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Clinical outcomes of an ultra-thin strut sirolimus-eluting stent with biodegradable polymer in all-comers patients undergoing coronary intervention

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Background: Thin stent struts may be associated with reduced vessel injury and use of biodegradable polymers may further improve long term outcomes. However, data with earlier stents has been inconsistent; thus further studies with newer devices are needed.

Purpose: To evaluate the efficacy and safety of a new ultra-thin (65um) strut cobalt chromium sirolimus-eluting stent with a hybrid design (closed cell at ends and open cells in middle to reduce edge injury and optimise conformability) in all-comers patients undergoing percutaneous coronary intervention (PCI).

Methods: We enrolled 752 patients from 14 sites undergoing PCI into a prospective, non-randomised, multi-centre, open-label, observational registry. Inclusion of patients with complex anatomy (long stent lengths, bifurcations and chronic total occlusions) was encouraged. Clinical follow-up was scheduled at 1, 9, 12 and 24 months. The primary endpoint was incidence of major adverse cardiac events (MACE) - cardiac death, non-fatal myocardial infarction (MI), or target vessel revascularization (TVR) - at 9 months.

Results: Mean patient age was 64.7±12.2 years, 20.7% had diabetes, 58.8% had dyslipidaemia, 40.4% had multi-vessel disease, 22% had previous PCI, 4.7% had previous coronary-artery bypass graft, and 19.6% had a clinical history of previous MI. Mean lesion length was 25.7±17.3 mm. The primary endpoint of cumulative MACE up to 9 months (from 624 patients reaching 9 months follow-up) occurred in 12 patients (1.92%), including 6 (0.96%) cardiac death, 5 (0.80%) MI and 6 (0.96%) clinically indicated TVR. Definite stent thrombosis was reported in 3 patients (0.48%) and probable stent thrombosis in 2 patients (0.32%).

Conclusions: Use of an ultra-thin strut biodegradable polymer sirolimus-eluting stent in all-comers patients undergoing PCI was associated with good clinical efficacy and safety.