CRT-100.41

The Safety and Efficacy of Biodegradable-Polymer Biolimus-Eluting Stent (BP-BES) Compared with Durable-Polymer Everolimus-Eluting Stent (DP-EES) in Patients Undergoing Complex Percutaneous Coronary Intervention

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BACKGROUND The likelihood of stent failure directly correlates with the complexity of underlying coronary artery disease. The biodegradable-polymer biolimus-eluting stent (BP-BES) has a relatively thick strut (120 μm) stainless steel platform, and the unfavorable effect of thick struts may be clinically apparent, particularly in vessels with complex features. We sought to evaluate the safety and efficacy of BP-BES compared with durable-polymer everolimus-eluting stents (DP-EES, 89 μm) in patients undergoing complex percutaneous coronary intervention (PCI).

METHODS Patients enrolled in the SMART-DESK registry were stratified into 2 categories based on the complexity of PCI. Complex PCI was defined as having at least 1 of the following features: unprotected left main lesion, ≥2 lesions treated, total stent length >40 mm, minimal stent diameter ≤2.5 mm, or bifurcation as target lesion. The primary outcome was target lesion failure (TLF), defined as a composite of cardiac death, target vessel-related myocardial infarction (TV-MI), or target lesion revascularization (TLR) at 2-year follow-up.

RESULTS Of 1,999 patients in the registry, 1,145 (57.3%) underwent complex PCI: 521 patients treated with BP-BES; and 624 patients with DP-EES. In the propensity-score matching (481 pairs), baseline characteristics were well-balanced between groups, the risks of TLF (adjusted hazard ratio [HR], 0.578; 95% confidence interval [CI], 0.246-1.359, p = 0.209), cardiac death (adjusted HR, 0.787; 95% CI, 0.244-2.539, p = 0.689), TV-MI (adjusted HR, 1.128; 95% CI, 0.157-8.093, p = 0.905), TLR (adjusted HR, 0.390; 95% CI, 0.139-1.095, p = 0.074), and definite or probable stent thrombosis (adjusted HR, 4.342; 95% CI, 0.484-38.927; p = 0.189) did not differ between 2-stent groups after complex PCI. Additionally, complex PCI was not associated with higher risks of TLF, cardiac death, TV-MI, and definite or probable stent thrombosis except TLR (adjusted HR, 3.209; 95% CI, 1.099-9.370; p = 0.033) compared with non-complex PCI.

CONCLUSIONS Clinical outcomes of BP-BES were comparable to those of DP-EES at 2 years after complex PCI. Our data suggest that use of BP-BES is acceptable even for high-risk complex PCI.

CRT-100.42

Safety And Efficacy Of A Novel Sirolimus-eluting Coronary Stent With Unique Coating Technology In Patients With Diabetes

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BACKGROUND After percutaneous coronary intervention, patients with diabetes mellitus have higher risk of death, restenosis, and stent thrombosis compared to non-diabetic patients. We hereby report the clinical outcomes of the Abluminus DES+™, which has unique fusion coating technology, merging the properties of a sirolimus-coated balloon with those of a bioresorbable-polymer DES in diabetic patients.

METHODS Two thousand three hundred seventy-two patients were enrolled in the en-ABL e-registry, 817 patients suffered from diabetes mellitus (DM), 128 of them being insulin-dependent (IDDM). The primary and secondary endpoints were major adverse cardiac events (MACE), composite of cardiac death, target vessel myocardial infarction (TV-MI), or target lesion/vessel revascularization (TLR/TVR) and stent thrombosis (ST) at 1 year, respectively.

RESULTS At 1 year, 83.56% of the patients were available for follow-up. Five patients (0.21%) were lost at follow-up. Clinical follow-up of remaining patients is yet to come. The event characteristics are shown in Table 1. The reported MACE rates at 1 year were 3.31% in DM group and 2.33% in non-DM group; (p= 0.198). In the DM group, the MACE rate in patients with IDDM was numerically but not statistically higher than in the non-IDDM subgroup (5.10% vs. 2.73%; p=0.209). The rate of ST at 1 year was not different among diabetic versus non-diabetic patients or IDDM versus NIDDM.

%	DM N=695*	NO-DM N=1287*	P	IDDM N=98*	Non-IDDM N= 597*	P
MACE	3.31	2.33	0.198	5.10	2.73	0.209
Cardiac Death	0.86	0.62	0.579	1.02	0.58	0.504
TV-MI	0.43	0.39	1.000	1.02	0.19	0.295
TLR	2.01	1.32	0.235	3.06	1.95	0.448
ST	0.86	0.54	0.379	1.02	0.39	0.409

CONCLUSIONS The overall performance of PCI in the treatment of patients with DM is still an unmet clinical need. The Novel Abluminus DES+ performed well in patients with DM, perhaps consistently with patients without DM. Patients with DM, particularly those with IDDM, had worse but not significantly different outcomes compared to non-IDDM. These results, to the best of our knowledge, are unprecedented with other second-/third-generation DES.

FFR

CRT-100.43

Effect Of Gender Differences On Instantaneous Wave-free Ratio And Fractional Flow Reserve In Intermediate Coronary Lesions: Results From A Single-center Registry

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BACKGROUND Instantaneous wave-free ratio (iFR) is a newly developed coronary artery pressure index measured in the wave-free period of diastole in absence of hyperemia. An iFR-guided revascularization strategy was shown to be noninferior to fractional flow reserve (FFR)-guided revascularization strategy in multiple recent randomized controlled trials. The effect of gender differences on iFR and FFR remains to be elucidated. The purpose of this study is to compare the effect of gender on iFR and FFR in the intermediate coronary lesions.

METHODS We retrospectively reviewed 1024 intermediate coronary lesions requiring functional evaluation using iFR in 837 patients referred for coronary angiography between January 2015 and June 2016. The standard protocol was the hybrid approach, where the intermediate iFR range lesions between 0.86 and 0.93 underwent additional FFR assessment and a cutoff value of 0.80 or less was used to indicate the presence of hemodynamically important stenosis. In our analysis, the threshold cutoff value of 0.89 or less for iFR was applied retrospectively for positive iFR.

RESULTS Among 1024 intermediate coronary lesions, 616 lesions (60.2%) were men compared to women with 408 lesions (39.8%). The hybrid protocol of measuring FFR was done in 451 coronary lesions. Women had significantly higher rate of positive iFR compared to men (23.8% vs. 18.3%, p=0.035). On the contrary, men had significantly higher rate of positive FFR compared to women (28.4% vs. 15.5%, p=0.001). Women had more diabetes mellitus and left anterior ascending artery. Men had more acute coronary syndrome presentation, concomitant chronic total occlusion, and left circumflex artery compared to women. Multivariate analysis showed diabetes mellitus and left anterior descending artery to be independent predictors of positive iFR (OR 1.64 and 6.95, p=0.002 and <0.001); however, female gender was not an independent predictor for positive iFR (OR 1.22, p=0.24). Multivariate analysis for FFR showed male gender, acute coronary syndrome, and concomitant chronic total occlusion to be independent positive predictors (OR 1.84, 2.02, and 2.29, p=0.02, 0.003, 0.03) while left circumflex artery was a negative predictor for positive FFR (OR 0.19, p=0.01).

CONCLUSIONS In this single-center, real-world retrospective study, women had higher rate of positive iFR while men had higher rate of positive FFR. Multivariate analysis showed female gender was not an independent predictor for positive iFR while male gender was an independent predictor for positive FFR.