

TCT-293

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

Maxwell Afari¹, Seung-Jin Oh², Piotr Buszman¹, Armando Tellez¹, Athanasios Peppas¹, William Rate¹, Jong Shuan Yeh¹, Greg Kaluz¹, Juan Granada³

¹Cardiovascular Research Foundation, Orangeburg, NY, ²Jack H. Skirball Center for Cardiovascular Research, Cardiovascular Research Foundation, Orangeburg, NY, ³CRF, Orangeburg, USA

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: $34 \pm 18\%$ versus POBA $68 \pm 21\%$, $p < 0.05$). 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: $16.68 \pm 5.3\%$, $p < 0.001$] than the non-homogeneous group (heterogeneous: $49.01 \pm 24.9\%$ and layered: $67.29 \pm 15.6\%$). 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

Hiromasa Otake¹, Hirotohi Hariki², Noritoshi Hiranuma³, Ken-ichi Hirata³, Takumi Inoue³, Masamichi Iwasaki⁴, Hiroto Kinutani⁵, Akihide Konishi¹, Masayuki Nakagawa², Toshiro Shinke⁶, Junya Shite¹, Yu Taniguchi¹

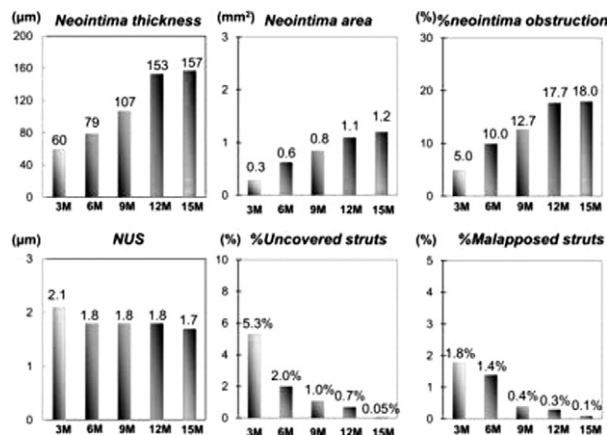
¹Kobe University Graduate School of Medicine, Kobe-city, Hyogo, ²Kobe University Graduate School of Medicine, Department of Cardiology, Kobe, Japan, ³Kobe University Graduate School of Medicine, Kobe City, Japan, ⁴Kobe University Graduate School of Medicine, Division of Cardiovascular, Kobe, Japan, ⁵Kobe University Graduate School of Medicine, Kobe, Hyogo, ⁶Kobe University Graduate School of Medicine, Kobe, Japan

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 $160 \mu\text{m}$ 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

Tomohisa Tada¹, Adnan Kastrati², Robert Byrne², Tibor Schuster³, Rezarta Cuni⁴, Lamin King⁵, Salvatore Cassese⁶, Michael Joner⁷, Steffen Massberg⁴, Albert Schömig⁶, Julinda Mehilli²

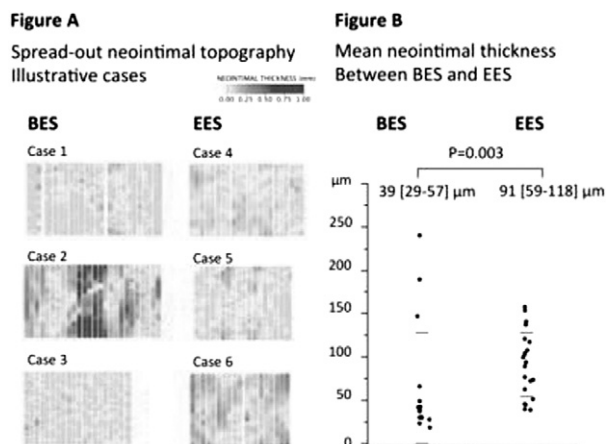
¹Deutsches Herzzentrum Munich, Munich, Bayern, ²Deutsches Herzzentrum Munich, Munich, Germany, ³Institute für Medizinische Statistik und Epidemiologie, Munich, Bayern, ⁴Deutsches Herzzentrum, Munich, Bayern, ⁵Deutsches Herzzentrum, Munich, Munich, Germany, ⁶Deutsches Herzzentrum, Munich, BAVARIA, ⁷Deutsches Herzzentrum München, Munich, Germany

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 months 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. $91 [59-118] \mu\text{m}$, $p = 0.003$, 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 ($50 [41-64] \mu\text{m}$ vs. $71 [59-85] \mu\text{m}$, $p = 0.01$).

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.



POSTERS

TCT-296

Comparison of Zotarolimus-Eluting stents versus Everolimus-Eluting stents versus Sirolimus-Eluting and in Patients with Long Coronary Artery Lesions Assessed by Volumetric Intravascular Ultrasound Analysis

Young-Rak Cho¹, Jung-Min Ahn², Soo-Jin Kang³, Young-Hak Kim¹, Won-Jang Kim², Jong-Young Lee², Woo Seok Lee¹, Gyung-Min Park², Seung-Jung Park³
¹Asan medical center, Seoul, Korea, Republic of, ²Asan Medical Center, Seoul, Korea, Republic of, ³Asan Medical Center, Seoul, South Korea

Background: As a substudy of the large, randomized LONG-DES-III and IV (Percutaneous Treatment of LONG Native Coronary Lesions With Drug-Eluting Stent-III and IV) trials comparing sirolimus-eluting stents (SES), everolimus-eluting stents (EES) and zotarolimus-eluting stents (ZES), we sought to investigate intimal hyperplasia (IH) and vascular changes using volumetric intravascular ultrasound analysis

Methods: Complete angiographic and volumetric intravascular ultrasound data immediately after stenting and at 9-month follow-up were available in 259 patients with 259 lesions (130 SES, 61 EES and 68 ZES). External elastic membrane (EEM), stent, lumen, and persistent plaque volumes (external elastic membrane minus stent) were normalized by stent length.

