TCT-663

Comparison of Conformability and Wall Shear Stress Between Resolute Integrity Zotarolimus-Eluting Stent and the XIENCE Xpedition Everolimus-Eluting Stent in Angulated Vessels: An Interim Analysis of the SHEAR-STENT Randomized Controlled Study

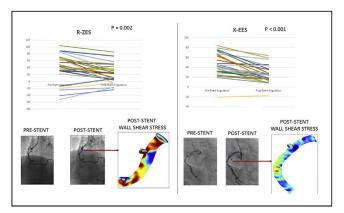


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BACKGROUND Given its continuous wire molding and sinusoidal design, we hypothesized that Resolute Integrity stent (R-ZES) is more conformable than the XIENCE Xpedition stent (X-EES) and therefore may induce more physiologic wall shear stress (WSS) in angulated coronary arteries.

METHODS Interim analysis of angiographic (angio) and intravascular ultrasound (IVUS) acquisitions of patients from the SHEAR STENT study (n=58/126), randomized to R-ZES (n=29) vs. X-EES (n=29) deployed in vessels $\geq\!30^\circ$ angulation was performed. Pre and post stent vessel angulations were calculated using quantitative coronary angiography. A paired sample t-test was used to compare pre and post stent vessel angulations. Wall Shear Stress (WSS) was calculated in the in-stent, upstream and downstream 5 mm segments and compared between the 2 platforms using a Mann-Whitney U Test. Low WSS was defined as < 1Pa

RESULTS There was an overall decrease in vessel angulation post-valve deployment (p < 0.01). Both R-ZES (p=0.002) and X-EES (p<0.001) demonstrated a significant straightening post stent-deployment (Figure). When compared to X-EES, the median WSS observed in R-ZES was not significantly different in the in-stent (1.59 Pa vs 2.22, p=0.62), 5 mm upstream (2.17 Pa vs 2.08 Pa, p=0.55), 5mm down-stream (1.48 Pa vs 1.57 Pa, p=0.67) segments. Similarly, the percentage in-stent segments of both R-ZES and X-EES were similarly exposed to low WSS (p=0.35). In a univariable logistic regression analysis, a trend was observed between higher pre-sent angulation and higher number of in-stent segments with low WSS (OR:1.02, p=0.08).



CONCLUSION Both R-ZES and X-EES showed significant conformability in angulated coronary arteries. The hemodynamic significance of conformability and pre-sent angulations remains to be fully elucidated at the completion of the study.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-664

Twelve-Month Clinical Outcomes Comparing Biodegradable Polymer Sirolimus-Eluting Stent Versus Durable Polymer Everolimus-Eluting Coronary Stents in Patients With De Novo Native Coronary Artery Lesions: The meriT-V Randomized Trial



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BACKGROUND The aim of this study is to compare the safety and efficacy of the biodegradable polymer coated sirolimus-eluting coronary stent (SES, BioMime™, Meril Life Sciences, India) with durable polymer coated everolimus-eluting coronary stent (EES, XIENCE family, Abbott Vascular, California, USA) in de novo coronary artery lesions.

METHODS The meriT-V is a prospective, multicentre, randomized, active-controlled, non-inferiority clinical trial. Subject at 15 investigational centers in Europe and Brazil with up to two de novo coronary artery lesions were randomly treated to SES (n=170) versus EES (n=86). The primary endpoint was angiography assessment of late lumen loss at 9-month follow-up. The secondary endpoints were clinical assessment of major adverse cardiac events (MACE) at 1, 5, 9, 12 and 24 months.

RESULTS At 9-month, angiographic results demonstrated non-inferiority of SES compared with EES regarding the primary endpoint of in-stent late lumen loss (0.15 \pm 0.27 mm vs. 0.15 \pm 0.29 mm, difference, -0.006 mm; 95% confidence interval, -0.085 to 0.072; p for non-inferiority <0.0001). Cumulative 12-month MACE were numerically lower for SES (4.17% vs. 7.14%; p=0.31) group, including lower rate of (1.19% vs. 4.76; p=0.08) myocardial infarction and comparatively similar (2.98% vs. 2.38; p=0.78) target lesion revascularizations when compared with EES group.

CONCLUSION In conclusion, biodegradable polymer coated SES is angiographically non-inferior to durable polymer coated EES at 9-month follow-up and cumulative MACE was comparable in both arms at 12-month follow-up. (Clinical registration: ClinicalTrials.gov, number NCT02112981).

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-665

Unselected use of ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stent for coronary revascularization



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BACKGROUND BP-SES have been reported to be non-inferior compared with DP-EES in a randomized clinical trial (RCT), while the superior benefits of BP-SES was noted in patients presenting with STEMI. RCTs frequently exclude high-risk patients, especially among those presenting with STEMI. We sought to compare the efficacy and safety of an ultrathin strut biodegradable polymer sirolimus-eluting