PROCEDURAL BLEEDING WITH VORAPAXAR VERSUS PLACEBO IN THE TRA 2°P-TIMI 50 TRIAL

Poster Contributions
Poster Sessions, Expo North
Sunday, March 10, 2013, 9:45 a.m.-10:30 a.m.

Session Title: Pre-Hospital ECG and Transfer: Time Is Myocardium
Abstract Category: 1. Acute Coronary Syndromes: Clinical
Presentation Number: 1212-183

Authors: Sabina A. Murphy, Erin Bohula May, Marc Bonaca, Benjamin Scirica, Eugene Braunwald, David Morrow, Brigham and Women’s Hospital, Boston, MA, USA

Vorapaxar is a selective antagonist of protease-activated receptor (PAR)-1 that potently blocks platelet activation by thrombin and has a long half-life (>7 days). The impact of vorapaxar on bleeding related to invasive procedures is unknown.

Methods: The TRA2°P-TIMI 50 trial was a randomized, double-blind, placebo controlled trial of vorapaxar 2.5mg daily in 26,449 patients with stable atherosclerosis followed for 2.5 yr (median). Study drug was to be continued before/after invasive procedures without interruption. Procedural bleeding was captured 1) by investigator classification as no bleeding, or bleeding that was less than, more than, or as expected, and 2) as GUSTO mod/severe bleeding adjudicated by a central CEC and identified as within 3 days of a procedure for this analysis.

Results: 81% of invasive procedures were performed while continuing vorapaxar. Among non-CABG surgeries (n=5954), in pts allocated to vorapaxar, 1.4% were associated with more bleeding than expected compared with 1.1% with placebo (p=0.40). GUSTO mod/sev bleeding within 3 days of the procedure in occurred 1.8% vs. 1.6% (p=0.56). Among non-surgical invasive procedures (n=5705), more than expected bleeding occurred in 0.6% vs. 0.3% (p=0.096) and GUSTO mod/sev in 1.8% vs. 1.3% with vorapaxar vs. placebo (p=0.20).

Results: In this large randomized placebo-controlled trial of vorapaxar, the rates of moderate or severe procedural bleeding were not significantly increased with vorapaxar.