

Results from PROSPECT ABSORB reported at TCT Connect and published simultaneously in JACC

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New data from PROSPECT ABSORB, a pilot randomized trial of percutaneous coronary intervention (PCI) of non-flow-limiting



vulnerable plaques in native coronary arteries, found that PCI was safe, substantially enlarged follow-up lumen areas, and was associated with favorable long-term clinical outcomes.

Findings were reported today at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation (CRF). TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The study was also published simultaneously in the *Journal of the American College of Cardiology*.

Acute coronary syndromes (ACS) commonly arise from plaque rupture and thrombosis of coronary artery lesions that angiographically appear mild but pathologically contain large plaque burden (PB) with an organized lipid-rich necrotic core that is separated from the lumen by a thin fibrous cap. Known as vulnerable plaques, these thin-cap fibroatheromas place patients at risk for future adverse events, including acute myocardial infarction (MI) and cardiac death. Vulnerable plaques may be identified by several noninvasive and invasive imaging techniques.

PROSPECT ABSORB was an investigator-sponsored, multicenter, single-blinded, active-treatment-controlled randomized trial that was embedded into the PROSPECT II natural history study. Between June 10, 2014 and December 20, 2017, 902 patients at 16 sites were enrolled in PROSPECT II.

Three-vessel imaging was performed with a combination intravascular ultrasound (IVUS) and near-<u>infrared spectroscopy</u> (NIRS) catheter after successful PCI of all flow-limiting coronary lesions in 898 patients presenting with MI. Among these, 182 patients at 15 centers with an angiographically non-obstructive stenosis not intended for PCI but with IVUS <u>plaque</u> burden 65% were randomized to treatment of the lesion with a bioresorbable vascular scaffold (BVS) plus guideline-directed



medical therapy (GDMT) (n=93) vs. GDMT alone (n=89).

The primary effectiveness endpoint was the IVUS-derived minimum lumen area (MLA) at protocol-driven 25-month follow-up. The primary (non-powered) safety endpoint was target lesion failure (TLF; composite of cardiac death, target vessel-related MI or clinically driven target lesion revascularization) at 24 months. Angiographic follow-up at 25 months was completed in 167 patients (91.8%), and median clinical follow-up was 4.1 years.

The follow-up MLA in BVS-treated lesions was 6.9±2.6 mm2 compared with 3.0±1.0 mm2 in GDMT alone-treated <u>lesions</u> (least square means difference 3.9 mm2, 95% CI 3.3-4.5, P

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