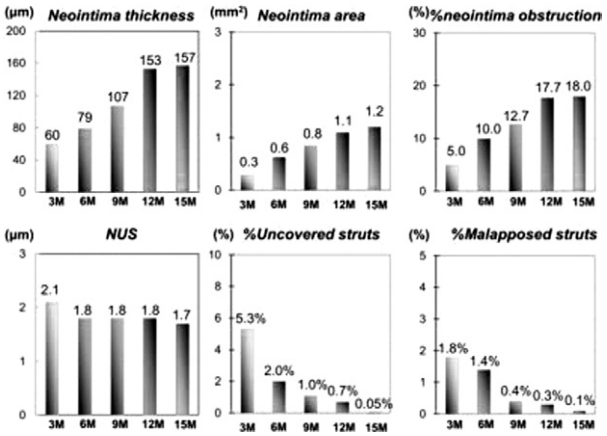
Background: Delayed arterial healing and late restenosis are a matter of concern of first generation drug-eluting stents (DES). Although everolimus-eluting stent (EES) is a widely-used second generation DES with biocompatible polymer, detailed time course of vessel healing after implantation is still unclear.
Methods: We prospectively enrolled 128 de novo coronary artery lesions in 88 patients treated with EES and performed follow-up (FUP) optical coherence tomography (OCT) at various FUP timing regardless of symptoms. Lesions were divided into groups according to the timing of FUP OCT: 3M (n=12), 6M (n=17), 9M (n=63), 12M (n=21), 15M group (n=15). To assess unevenness of neointima thickness (NIT), neointimal unevenness score (NUS: max NIT in the cross section/average NIT of the same cross section) was calculated and averaged for each stent.
Results: Average NIT, neointima area, and %neointima obstruction progressively increased within the first 12 months, and then slowed down at the level of around 160μm for NIT, 1.2 mm^2 for neointima area, and 18% for %neointima obstruction. Also, % uncovered and malapposed struts decreased along with Fup durations with a very few incidences of those findings at 12M. NUS reached the highest level at the earliest FUP of 3 months and then reached a plateau 6M after stenting.
Conclusions: Progressive vessel healing was observed within the first year after EES implantation. Neointimal progression within EES appears to slow down 1 year after stenting with a very few incidences of uncovered and malapposed struts at that time.



TCT-295

Neointimal growth patterns after between biodegradable polymer biolimus-eluting or permanent polymer everolimus-eluting stent implantation assessed with newly developed "spread-out neointimal topography": Results from ISAR-TEST6 OCT trial

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Background: Neointimal growth patterns of new generation drug-eluting stents are not yet fully elucidated. We developed a new visualization method and compared neointimal growth patterns between biodegradable polymer biolimus-eluting stent (BES) and permanent polymer everolimus-eluting stent (EES) using optical coherence tomography (OCT).
Methods: A total of 34 patients (41 lesions), who were randomly assigned to receive BES (n=15) or EES (n=19) and performed OCT follow-up at 6-8 moths in the ISAR-TEST6OCT trial were included in this analysis. The thickness of the neointima was calculated circumferentially in the area between luminal side of the stent and lumen contour semi-automatically. Neointimal thickness was measured a total of 287280 points (135000 in BES, 152280 in EES). "Spread-out neointimal topography" was constructed (Figure A) and neointimal growth patterns were compared between BES and EES.
Results: Inter-lesion analysis showed that mean neointimal thickness was significantly lower in BES group than in EES group (39 [29-57] vs. 91 [59-118] μm, p=0.003, Figure B). However Figure B showed a broader distribution of mean neointimal thickness in BES group. Intra-lesion analysis showed more consistent suppression of neointima in the lesion implanted BES comparison with the lesion implanted EES (50 [41-64] μm vs. 71 [59-85] μm, p=0.01).
Conclusions: A circumferential evaluation of the neointima using OCT showed that BES as compared to EES lead to lower mean neointimal thickness, higher inter-lesion and lower intra-lesion heterogeneity in terms of suppression of the neointimal hyperplasia.