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Clinical experience after implantation of ultrathin strut biodegradable polymer-coated everolimus-eluting stents for treatment of atherosclerotic lesions: all-comer single-centre registry with a subgroup analysis of patients with ultra-long stents

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

AIMS
The registry investigated clinical outcomes after 12 months of implantation of ultrathin strut (60 Î¼m) biodegradable polymer coated Tetrilimus everolimus-eluting stents (EES) [Sahajanand Medical Technologies Pvt. Ltd., Surat, India] in patients with atherosclerotic coronary lesions. In addition, sub-group analysis was performed to evaluate the outcomes of ultra-long (44/48 mm) EES in patients with long atherosclerotic coronary lesions.

METHODS AND RESULTS
This was an observational, single-center, single-arm and investigator initiated retrospective registry. In this all-comers registry, 558 patients who underwent implantation of the Tetrilimus EES for the treatment of coronary artery disease during routine clinical practice between February-2016 and August-2016 at a tertiary care center of India were examined. Patients who had been implanted with some other stents were excluded. Patients' data were obtained from medical records. Follow-up was achieved by either clinical database review or telephonic follow-up for clinical events. Primary endpoint was occurrence of any major adverse cardiac event (MACE) up to 12-month follow-up. MACE was considered as a composite of cardiac death, Q-wave or non-Q wave myocardial infarction (MI), emergent coronary artery bypass graft (CABG) and clinically driven target lesion revascularization (TLR). The occurrence of stent thrombosis (ST) was also analysed as per the Academic Research Consortium. In subgroup analysis, clinical outcomes were assessed for 143 patients with long atherosclerotic coronary lesions who were implanted with long (44/48 mm) Tetrilimus EES. Total 766 stents were implanted to treat 695 lesions in 558 patients, with an average of 1.3±0.5 stents per patient. Out of 558 patients, 393 (70.4%) were males and mean age was 57.0±10.2 years. There were 215 (38.5%) diabetics and 273 (48.9%) hypertensives. Non-ST-elevation myocardial infarction (n=197; 35.3%) was the most prevalent clinical presentation, followed by stable angina (n=153; 27.4%). Of treated lesions, 79 (11.4%) lesions were type B2 and 544 (78.3%) were type C lesions, including 73 (10.5%) totally-occluded lesions. The average stent length and diameter were 33.5±10.7 and 2.8±0.3 mm respectively. At 12 months follow up, 4 (0.7%) incidences of cardiac death, 8 (1.4%) incidences of MI, and 2 (0.4%) incidences of TLR were reported, resulting to 12 months MACE of 2.5%. In sub-group analysis of 143 patients who underwent implantation of 44 or 48 mm long Tetrilimus EES, 65 (45.5%) were males and average age was 58.9±9.5 years. The rates of hypertension and diabetes were 53.8% and 40.6% respectively. A total of 155 long coronary lesions were intervened successfully with only one stent been implanted per lesion. There were 12 (7.7%) totally occluded lesions and the average stent length and diameter were 46.3±2.0 mm and 2.8±0.3 mm respectively. MACE at 12 months follow-up was 2.8% with 1 (0.7%) incidence of cardiac death, 2 (1.4%) incidences of MI, and 1 (0.7%) incidence of TLR.

CONCLUSIONS
The 12-month clinical data demonstrated good safety and performance of the Tetrilimus EES even in high-risk patients and

complex coronary lesions in routine clinical practice. Moreover, subgroup analysis supported the use of long Tetrilimus EES in the treatment of long atherosclerotic lesions, with excellent procedural performance and clinical outcomes.