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Drug-coated balloon versus drug-eluting stent after rotational atherectomy for calcified coronary lesions

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Background: Rotational atherectomy (RA) could facilitate percutaneous coronary intervention (PCI) for calcified lesions. However, late outcomes after PCI for lesions requiring RA have not been satisfactory even when combined with drug-eluting stent (DES). Recently, stent-less PCI with drug-coated balloon (DCB) has emerged as an alternative strategy. However, little is known about efficacy of DCB, as compared with DES, for calcified coronary lesions requiring RA. The objective of the present study is to compare the late outcomes after DCB angioplasty with RA and DES implantation with RA in patients with calcified coronary lesions.

Methods: We enrolled a total of 168 consecutive patients (238 lesions) with calcified coronary lesions who electively underwent RA. After lesion modification by RA, 88 patients (113 lesions) were treated with DCB (the RA-DCB group) and 80 patients (125 lesions) were treated with DES (the RA-DES group). Angiographic follow-up was planned at 6 months after PCI, and patients were clinically followed up for 2 years. The incidence of restenosis as well as clinical events including target lesion revascularization (TLR) and major adverse cardiac events (MACE) as the composite endpoint defined as TLR, all-cause death or nonfatal myocardial infarction were investigated. To reduce the selection bias between the two procedures, propensity score from all baseline variables was calculated, then the score was incorporated into Cox analysis as a covariate.

Results: Age, sex and comorbidities of patients were similar between the groups. Of all patients, 59.5% were diabetic and 27.1% were on chronic hemodialysis. Moderate/heavy calcification was observed in 79.0% of all lesions (77.9% in the RA-DCB group vs 80.0% in the RA-DES group, $p=0.81$). Ostial/bifurcation lesions were more frequent in the RA-DCB group than in the RA-DES group (47.8% vs 29.6%, $p=0.006$). In the RA-DCB group, reference vessel diameter was smaller (2.38mm vs 2.57mm, $p=0.0025$), while the burr-to-artery ratio was higher, as compared with the RA-DES group (0.75 vs 0.65, $p<0.0001$). The rates of restenosis at follow-up angiography were comparable between the groups (17.3% vs 12.3%, $p=0.61$). During the clinical follow-up period, 39 TLRs and 17 deaths occurred. The unadjusted survival rates for TLR and MACE at 2 years were not statistically different between the groups [72.3% vs 80.6%, hazard ratio (HR) 1.67, 95% confidence interval (CI) 0.88–3.15, $p=0.11$, and 66.5% vs 73.0%, HR 1.56, 95% CI 0.92–2.64, $p=0.10$, respectively]. However, the HRs in the RA-DCB group, adjusted by propensity score, were 5.42 (95% CI 2.08–14.1, $p=0.00053$) for TLR and 3.94 (95% CI 1.72–9.04, $p=0.0012$) for MACE.

Conclusion: Although the restenosis rates at follow-up angiography were similar, RA-DCB would be associated with worse long-term clinical outcomes, as compared with RA-DES, in patients with calcified coronary lesions.

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The use of 48mm Everolimus eluting stents for the percutaneous treatment of long coronary lesions

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Aims: Percutaneous coronary intervention of long coronary lesions remains a challenge. Although the incidence of adverse events after drug-eluting stent implantation is low, stent overlap (especially long or multiple) is associated with major adverse cardiac events (MACE). Implanting a single long stent avoids stent overlap, geographical miss and allows possible cost savings. Our study reviewed procedural safety and clinical outcomes of patients with long coronary lesions treated with 48mm Xience Pro everolimus drug eluting stents (EES).

Methods and results: This was a cohort study based on the Barts Heart Centre PCI registry. A total of 610 patients who had long coronary lesions (lesions ≥ 40 mm) undergoing coronary angioplasty between 2013 to 2017 were included in the study. 305 patients with 48mm EES implanted were propensity matched with 305 patients undergoing PCI with overlapping stents. The primary end-points were MACE (target vessel revascularisation, myocardial infarction and all-cause mortality) recorded at a median follow up of 23 months. Groups were comparable for patient characteristics (age, DM, ACS presentation) (matched groups). Lower MACE rates were observed over follow-up in patients who underwent single stent (4.6%) compared to multiple overlapping stents (8.1%, $p=0.038$). This difference was mainly driven by reduced rates of target vessel revascularisation. This difference persisted after multivariate Cox analysis (HR 0.82, 95% CI 0.44–0.96).

