Comparison of Ischemic and Bleeding Events After Drug-Eluting Stents or Bare Metal Stents in Subjects Receiving Dual Antiplatelet Therapy: Results from the Randomized Dual Antiplatelet Therapy Study

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INTRODUCTION: Treatment of coronary stenosis with drug-eluting stents (DES) might lead to higher rates of stent thrombosis (ST) compared with bare metal stents (BMS), yet few trials have had adequate power or follow-up beyond one year. Additionally, trials of BMS have not systematically ascertained the appropriate duration of dual antiplatelet therapy (DAPT). We evaluated the impact of DES vs BMS on rates of late ischemic events, and the effect of 12 vs 30 months of DAPT in BMS-treated subjects.

METHODS: The DAPT Study enrolled BMS- (2,816) and DES-treated (22,866) subjects with identical criteria for enrollment (at index procedure) and randomization (at 12 months). At 12 months, subjects without major bleeding or recurrent cardiovascular events continued on aspirin and were randomized 1:1 to either continued thienopyridine (clopidogrel or prasugrel) or placebo for 18 months. Subjects providing consent for full follow-up with an endpoint event or >29 months of follow-up were propensity score-matched (ratio of up to 8 DES:1 BMS) according to 55 clinical and procedural variables. Among matched subjects, non-inferiority of DES vs. BMS will be assessed for the primary effectiveness endpoints of ST and MACCE (composite of death, MI, stroke) occurring after the index procedure through 33 months. Among randomized BMS-treated subjects, the incidence of ST, MACCE, and major bleeding (GUSTO moderate or severe) will be compared between treatment arms (30 vs 12 months of DAPT) according to ITT.
RESULTS: Among 15,206 total eligible subjects for propensity-score matching (2,056 BMS; 13,150 DES), 1,720 BMS and 8,185 DES-treated subjects were matched with a standard deviation of <10% for all variables, indicating minimal residual difference in baseline characteristics. Among matched subjects, 28% had diabetes mellitus, 59% had >1 risk factor for ST at the index procedure (43% acute coronary syndromes, 15% acute STEMI, 15% with a thrombus-containing lesion), 80% were treated with clopidogrel, and 20%, prasugrel.

CONCLUSION: The analysis of ST and MACCE at 33 months between DES- and BMS-treated subjects, and the comparison of 12 vs. 30 months of DAPT with regard to ischemic and bleeding outcomes in BMS-treated subjects will be available at the time of presentation.

DISCLOSURE:
D.J. Kereiakes: Consultant/Advisory Board; Modest; Harvard Clinical Research Institute, Ablative Solution, Inc. Consultant/Advisory Board; Significant; Boston Scientific, Abbott Vascular, REVA Medical Inc. R.J. Yeh: Other Research Support; Modest; Harvard Clinical Research Institute. Consultant/Advisory Board; Modest; Abbott Vascular, Gilead Sciences. J.M. Massaro: None. P. Driscoll-Shempp: Employment; Significant; Harvard Clinical Research Institute. D.E. Cutlip: Research Grant; Modest; Medtronic, Boston Scientific, Celonova, STENTYS. Research Grant; Significant; Modest, Modest, Modest, Modest. S.T. Normand: None. P.G. Steg: Research Grant; Significant; Sanofi, Servier. Honoraria; Modest; Amarin, Bayer, Bristol Myers Squibb, Daiichi Sankyo, GlaxoSmithKline, Lilly, Merck, Pfizer, The Medicines Company, Vivus. Honoraria; Significant; Astra Zeneca, Sanofi, Servier. Ownership Interest; Significant; Aterovax. Consultant/Advisory Board; Modest; Novartis, Otsuka. A.H. Gershlick: Other Research Support; Modest; Boehringer Ingleheim. Speakers Bureau; Modest; Abbott Vascular, Metronic Corp, The Medicines Company. Consultant/Advisory Board; Modest; Abbott Vascular, Medtronic, Eli Lilly, The Medicines Company. Other; Modest; Boehringer Ingleheim. J. Tanguay: Research Grant; Modest; Abbott Vascular, Astra Zeneca, Eli Lilly, GlaxoSmithKline, Merck, Roche, Accumetrics, Ikaria. Speakers Bureau; Modest; Abbott Vascular, Astra Zeneca, Eli Lilly. Honoraria; Significant; Sanofi-Aventis, Servier. Consultant/Advisory Board; Modest; Abbott Vascular, Accumetrics, Astra Zeneca, Bayer, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Ikaria, Roche, Sanofi-Aventis, Servier. Consultant/Advisory Board; Modest; Abbott Vascular, Accumetrics, Astra Zeneca, Bayer, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Ikaria, Roche, Sanofi-Aventis, Servier. S. Windecker: Research Grant; Significant; St Jude Medical, Biotronik. K.N. Garratt: Research Grant; Modest; The Medicines Company. Research Grant; Significant; Boston Scientific, Abbott Vascular, CeloNova, Mayo Foundation. Honoraria; Modest; DSI/Lilly. Ownership Interest; Significant; Guided Delivery Systems, Infarct Reduction Technologies. Consultant/Advisory Board; Modest; The Medicines Company. Consultant/Advisory Board; Significant; Boston Scientific. D.E. Kandzari: Research Grant; Modest; Boston
Scientific, Biotronik. Research Grant; Significant; Medtronic. Consultant/Advisory Board; Modest; Boston Scientific, Zoll. Consultant/Advisory Board; Significant; Medtronic. **D.P. Lee**: Research Grant; Modest; Boston Scientific. Consultant/Advisory Board; Modest; Boston Scientific. **D.I. Simon**: Honoraria; Modest; Medtronic, Janssen/Johnson & Johnson, Cordis/Johnson & Johnson, Merck. Consultant/Advisory Board; Modest; Medtronic, Janssen/Johnson & Johnson, Cordis/Johnson & Johnson, Merck. **A. Iancu**: None. **J. Trebacz**: None. **L. Mauri**: Research Grant; Significant; Abbott, Boston Scientific, Cordis, Medtronic, Eli Lilly, Daichii Sankyo, Bristol Myers Sqbib, Sanofi-Aventis. Consultant/Advisory Board; Modest; Biotronik, St. Jude, Medtronic.