Results: Normalized IH volume was greater in EES than SES (0.7±0.4 mm² vs. 0.5±0.4 mm², P <0.05), whereas normalized IH volume in ZES was similar to those in SES (0.5±0.4 mm² vs. 0.5±0.4 mm²). Change in normalized EEM volume was smaller in EES than in SES (0.1± 1.2 mm² vs. 0.6±1.5 mm², P<0.05). However, the changes in normalized EEM volume were not different between ZES vs. SES (0.6 ± 1.5 mm² vs. 0.6 ± 1.1 mm²). Late stent malapposition was identified in 7 (5%) SES and 1 (1%) ZES, there was no EES lesion with malapposition.

Conclusions: In the coronary lesions with long stent length, the degree of neointimal growth in ZES was similar to SES, but less than that in EES. Expansive vascular remodeling in ZES was comparable to SES, but greater than EES.

	sirolimus stent	zotarolimus stent	everolimus stent
N	130	68	61
stent length	41.1 ± 14.1	42.7 ± 13.2	45.9 ± 14.9
Post stenting			
Minimal stent area	5.5 ± 1.6	5.7 ± 1.5	5.5 ± 1.5
Normalized stent volume	7.7 ± 1.8	7.7 ± 1.6	7.8 ± 1.6
Normalized lumen volume	7.7 ± 1.8	7.7 ± 1.6	7.8 ± 1.6
Normalized EEM volume	14.9 ± 4.0	15.4 ± 3.5	14.7 ± 3.9
F/U			
Minimal stent area	5.8 ± 1.9	6.3 ± 1.9	5.7 ± 1.7
Minimal lesion area	5.2 ± 1.7	5.4 ± 1.4	4.9 ± 1.6
Intimal hyperplasia volume	21.2 ± 20.0	21.9 ± 17.1	32.1 ± 23.1‡
Normalized stent volume	7.9 ± 2.0	8.2 ± 1.7	7.9 ± 1.7
Normalized EEM volume	15.5 ± 4.1	16.4 ± 3.5	14.9 ± 3.8
normalized lumen volume	7.4 ± 1.9	7.7 ± 1.6	7.2 ± 1.6
Normalized IH volume	0.5 ± 0.4	0.5 ± 0.4	0.7 ± 0.4‡
Changes(f/u volume - poststenting volume)			
ΔNormalized lumen volume	-0.2 ± 0.9	-0.2 ± 0.7	-0.6 ± 0.7‡
ΔNormalized EEM volume	0.6 ± 1.5	0.6 ± 1.1	0.1 ± 1.2
Late stent malapposition	7/130 (5%)	1/68 (0%)	0/61 (0%)
	(‡ P <0.05)		

TCT-297

Stent edge dissections detected by Optical Coherence Tomography, incidence, predictors and 12-month outcome

Rasmus Christensen¹, Niels Holm¹, Trine Ørholm¹, Michael Maeng¹, Lars Krusell¹, Christian Terkelsen¹, Jouke Dijkstra², Anne Køltoft¹, Steen Kristensen¹, Hans Erik Bøtker¹, Leif Thuesen¹, Jens Flensted Lassen¹, Evald Høj Christiansen¹
¹Department of Cardiology, Aarhus University Hospital, Skejby, Aarhus N, Denmark, ²Leiden University Medical Center, Leiden, The Netherlands

Background: Percutaneous coronary intervention carries a risk of dissections at the edges of the implanted stent. Optical coherence tomography (OCT) enables detection and detailed characterization of edge dissections (ED). We investigated the incidence, predictors and outcome of OCT detected EDs.

Methods: All patients with OCT evaluation at baseline and 12-month follow-up (FU) in the SORT-OUT V OCT substudy were included in the analysis. Plaques present in the edge segments 5 mm proximal and distal to the study stent were characterized by plaque type. All EDs were characterized by size and underlying plaque type.

Results: A total of 123 patients were included in the OCT substudy. Of these, 23 were not available for analysis due to patient drop out, contraindication to the FU OCT or poor image quality. No baseline EDs were found in three coronary event patients with no OCT FU. One patient with stent thrombosis (ST) within 2 hours had ED in a fibroatheroma. In the 97 patients included in the analysis 177 edges were visualized by OCT. A total of 37 (20.1%) EDs were detected in 33 patients (34% of patients). Size of EDs were longitudinal length: 1.90±0.97 mm, transversal length: 1.12±0.61 mm, and distance from tip of flap to vessel wall was 0.31±0.18 mm. Edge tissue characteristics for the analyzed edges were fibrotic plaques 94 (53.1%), calcific plaques 11 (6.2%), 25 lipid plaques (14.1%), and 47 (26.6%) edge segments with normal tissue. EDs occurred in fibrotic plaques in 28 (15.8%), 6 (3.3%) in fibrocalcific plaques and 3 (1.7%) in lipid plaques. None of the EDs were visible on XA. Two EDs were partially healed at 12 month FU, one located in a residual stenosis after stenting. At FU the stenosis had progressed to clinical significance.

Conclusions: Coronary EDs undetectable by XA were identified by OCT in 34% of the study population and left untreated. One ED over a fibroatheroma may have caused acute ST. All other EDs were completely or almost healed at 12 months FU. These results do not support additional intervention when EDs in fibrotic or fibrocalcific plaques are detected by OCT only.