Increased Risk of Ischemic Events Upon Discontinuation of Prasugrel After 12 or 30 Months of Therapy Following Placement of the Taxus Liberté Paclitaxel-Eluting Coronary Stent

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Introduction:

The TAXUS Liberte Post-approval Study (TL-PAS) studied long-term clinical outcomes for the TL stent in conjunction with the use of prasugrel and aspirin. A portion of patients from TL-PAS contributed to the Dual Anti-Platelet Therapy (DAPT) trial.

Methods:

Eligible and consecutive patients in the United States treated with TL stents were enrolled into TL-PAS (N=4199). Those meeting inclusion and exclusion criteria were recruited for participation in the DAPT trial (N=3904). Patients received open-label prasugrel plus aspirin for 12 months after stent placement. At 12 months, patients without ischemic or bleeding events continued aspirin therapy and were randomized 1:1 to continued blinded treatment with either prasugrel or placebo for an additional 18 months (N=2202). At 30 months, study drugs were discontinued, and aspirin was continued through at least 33 months after stent placement. Events were adjudicated by a clinical events committee and monitored by the TL-PAS Data Monitoring Committee (DMC).

Results:

Nearly 3 years following randomization, the DMC noted a significant increase in spontaneous ischemic events following withdrawal of prasugrel therapy in randomized patients. This risk was observed in both randomized arms: patients who switched to placebo after the first 12 months of unblinded DAPT and in patients randomized to blinded prasugrel who had completed an additional 18 months of drug therapy. In response, the DMC recommended that treatment be unblinded for TL-PAS patients when they completed 18 months of randomized drug treatment, to allow discussion of continuing prasugrel in those patients randomized to the active drug arm. Completed patient follow-up and the adjudicated death, unplanned revascularization, myocardial infarction, stroke and bleeding events will be available for presentation.

Conclusion:
An increased risk of ischemic events was observed after prasugrel cessation in patients randomized to either 12 months or 30 months of DAPT following placement of a TAXUS Liberté paclitaxel-eluting coronary stent and prompted the recommendation for unblinding of therapy by the DMC. A complete analysis of ischemic and bleeding events with the results of 12 versus 30 month treatment comparisons will be presented.

DISCLOSURES:

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