LATE-TERM SAFETY AND EFFICACY OUTCOMES FOLLOWING TREATMENT WITH ZOTAROLIMUS-ELUTING STENTS: 5-YEAR RESULTS OF THE POOLED ENDEAVOR TRIALS PROGRAM

i2 Poster Contributions
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Background: Emphasis on drug-eluting stent-related outcomes has temporally shifted from early to late occurring events. However, individual randomized trials have not had sufficient power to ascertain late-term safety and efficacy.

Methods: Pooled patient level efficacy and safety data were analyzed from 6 prospective multicenter international trials involving patients treated with zotarolimus-eluting stents (ZES; N=2,132) and bare metal stent (BMS) control (N=596). Data from the latest year of follow-up available from each study were pooled for analysis, with 5-year follow-up completed in 1256 patients (97% of eligible) and median follow-up of 4.1 years. Long-term outcomes of the ZES group versus the BMS group were compared after adjustment for between trial variation and for individual patient clinical and angiographic characteristics by propensity score.

Results: Compared with BMS, the cumulative rate of target lesion revascularization (TLR) was 7.0% ZES vs 16.5% BMS (adjusted hazard ratio [HR] 0.42, 95% confidence interval [0.29,0.60]; P<0.001). In the ZES cohort, the average annualized rate of repeat TLR from year 1 to 5 is 0.4% (year 1: 5.4%; year 5, 7.0%). The cumulative incidence of adverse safety events at 5 years for ZES and BMS were, respectively: cardiac death 2.4% vs 3.7% (adjusted HR 0.83, [0.44,1.57]); P=0.57), myocardial infarction 3.4% vs 4.8% (adjusted HR 0.77, [0.44,1.35]; P=0.37), ARC definite or probable stent thrombosis 0.8% vs 1.7% (adjusted HR 0.50, [0.17,1.48]; P=0.21). There was no increase in stent thrombosis risk within 1 year (0.6% vs 1.3% ARC definite and probable) or very late (year 1- 5, 0.2% vs 0.4%). After adjustment for variation in study and patient characteristics, there were no significant differences in stent thrombosis or the clinical safety event rates at 5 years between ZES and BMS.

Conclusions: In a patient-level pooled analysis of 6 clinical trials, treatment with ZES is associated with a significant and durable reduction in TLR through 5 year follow-up. Adverse safety events, including stent thrombosis, myocardial infarction and cardiac death over five years did not differ significantly between patients with ZES and BMS.