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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**BACKGROUND**
The aim of this trial was to compare healing (assessed by optical coherence tomography-OCT) of biolimus A9 and everolimus drug-eluting stents at 9-month follow-up in patients with ST-segment elevation myocardial infarction (STEMI) treated by primary PCI (pPCI). 9-month clinical and angiographic data were also compared in both groups.

**METHODS**
201 patients with STEMI treated by primary PCI were randomly enrolled in the trial. 101 patients were randomized to the biolimus A9 stent group and 100 patients to the everolimus group. All patients were pre-treated with a standard therapy (unfractionated heparin, aspirin and clopidogrel). The use of inhibitors of GP IIb/IIIa and thienopyridine were well balanced in both groups. Therapy of MACC did not differ significantly at 30 days between both groups. There was one acute stent thrombosis requiring immediate re-PCI in the everolimus stent group and one asymptomatic stent thrombosis in the biolimus group (revealed during stage PCI of non-culprit lesion). Furthermore, there was one non-cardiac death in the biolimus group. 9-month angiographic and OCT follow-up underwent 87% patients in everolimus and 90% patients in biolimus group respectively. At 9-month follow-up, the rate of MACE and angiographic restenosis were comparable and very low in both groups (2% vs. 1% and 1% respectively; P=NS). All in-stent and in- and in-stent angiographic data (reference diameter, minimal diameter, mean diameter, % stenosis) were comparable at 9-month in both groups. OCT data presents Table. The rate of uncovered struts were significantly higher in biolimus group (19.6%±16.2% vs. 9.9%±10.8%; P<0.0001). On the other hand, there was a trend to higher mean and minimal diameter (1.35mm±0.56 vs. 3.2mm±0.43; P=0.06 and 2.88mm±0.55 vs. 2.74mm±0.49; P=0.09).

**RESULTS**
At 9-month follow-up, second generation everolimus drug-eluting stents show better healing when compared to biolimus second generation drug-eluting stent. However, the stent struts coverage is considerably high in both groups.

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

**METHODOLOGY**
The cardiac interventional 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 and stent used, complications and follow up details were recorded and analyzed.

**RESULTS**
From August 2014 - May 2015, 1690 stent cases were identified of which 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 31 (51.6%) and staged procedure 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 rotational atherectomy was performed prior to stent deployment in 8 (13.3%) and 3 (5%) respectively. The mean stent diameter was 3.08±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 approach to conventional DAPT.

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

**KEYWORDS**
Biolimus, BioMatrix family products, Bleeding

**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 mechanism 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 (G1=2: eGFR >60ml/min; n=673, G2=45-59 ml/min; n=308, G3b: 30-44 ml/min; n=118, G4: 29-15 ml/min; n=34, G5: <15ml/min; n=103), and investigated occurrence of major adverse cardiac event (MACE) comprised from all cause death, non-fatal myocardial infarction, target vessel revascularization, and any other unplanned revascularization.

**RESULTS**
Prevalence of CRP elevation at baseline was increased with advance of CKD grade (G1=2: 35.0%, G2: 22.5%, G3b: 39.0%, 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=0.12, and 60.6%; P<0.58). Survival analysis revealed that MACE was frequently observed in CKD G5 than CKD G4 (Figure), and multivariate analysis revealed 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=0.001), and CKD G5 (HR:1.15, 95%;CI: 1.25-4.41, <P=0.001) was positive predictor of occurrence of MACE, while statin was negative predictor (HR:0.75, 95%;CI: 0.56-0.99, <P=0.048). Prognosis score-scored analysis also confirmed effect of late-phase CRP elevation on MACE (HR: 3.50, 95% CI: 2.63-4.65, <P<0.0001).

**TCT-604**
Contemporary DES for high risk bleeding patients: Real world experience of the polymer-free Biofreedom stent

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**BACKGROUND**
The Biolimus A9 coated Biofreedom stent is a polymer free stainless steel drug eluting stent. In an animal models 98% of the drug has diffused into the vessel wall in 1 month and it is reasonable to consider short term DAPT of 1 month for patients with this stent. Moreover, Biofreedom stent would be ideal in patients who may not tolerate 12 months of DAPT therapy. The aims of this study was to evaluate the indications, safety, efficacy and medium term outcome of real world patients who had PCI using Biofreedom stent and short term DAPT therapy.