Novel polymer-free amphilimus-eluting stent is noninferior to durable polymer zotarolimus-eluting stent

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The first large, randomized trial comparing a novel polymer-free amphilimus-eluting stent to the latest-generation permanent polymer drug-eluting stent found that the polymer-free stent was clinically safe and effective.

Findings from the ReCre8 trial were reported today at the 30th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

ReCre8 is a physician-initiated, prospective, multicenter, randomized, non-inferiority trial of all-comer patients requiring percutaneous coronary intervention. Patients were randomized 1:1 to either polymer-free amphilimus-eluting stents (PF-AES) or durable polymer zotarolimus-eluting stents (PP-ZES).

Between November 2014 and July 2017, 1,532 patients were enrolled at three European sites. Of those randomized, approximately 40% were troponin-positive and 60% were troponin-negative. In both treatment arms, patients with troponin-positive acute coronary syndromes were treated with 12 months of dual antiplatelet therapy (DAPT), whereas low-risk troponin-negative PF-AES patients were treated with an ultra-short (one month) duration of DAPT. In addition, total of 304 (20%) patients were diabetic.

The device-oriented primary endpoint of target lesion failure was defined as cardiac death, target-vessel myocardial infarction, or target-lesion revascularization at 12 months. TLF occurred in 6.2% of the PF-AES group and 5.6% of the PP-ZES group (Risk difference: 0.5%, One Sided 95% CI: 2.6%, pnoninferiority=0.0086). The secondary endpoint of net adverse clinical events at 12 months was 12.2% for PF-AES and 11.6% for PP-ZES. Results were consistent across all subgroups, including DAPT duration.

"ReCre8 is the first randomized clinical trial of its kind and found that polymer-free amphilimus-eluting stents are shown to be clinically non-inferior to latest-generation zotarolimus-eluting stents in terms of target-lesion failure at 12 months in an all comers PCI population," said Pieter R. Stella, MD, Ph.D. Dr. Stella is Head, Interventional Cardiology and Manager, Research Division Heart & Lungs at University Medical Center Utrecht in The Netherlands. "Although further study is warranted, one-month DAPT following these latest-generation drug-eluting stents in troponin-negative patients may be safe regarding stent thrombosis, especially in non-complex lesions."

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