MULTIVARIABLE PREDICTORS OF CLINICAL RESTENOSIS, CARDIAC DEATH OR MYOCARDIAL INFARCTION TO 2 YEARS FOLLOWING EVEROLIMUS OR PACLITAXEL DRUG-ELUTING STENT DEPLOYMENT: THE SPIRIT II, III, IV AND COMPARE TRIAL EXPERIENCE

i2 Oral Contributions
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Background: Although large scale randomized controlled clinical trials of drug-eluting stents (DES) have demonstrated superior clinical efficacy and improved safety of the everolimus eluting stent (EES) compared with paclitaxel eluting stent (PES), the clinical, angiographic and procedural factors associated with adverse outcomes following DES have not been analyzed. The SPIRIT II, III, IV and COMPARE trials randomly assigned 6,789 eligible subjects to treatment with either the Xience V EES (n=4247) or the Taxus PES (n=2542). All subjects were followed through at least 2 years.

Methods: To determine predictors of clinical restenosis (ischemia-driven target lesion and vessel revascularization: IDTLR/IDTVR), myocardial infarction (MI) as well as the composite occurrence of cardiac death (CD) or MI, we analyzed 30 clinical, angiographic and procedural variables using multivariable Cox proportional hazards stepwise regression analysis with independent variables entered into the model at the 0.1 significance level and removed at the 0.1 level.

Results: Independent predictors of both IDTLR and IDTVR included stent type (EES vs PES; HR [95% CI = 0.59 [0.47,0.74] p<0.0001 and 0.70 [0.58, 0.84] p=0.0002 respectively), age, diabetes treated with insulin, # treated lesions, preprocedure RVD, baseline TIMI 0-1 flow and prior PCI. Independent predictors of both MI as well as the composite of CD plus MI included stent type (EES vs PES; HR [95% CI =0.54 [0.41, 0.71] p<0.0001 and 0.63 [0.49, 0.80] p=0.0002 respectively), smoking, diabetes treated with insulin, hypercholesterolemia, hypertension, LAD target vessel, lesion length, # treated lesions and prior MI.

Conclusions: In this large, pooled patient level database from 4 randomized trials, multivariable analysis identified readily available clinical, angiographic and procedural variables that are significant independent predictors of subsequent adverse events. Treatment with EES is a powerful independent predictor of IDTLR/IDTVR, CD and MI at 2 years following PCI.