NINE-MONTH PRIMARY ENDPOINT RESULTS OF THE EVOLVE II QCA STUDY: A PROSPECTIVE, MULTICENTER TRIAL ASSESSING CLINICAL, ANGIOGRAPHIC, AND INTRAVASCULAR ULTRASOUND OUTCOMES WITH THE NOVEL PLATINUM-CHROMIUM ABLUMINALLY-COATED BIOABSORBABLE POLYMER SYNERGY EVEROLIMUS-ELUTING STENT IN DE NOVO CORONARY STENOSES

Poster Contributions
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Background: Delayed healing and incomplete endothelialization have been reported with durable polymer drug-eluting stents (DES); these may contribute to increased risk of late/very late stent thrombosis (ST) and a need for prolonged dual antiplatelet therapy. The SYNERGY everolimus-eluting stent (EES; Boston Scientific Corporation, Marlborough, MA), designed to reduce stent thrombosis risk, consists of a thin-strut, platinum chromium metal alloy platform abluminally-coated with an ultrathin bioabsorbable poly(DL-lactide-co-glycolide) polymer. Drug release and polymer absorption are complete within 4 months. The EVOLVE II QCA trial evaluated angiographic outcomes with SYNERGY; this is the first report of 9 month QCA outcomes with the SYNERGY stent.

Methods: EVOLVE II QCA is a prospective, single-arm, multicenter study. Patients enrolled had de novo atherosclerotic coronary artery lesions ≤34 mm in length and diameter ≥2.25 mm to ≤4.50 mm. Patients were ≥18 years old with silent ischemia or symptomatic coronary artery disease with objective evidence of ischemia. Up to 3 native coronary artery lesions in 2 major epicardial vessels could have been treated. Exclusion criteria included STEMI and complex lesion morphology. The primary endpoint is in-stent late loss at 9 months post-procedure (independent core lab assessment).

Results: Subjects (N=100) were enrolled at 12 clinical sites in Australia, New Zealand, Singapore, and Japan between March 25 - October 15, 2013 Mean age was 64 years, 20% of patients were female, and 17% of patients had medically-treated diabetes mellitus. Baseline RVD was 2.66±0.46 mm; lesion length was 14.38±7.49 mm. In-stent late loss at 9-months (the primary endpoint) was 0.23±0.34 mm, significantly below the prespecified performance goal of 0.4 mm (P<0.01). Net volume obstruction was 5.19±5.67%. To 9-months, there were no deaths or ST. Five patients had peri-procedural non-Q-wave MI (primarily defined as CK-MB>5x ULN; mean CK-MB 29.0±14.44 ng/mL) and 1 patient had a target lesion revascularization.

Conclusion: Through 9-months, SYNERGY had an acceptable safety profile with low in-stent late loss. One-year results will be available for presentation at ACC 2015.