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Clinical outcomes with cobalt chromium biolimus eluting drug-eluting stents compared with stainless steel biolimus eluting drug-eluting stents in all-comers patients

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Aims: Thinner stent struts may improve deliverability, conformability and reduce vessel injury. We report the first clinical outcomes of the thinner strut (84–88um) cobalt chromium biolimus eluting stent from the Biomatrix Alpha registry and compare these with objective performance criteria from the stainless steel BioMatrix Flex arm of the Leaders study.

Methods: A total of 1257 patients were studied: 400 patients from 12 centres receiving $\geq$1 Biomatrix Alpha stent were prospectively enrolled into the Biomatrix Alpha registry and then underwent a pre-specified comparison with 857 patients who received a Biomatrix Flex stent in the Leaders study. The primary endpoint was major adverse cardiac events (MACE) defined as the composite of cardiac death, myocardial infarction (MI) or clinically driven target vessel revascularization (TVR) at 9 months. Assuming a 9.2% event rate with BioMatrix Flex, a one-sided type I error (α) of 0.05, and a 4% non-inferiority margin, a sample size of 400 in the Biomatrix alpha registry had $>$80% power to conclude non-inferiority.

Results: Baseline characteristics in the Alpha registry were typical of an all-comers population with a mean age of 64.7±11.3, diabetes 19%, current smoking 21%, dyslipidemia 57%, hypertension 57%, total stent length per lesion 25.49±13.45, mean stents per procedure 1.59±0.88 and overlapping stents in 13.4%. Observed MACE at 9 months with Alpha was 3.94% (upper limit 5.98%) vs. 9.28% MACE rate with Flex stents in Leaders, which met pre-specified criteria for non-inferiority ($p<0.001$) and on post hoc testing for superiority yielded $p<0.001$ for Alpha vs Flex. Secondary endpoints with Alpha included clinically-driven TVR 2.6%, all-cause mortality rate 1.51% and definite/probable stent thrombosis 0.25%.

While both Alpha and Leaders enrolled all-comers, Alpha included longer total stent length per lesion (25.49 vs 23.85mm, $p<0.001$) and more stents per procedure (mean 1.59 vs 1.34; $p<0.001$) but fewer patients with diabetes (19% vs 26%; p=0.0087), dyslipidemia (57 vs 65%; p=0.0037), prior MI (18.8% vs 32.2%; $p<0.001$) or acute coronary syndrome (41% vs 55%; $p<0.001$). To correct for these imbalances and to assess robustness further, a propensity score at the patient level data was undertaken (total sample size of 1257 patients; 400 from the Alpha registry and 857 from the LEADERS study). A propensity score stratification method was used obtaining 5 quintiles for adjusted analysis (each of the 5, containing 251 or 252 patients, 20%). In each of the strata as well as at the aggregate level, a p valve$<$0.005 was obtained confirming non-inferiority for the primary endpoint.

Conclusion: The thinner strut (84–88um) cobalt chromium Biomatrix Alpha stent demonstrated low MACE rates at 9 months which were non-inferior to MACE outcomes with the stainless steel Biomatrix Flex in the Leaders study. The robustness of this finding was further confirmed by a propensity score analysis.