

**Session Type:** ACC.Special Sessions

**Session Number:** 407

**Session Title:** ACC.08 Late Breaking Clinical Trials I

**Location:** McCormick Place, North Hall B1

**Session Time:** Monday, March 31, 2008, 10:00 am - 11:30 am

**Presentation Number:** 407-6

**Topic 1:** Special Topics (quality of care; outcomes assessment; info tech; other misc topics)

**Publishing Title:** Cardiovascular Risk of Celecoxib in Six Randomized Placebo-Controlled Trials: The Cross-Trials Safety Assessment Pooled Analysis

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**Background:** Observational studies and randomized trials have reported increased cardiovascular risk associated with cyclooxygenase-2 inhibitors, although their ability to clarify the dose-response or the relationship between baseline cardiovascular risk and celecoxib risk has been limited.

**Methods:** The NIH-sponsored Cross Trials Safety Assessment was a patient-level pooled analysis of adjudicated data from 7,950 patients in six randomized controlled trials with a planned follow-up of at least 3 years comparing celecoxib to placebo in 3 dose regimens - 400mg qd, 200mg bid, or 400mg bid - for conditions other than arthritis. A modified Framingham cardiovascular risk score was used to assign cardiovascular risk for each patient. All cardiovascular endpoints were adjudicated from source documents, and hazard ratios for all dose-regimens combined and individual hazard ratios for each dose regimen were calculated. The primary endpoint was the combination of cardiovascular death, myocardial infarction, stroke, heart failure or thromboembolic event.

**Results:** Cardiovascular risk for each of the dose regimens, across the three dose regimens, and the relationship between baseline cardiovascular risk and celecoxib risk will be reported, as will the individual components of the endpoints, and the effect of low-dose aspirin use.

**Conclusions:** With 16,070 patient-years of follow-up, the Cross-Trials Safety Analysis provides the most comprehensive placebo-controlled assessment of cardiovascular risk of celecoxib for the doses tested. Moreover, by adding the results of four additional trials to the previously reported APC and PreSAP trials, this analysis has the power to address dose and regimen differences and the interaction between baseline cardiovascular risk and the risk associated with celecoxib. By further clarifying the extent of celecoxib-related cardiovascular risk, these findings may help guide treatment decisions for patients who derive clinical benefit from selective Cox-2 inhibition.

**Abstract Body:**