TCT-205

One-year outcomes of percutaneous coronary intervention with a modern drug-eluting stent in patients with moderate and severe coronary calcification: A pooled analysis from the Nobori-2 and e-Nobori all-comer registries

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Background: Percutaneous coronary intervention (PCI) of moderate and severely calcified lesions has been described as a predictor of worse outcomes when bare-metal stents or first-generation drug-eluting stents (DES) have been used. Little is known about the impact of coronary calcification on outcome after PCI with modern DES.

Methods: 14,134 patients treated with a biolimus A9-eluting stent with a biodegradable polymer (Nobori, Terumo, Japan) were pooled from 2 all-comer registries (Nobori-2 and e-Nobori). An independent clinical event committee adjudicated all adverse events and an independent core lab analyzed baseline and adverse events' angiograms. Patients were divided into 2 groups based on whether or not PCI was performed on moderate/severely calcified lesions. Target lesion failure (TLF), defined as cardiac death, target vessel-related myocardial infarction and target lesion revascularization, and stent thrombosis were assessed at 1 year.

Results: Overall, 4,321 patients (30.6%) had moderate/severe coronary calcification. Patients with calcified lesions were older and had a higher rate of diabetes mellitus, hypertension, renal failure, peripheral arterial disease and previous bypass surgery, but less commonly presented with an acute coronary syndrome. Patients with calcified lesions more commonly required multivessel treatment and needed longer stents. Pre- and post-implantations were mostly performed in the calcified lesions group. Rotational atherectomy or cutting balloons were used in only 5.49%. Preliminary data at 1-year follow-up (currently available in 9,089 patients) revealed low rates of TLF and stent thrombosis, but both were significantly higher in patients with moderate/severe calcification (TLF in 5.03% vs. 2.83%, p<0.001, stent thrombosis in 0.72% vs. 0.34%, p=0.03). By multivariate analysis, the presence of moderate/severe calcification was a strong independent predictor of TLF at 1-year (OR1.77, 95%CI 1.23-2.55, p=0.002).

Conclusions: Moderate/severe coronary calcification independently predicts increased rates of TLF at 1-year after PCI with the biolimus A9-eluting Nobori stent, but overall stent performance remains excellent and event rates are surprisingly low.

TCT-204

Comparable Outcomes despite Differences in Patient Representation between Premarket and Postmarket coronary Intervention Studies: Findings from the ENDEAVOR and PROTECT Programs

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Background: Differences in enrollment criteria and protocol requirements are thought to affect patient representation and outcomes from premarket and postmarket surveillance (PMS). We assessed differences between premarket vs. PMS trials assessing implantation of the Endeavor-zotarolimus eluting stent (E-ZES).

Methods: We analyzed data from 2132 and 4357 E-ZES treated subjects (ENDEAVOR premarket and PROTECT PMS trials, respectively). We analyzed differences in 3-year outcomes and adjusted them for differences in baseline characteristics.

Results: The two groups differed significantly in baseline characteristics. However, the rates of 3-year major adverse cardiac event (MACE), major adverse cardiac and cerebrovascular event (MACCE) and target vessel failure (TVF), were similar (12.67% vs. 11.88%, p=0.191; 11.88% vs. 12.68%, p=0.369; and 13.81% vs. 13.01%, p=0.419, respectively). PMS trials had less clinically driven target vessel revascularizations (CD-TVR, p=0.001) and more myocardial infarctions (MI, p=0.005). Differences emerged at 8 months and immediately post-procedurally, respectively. After propensity score adjustment, CD-TVR rates no longer differed significantly (HR 0.72, 95% CI 0.51-1.01).

Conclusions: Premarket and PMS trials assessing E-ZES implantation had similar 3-year composite outcomes. Differences in CD-TVR were attributed to different protocol requirements and in MIs to different outcome definitions. It is yet to be determined if these settings reflect everyday practice.