Conclusions: Our study showed that the 48mm EES appeared safe and effective and had potentially lower adverse event rates compared to overlapping stents. This has important implications and potential cost savings for this group of patients.

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A polymer-free biolimus-coated stent for the management of real-world high bleeding risk patients with coronary artery disease

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Background: A polymer-free biolimus A9 coated and eluting stent (PF-BCS) followed by 1-month dual antiplatelet therapy has been shown to be safer and more effective than a bare-metal stent in high bleeding risk (HBR) patients undergoing PCI in a clinical trial setting. However, little is known about the performance of this PF-BCS in HBR patients encountered during every day, routine clinical practice.

Purpose: This study aimed at assessing the performance of a PF-BCS (Biofreedom™) in real-world HBR patients with severe coronary artery disease (CAD).

Methods: A retrospective cohort analysis was performed on HBR patients (defined according to the LEADERS FREE Trial criteria) with severe CAD underwent PCI in five Centers. Primary safety end-point was to assess the incidence of a composite of cardiac death, myocardial infarction (MI), or definite/probable stent thrombosis (ST). The primary efficacy endpoint was target lesion revascularization (TLR). The incidence of type 3 and 5 bleedings according to the Bleeding Academic Consortium (BARC) were also evaluated.

Results: A total of 499 HBR patients with 693 lesions received a PF-BCS between January 2016 and October 2017. Main indications for the implantation of this novel intra-coronary device were: need for oral anticoagulation in 115 patients (23%) and age more than 75 years in 111 patients (22.2%); 49 (9.8%) patients had cancer while 37 (7.4%) experienced a prior major bleeding. More than half of the patients (263, 52.7%) were admitted because of acute coronary syndrome while 155 (31.1%) were diabetics. Among the 693 lesions treated, 132 (19%) were bifurcations, 96 (13.8%) heavily calcified, 31 (4.4%) unprotected left main while 29 (4.2%) aorto-ostial. Angiographic success was obtained in 98.2% of the cases while the rate of peri-procedural MI was 2.2%. At a median of 9 months follow-up (IQR 3–19) the incidence of the composite safety end-point was 2.8% (cardiac death 1.6%, MI 1.2% and definite/probable ST 0.4%) while the incidence of TLR was 0.6%. BARC defined type 3 and 5 bleedings rate was 6.2%.

Conclusions: In our real-world experience, the implantation of a PF-BCS in HBR patients is associated with favorable clinical results, pointing toward the overall mid-term efficacy and safety of this novel device in complex clinical scenarios.

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Impact of Body Mass Index on 3 years clinical outcomes in patients treated with platinum chromium-everolimus eluting stent implantation

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Background: Impact of Body Mass Index (BMI) on 3 years clinical outcomes in patients treated with platinum chromium-everolimus eluting stent (PtCr-EES) implantation remains unclear.

Methods: Between March 2012 and August 2013, 809 consecutive patients with 1054 lesions were treated only with PtCr-EES implantation. Of these, the BMI was calculated in 807 patients with 1050 lesions. Patients were divided into three groups: three groups for BMI (underweight [<18.5], $n=44$; normoweight [$18.5-24.9$], $n=469$; and overweight [≥ 25.0], $n=294$). We assessed the cumulative 3-year incidences of all-cause mortality and major adverse cardiac events (MACE) based on BMI groupings. MACE was defined as a composite of cardiac death, myocardial infarction, definite stent thrombosis, and clinically driven target lesion revascularization (CDTLR).

Results: Cumulative 3-year incidence of all-cause mortality was significantly higher in the underweight group than in the other groups (47.7% vs. 12.1% vs. 4.2%, $p<0.001$). The cumulative incidence of MACE, cardiac death, myocardial infarction, stent thrombosis and CDTLR were no significant differences in the

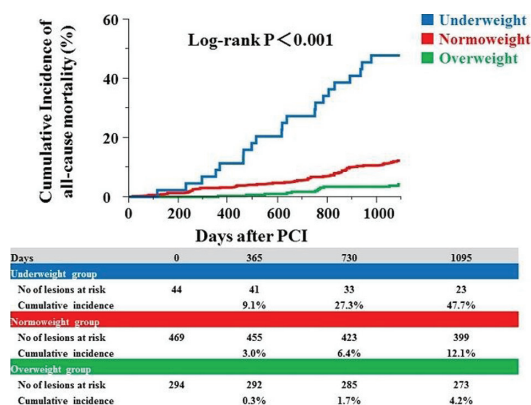


Figure. Cumulative Incidences of all-cause mortality Through 3-Year Follow-up