**TCT-603**

Randomized comparison of 9-month stent struts coverage of biolimus and everolimus drug-eluting stents assessed by OCT in patients with STEMI

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**METHODS**

The cardiac intervention center at the Royal Bournemouth Hospital, UK has been one of the leading recruiting centers in the world for the Biofreedom stent LEADERS Free trial. After the recruitment period was complete, open label Biofreedom stent was incorporated in selected PCI cases who had high risk of bleeding and would benefit from short term DAPT therapy. The indication for PCI, procedural details, imaging, stent used, complications and follow up details were recorded and analyzed.

**RESULTS**

From August 2014 - May 2015, 1690 stent cases were identified that of Biofreedom stent was used in 60 cases (3.6%). Mean age of these 60 was 76.6±10.5 years, 41 (68%) were males. The indication for PCI was STEMI 4 (6.7%), Non-STEMI 18 (30%), unstable angina 5 (8.3%), stable angina 10 (16.7%) and the age was in 12 (20%) patients. Left ventricular systolic function was normal in 56.6%, mildly impaired 6.6%, moderately impaired 21.6% and severely impaired in 6.6%. A Biofreedom stent was selected during PCI in view of concomitant warfarin therapy in 27 (56.5%), elderly age 9 (15%), awaiting noncardiac surgery 8 (13.3%), anemia 3 (5%), bleeding issues 9 (15%) and due to poor compliance of medication in 4 (6.6%). Stent was deployed in LMS in 2, LAD 34, circumflex 17, RCA in 12 and 2 in venous graft. The lesion was predilated in 48 (80%) of cases and rotablation and laser atherectomy was performed prior to stent deployment in 8 (13.3%) and 3 (5%), respectively. The mean stent diameter was 3.04±0.40mm and length 35.8±18.8mm. No major complications was recorded during the stent deployment 1 month DAPT therapy was advised in 51 (91.6%), 6 months in 1 and 12 months in 4 patients. Patients were followed up for a period of 160±84 days. Fifty three (88%) had a good medium term outcome. Five (8.3%) died during the follow up period (4 patients with either cardiogenic shock, ventilated primary PCI and VT). One patient each developed restenosis and subacute stent thrombosis (Biofreedom deployed after laser PCI for uncovered stent).

**CONCLUSIONS**

The use of very short term DAPT with the Biofreedom stent in patients at high risk of bleeding events was associated with event free survival of 88% within this small case series. When prolonged DAPT is contraindicated, Biofreedom offers an alternative option to conventional DES/ BMS.

**CATEGORIES CORONARY:** Stents: Drug-Eluting

**KEYWORDS**

Biolimus, BioMatrix family products, Bleeding

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**TCT-605**

Serial C-reactive Protein Measurement-Based Assessment Of Long-term Outcomes Among Patients With Chronic Kidney Disease Undergoing Drug Eluting Stent Implantation

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**BACKGROUND**

Inflammation is well known as predictor of survival among patients with chronic kidney disease (CKD), and the CKD was reported as predictor of drug eluting stent (DES) stent failure. Assessment of inflammation may be helpful to understand mechanisms of DES failure among CKD patients.

**METHODS**

We investigated consecutive 1238 patients who have available paired C-reactive protein (CRP) (pre-procedure as baseline and 8-12 months later PCI as late-phase) among patients undergoing DES implantation. CRP elevation was defined as >0.2mg/dl. We divided them into 5 groups according to CKD grade (GI-2: eGFR >60ml/min; n=673, G2a: 45-59 ml/min; n=208, G3b: 30-44 ml/min; n=118, G4: 29-15 ml/min; n=34, G5: <15ml/min; n=105), and investigated occurrence of major adverse cardiac event (MACE) comprised from all cause death, non-fatal myocardial infarction, target vessel revasculatization, and any other unplanned revascularization.

**RESULTS**

Prevalence of CRP elevation at baseline was increased with advance of CKD grade (G1-2: 35.0%, G2a: 22.5%, G3b: 29.0%, G4: 51.4%, and G5: 65.4%), and that was not decreased among patients with CKD G4 and G5 at late phase (vs. baseline; 18.8%: P<0.0001, 20.8%: P=0.0002, 21.2%: P=0.003, 34.3%: P=0.02, and 60.6%; P=0.58). Survival analysis revealed that MACE was frequently among patients with CKD G5 that CRP elevation was higher (Figure), and multivariate analysis identified that elevated late-phase CRP (HR:3.24, 95%CI: 2.46-4.26, P<0.0001), number of diseased segment (HR:1.14, 95%CI: 1.07-1.20, P<0.0001), diabetes mellitus (HR:1.41, 95%CI:1.08-1.83, P=0.01), and CKD G5 (HR:2.15, 95%CI:2.25-4.41, P<0.0001) was positive predictor of occurrence of MACE, while statin was negative predictor (HR;0.75, 95%CI: 0.43; 0.96). The predictive score matched analysis also confirmed effect of late-phase CRP elevation on MACE (HR: 3.50, 95% CI: 2.63-4.65, P<0.0001).

