Title: Comparative safety analysis of aspirin-based dual antiplatelet therapies on incidence of major and minor bleeding events in a healthcare system

Purpose: In patients at a tertiary care based medical system taking aspirin following percutaneous coronary intervention (PCI), we evaluated the comparative safety of three P2Y12 inhibitors, including crossover, to determine the incidence of major and minor bleeding at 12 and 24 months.

Methods: This study was approved by the local IRB. We assessed patients who were at least 18 years old and underwent any PCI from July 1, 2010 to December 31, 2013 at a multi-center system, who received aspirin-based dual antiplatelet therapy with a P2Y12 inhibitor. Patients were divided into groups based on use of clopidogrel, ticagrelor, or prasugrel, including crossover. Primary endpoint was the cumulative incidence of major bleeding defined by modified TIMI and GUSTO criteria at 12 and 24 months following PCI between groups. Secondary endpoints was the composite incidence of any major or minor bleeding after receiving a different antiplatelet therapy upstream or premature discontinuation of therapy.

Planned subgroup analyses were performed on the original groups stratified by diabetes, hypertension, smoking, and other comorbidities. Parametric and nonparametric comparative tests were used to assess differences in baseline characteristics of patients in each group. Kaplan-Meier method with log-rank conversion was used to assess time-to-event between groups. Univariate and multivariate logistic regression were used to assess the impact of regimen on primary and secondary endpoints.

Results: Sample size included (clopidogrel = , ticagrelor = , prasugrel = ). Data are being collected and analyzed and results will be described.

Conclusion: Conclusions will be drawn and presented upon completion of data analysis.