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Safety and clinical performance of biodegradable polymer-coated ultrathin everolimus-eluting stents in "real-world" patients: a multicentre registry (PERFORM-EVER)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS
To report 1-year clinical safety and efficacy outcomes for ultrathin-strut (60 ?m) biodegradable polymer coated Tetrilimus everolimus-eluting stent (EES) [Sahajanand Medical Technologies Pvt. Ltd., Surat, India] in patients with coronary artery disease in real-world clinical practice.

METHODS AND RESULTS
The PERFORM-EVER was an observational, multicenter, single-arm and investigator-initiated retrospective registry. All ?real-world? patients who had received Tetrilimus EES between July-2015 and October-2016 at our centers were analyzed. The data were collected retrospectively either by extraction from existing databases in consecutive fashion where index and follow-up data existed or the follow-up was obtained by telephonic contact. Primary endpoint was 1-year incidence of target lesion failure, which was defined as a composite endpoint of cardiac death, myocardial infarction, and target lesion revascularization by percutaneous or surgical methods. The Academic Research Consortium-defined stent thrombosis was assessed as additional safety endpoint.During the study period, 815 Tetrilimus EES (1.4±0.5 stent/patient) were implanted to treat 735 coronary lesions (1.1±0.3 stent/lesion) in 594 patients (mean age: 55.6±12.1 years). Among them, 453 (76.3%) were males, 192 (32.3%) were hypertensives, 138 (23.2%) were diabetics, 205 (34.5%) were alcoholics, 141 (23.7%) were smokers, 106 (17.8%) were tobacco chewers, 46 (7.7%) had previous revascularization, and 225 (37.8%) displayed multi-vessel coronary disease. Of treated lesions, 577 (78.5%) were complex (i.e. Type B2/C) and 103 (14.0%) had total occlusion. The average length and diameter of implanted Tetrilimus EES were 27.6±9.7 mm and 3.0±0.3 mm respectively. Post-implantation, events of target lesion failure were reported in 5 (0.8%) patients at 30-day follow-up and 13 (2.2%) patients at 6-month follow-up. The cumulative major adverse cardiac event rate at 1-year follow-up was 3.7%, which included 9 (1.5%) cardiac deaths, 8 (1.4%) myocardial infarctions, and 5 (0.8%) target lesion revascularizations. There were 5 (0.8%) cases of probable stent thrombosis and 4 (0.7%) cases of possible stent thrombosis at 1-year follow-up.

CONCLUSIONS
Low incidences of target lesion failure and stent thrombosis at 1-year follow-up indicates that Tetrilimus EES may have encouraging safety and efficacy in unselected real-world patients with coronary artery disease, including those with high-risk characteristics and complex lesions.