**CATEGORIES CORONARY:** Stents: Drug-Eluting

**KEYWORDS**

Biolimus, BioMatrix family products, Bleeding
CONCLUSIONS Resistant inflammation of patients with advanced CKD may attenuate efficacy of DES.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Inflammation, Long-term clinical outcomes

TCT-607
Early DES and BMS healing profile assessed by OCT and proteomics in a pig model

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BACKGROUND The strut coverage in OCT is used as a surrogate marker of chronic stent healing, however less data is available regarding the acute healing response in the first week.

METHODS There were 13 BMS and 15 DES implanted into the coronary arteries in an overstitch model. OCT follow-up was performed at 1, 3, 7, 14, and 28 days post implantation and assessed strut apposition, coverage and neointimal volume per 1 mm of stent (CAAS intravascular, Pie Medical). A proteomic approach was used to measure changes in proteins expression in the arterial neointima over time following implantation of drug-eluting (DES, Xience Pro, Abbott, USA) and same metallic platform bare-metal stents (BMS, MLVision, Abbott, USA) compared to balloon angioplasty in porcine coronary arteries.

RESULTS In the early period after implantation a higher neointimal volume per 1 mm for BMS (0.24±0.028mm3 vs. 0.25±0.024mm3; p=0.025) without differences between BMS and DES in the stent struts malapposition (6.84±2.63% vs. 8.04±1.25%; p=0.75) and in strut strut coverage (45.50±4.94% vs. 36.73±4.41%; p=0.25) was found. At 28 days post implantation the difference in in-stent neointimal volume per 1 mm (0.70±0.13 vs. 0.68±0.02; p=0.89), struts coverage (94.84±2.82 vs. 98.93±0.51 p=0.778) and number of malapposed struts (0.866±0.52 vs. 0.407±0.40 p=0.238) were similar for BMS and DES. Animals were sacrificed at each of these time-points and their coronary arteries were retrieved with subsequent separate analysis of the vascular media and neointima (for time-point 28). A total of 145 ECM and ECM-associated proteins were identified by mass spectrometry. A comparison of the media versus neointima revealed an increase of collagens and regulatory proteins, such as small leucine rich proteins in the media, while basement membrane proteins were predominantly found in the neointima. Only by day 28, the neointima in DES compared to BMS showed increased expression of proteins involved in the regulation of calcification.

CONCLUSIONS Early healing events in first week after stent implantation involve less neointimal volume in DES and initially similar proteomic profiles for DES and BMS. After 28 days there are differences in extracellular matrix-related proteins between DES and BMS. It suggest the high biocompatibility of permanent fluorinated polymer coated DES in the acute phase after implantation.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS DES

TCT-607
Neointimal Transformation and Late Stent Failure from 2 months to 2 years of the New Dual Therapy Endothelial Progenitor Cell Capturing Sirolimus-eluting COMBO Stent by Longitudinal Sequential OCT: The EGO-COMBO Study

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BACKGROUND Late stent failures (late stent thrombosis, late catch-up, and accelerated neatherosclerosis) were reported in monotherapy drug eluting stents (DES). The benefits of the new “dual” therapy endothelial-progenitor-cell capturing sirolimus-eluting COMBO stent (OrbusNeich, FL, US) were analyzed.

METHODS Four longitudinal sequential OCTs in each patient were obtained in this prospective, single center study; at baseline (for best stent optimization); at early FUs from 2-5M (4 monthly groups in 1:2:2:1 ratio for % strut coverage), at 9M (for neointima metrics), and at 24M (for neointimal changes). Clinical event adjudication & OCT analyses were performed by CRF core laboratory.

RESULTS 61 patients (33% DM and 74 lesions) received 88 COMBO stents. All 61 patients completed 9M OCT FU but 17 asymptomatic cases refused 24M OCT (FU rate 68.3%). Median strut coverage increased from 77.1, 92.5, 92.7, 94.9, 99.5, to 99.2% from 2M, 3M, 4M, 5M, 9M, to 24M, respectively. No late stent thrombosis was recorded (p=0.02; p=0.778) and number of malapposed struts (p=0.44 1.18; p=0.49 0.49; p=0.045 0.49; p=0.001 0.49) were significantly lower in COMBO stent versus BMS. Late stent failures (late stent thrombosis, late catch-up) were reported in 5 (8.2%) of 61 COMBO cases and in 17 (21.2%) of 79 BMS cases (p=0.001). The COMBO stent exhibited an enhanced late luminal and neointimal expansion (p<0.001) compared to BMS at all time-points. Analysis of the immediate OCT (2 to 5M); this difference diminished significantly by 9M, representing rapid vessel healing. Progressively increase in homogeneous neointima (conversion from heterogeneous & layered neointima) with reduction in peri-strut-low-density area was observed (Figure 2), representing neointimal maturation without accelerated neatherosclerosis.