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TCT@ACC-i2: The Interventional Learning Pathway | April 2014

## IMPACT OF SHORT- VERSUS LONG-TERM DAPT IN PATIENTS WITH DIABETES MELLITUS UNDERGOING PERCUTANEOUS INTERVENTION WITH ENDEAVOR ZOTAROLIMUS-ELUTING STENTS – A SUBANALYSIS OF THE LARGE, PROSPECTIVE, RANDOMIZED, MULTICENTER OPTIMIZE TRIAL

Fausto Feres; Ricardo Costa; Deepak Bhatt; Joao De Paula; Roberto Botelho; J. Antônio Marin-Neto; Sérgio Berti; Pablo Teixeirens; Rone Padilha; Rogério Sarmiento-Leite; Adrian Korman; Andres Sanchez; Aurea Chaves; Andrea Abizaid; Alexandre Abizaid

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## TCT@ACC-i2: The Interventional Learning Pathway

### IMPACT OF SHORT- VERSUS LONG-TERM DAPT IN PATIENTS WITH DIABETES MELLITUS UNDERGOING PERCUTANEOUS INTERVENTION WITH ENDEAVOR ZOTAROLIMUS-ELUTING STENTS - A SUBANALYSIS OF THE LARGE, PROSPECTIVE, RANDOMIZED, MULTICENTER OPTIMIZE TRIAL

Poster Contributions

Hall C

Sunday, March 30, 2014, 3:45 p.m.-4:30 p.m.

Session Title: Complexities and Complications

Abstract Category: 38.TCT@ACC-i2: Complex Patients/Comorbidities

Presentation Number: 2108-297

Authors: *Eausto Feres, Ricardo Costa, Deepak Bhatt, Joao De Paula, Roberto Botelho, J. Antônio Marin-Neto, Sérgio Berti, Pablo Teixeira, Rone Padilha, Rogério Sarmento-Leite, Adrian Korman, Andres Sanchez, Aurea Chaves, Andrea Abizaid, Alexandre Abizaid, Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil, Cardiovascular Research Center, São Paulo, Brazil*

**Background:** Current recommendation is for  $\geq 12$  months dual antiplatelet therapy (DAPT) after drug-eluting stents (DES). Patients with diabetes mellitus (DM) have higher incidence of thrombotic events after DES compared to non-diabetics. Still, the optimal DAPT duration with specific DES type remains unknown. Our objective was to assess the clinical impact of short- (3 months) versus long-term (12 months) DAPT in patients undergoing percutaneous coronary intervention (PCI) with the 2nd generation DES Endeavor zotarolimus-eluting stents (E-ZES).

**Methods:** The OPTIMIZE trial was a randomized (1:1), active-controlled, open-label non-inferiority study including 3,119 patients in 33 sites in Brazil between April/2010-March/2012. After PCI with E-ZES, patients were prescribed aspirin 100-200mg daily and clopidogrel 75mg for 3 months (n=1,563) or 12 months (n=1,556) DAPT. Clinical follow-up was performed at 1, 3, 6 and 12 months. The 1ary endpoint was net adverse clinical and cerebral events (NACCE), a composite of all-cause death, MI, stroke, or major bleeding at 1 year follow-up. Stent thrombosis (ST) was defined according to the Academic Research Consortium. Overall, 35% of patients had DM and randomization was stratified by its presence. Also, a DM subgroup analysis was pre-specified in the protocol.

**Results:** Considering 1,103 patients with DM at 3 months (n=554) vs. 12 months (n=549) DAPT, mean age was 62.1 vs. 61.7 yrs (p=0.52), female gender 44% vs. 47% (p=0.08), prior MI 38% vs. 32% (p=0.04), renal insufficiency 11% vs. 6% (p=0.003), and clinical presentation of unstable angina (19% vs. 18%, p=0.53) or non-ST MI (5% vs. 6%, p=0.49), for 3 vs. 12 months groups, respectively. At 12 months, there were comparable rates of NACCE (6.3 vs. 6.9%, [difference -0.68, 95% confidence interval (CI) -3.65, 2.29], p=0.65] and definite/probable ST (1.7 vs. 1.1%, [dif. 0.53, 95% CI -0.87, 1.93], p=0.46), for 3 vs. 12 months, respectively.

**Conclusions:** In this pre-specified subgroup analysis of the OPTIMIZE trial, short-term DAPT did not significantly increase risk for clinical events at 1 year in patients with DM undergoing PCI with a specific 2nd generation DES.

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