FIVE YEAR CLINICAL RESULTS FROM ENDEAVOR III: A RANDOMIZED COMPARISON OF THE ZOTAROLIMUS-ELUTING VERSUS SIROLIMUS-ELUTING STENTS IN DE NOVO NATIVE CORONARY LESIONS

i2 Poster Contributions
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Background: Despite significantly higher angiographic late lumen loss and restenosis for zotarolimus- (ZES, Endeavor) versus sirolimus-eluting (SES, Cypher) stents in the randomized ENDEAVOR III trial, differences in clinical outcome over intermediate term follow-up were less disparate. Whether disparity in early angiographic measures translates to clinically relevant differences over late-term (5 year) follow-up is undetermined.

Methods: ENDEAVOR III trial is a prospective, multi-center trial evaluating the safety and efficacy of the Endeavor stent in 436 patients undergoing elective percutaneous revascularization of de novo native coronary lesions with reference vessel diameters between 2.5 mm and 3.5 mm and lesion length ≥14 mm and ≤27 mm. Patients were randomized in a 3:1 fashion to ZES or SES to examine the primary endpoint of in-segment late lumen loss at 8-month angiographic follow-up. Clinical safety and efficacy outcomes were assessed annually through 5 years.

Results: Angiographic outcomes of late lumen loss and binary restenosis at 8 months were significantly higher for ZES (N=323) compared with SES (N=113), yet the composite clinical outcome of target vessel failure at 9 months did not statistically differ and remained similar to 4 years follow-up. At 4 years, the rates of cardiac death/myocardial infarction were significantly lower in the ZES cohort (1.3% ZES vs 5.5% SES, P=0.02) with no significant difference in target lesion revascularization (TLR; 7.8% ZES vs 6.4% SES, P=0.83) and near identical target vessel failure (16.3% ZES vs 16.4% SES, P=1.0). The margin in TLR between DES decreased from 2.6% at 1 year to 1.4% at 4 years. The 5-year clinical results for the ENDEAVOR III trial will be available for presentation at ACC 2010.

Conclusions: Late-term follow-up of a randomized, multicenter trial comparing ZES and SES provides insight regarding the correlation of early angiographic and late clinical endpoints. Despite early differences in angiographic measures, clinical safety outcomes at 4 years significantly favored ZES yet with similar efficacy between the two DES. Results reported in March 2010 should inform late-term efficacy and safety events for both DES at 5 years.