COMPARISON OF THE SYNERGY STENT WITH PROMUS (XIENCE V) AND BARE METAL AND POLYMER-ONLY ELEMENT CONTROLS IN PORCINE CORONARY ARTERIES

i2 Oral Contributions
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Background: The objective of this study was to evaluate vascular compatibility of the novel platinum chromium alloy Element platform with everolimus (150μg) delivered abluminally from a poly-lactide-co-glycolide bioabsorbable polymer (SYNERGY), currently undergoing clinical trial, comparing with PROMUS (Xience V) and bare metal and polymer-only Element controls.

Method: Stent pairs (n = 161), distributed among the 4 stent types were implanted in 72 swine at a targeted stent-to-artery ratio of 1.1:1. Similar numbers (device group N's of 11-13 for the drug-eluting stents and 8-10 for bare and polymer-only controls each follow-up interval) were explanted at each of 30, 90, 180 and 360 days (no PROMUS at 360 days) for pathological analysis.

Results: There was no stent thrombosis or myocardial infarction with all stented vessels widely patent on angiography and histology with no strut fractures. Vascular response was similar between SYNERGY and PROMUS, with no thrombi and complete endothelialization on both scanning electron microscopy and histology at 30, 90 and 180 days, and only mild parastrut fibrin at 30 days clearing at 90 days. Inflammation was predominantly minimal to mild for all device types compared at 90, 180 or 360 days, including luminal thrombus, endothelial cell coverage, strut tissue coverage, inflammation, para-strut fibrin, IEL disruption, EEL disruption and medial smooth muscle cell loss. No morphometric parameters, including intimal thickness, stent profile-based area stenosis and EEL area, were significantly different comparing SYNERGY with bare metal Element and polymer-only Element controls at 90, 180 and 360 days. The stent profile-based area percent stenosis at 180 days was 23.3 ± 7.1% (mean ± standard deviation) for SYNERGY, 26.8 ± 8.6% for PROMUS, 20.0 ± 7.5% for bare metal Element and 20.1 ± 5.8% for polymer-only Element (not significantly different across the 4 groups).

Conclusion: In this non-injured porcine coronary artery model SYNERGY stents demonstrated vascular compatibility equivalent to PROMUS and also similar to the bare metal and polymer-only Element stents.