Results of the TRIGGER-PCI trial reported at TCT 2011

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A clinical trial comparing prasugrel to clopidogrel for patients with high on-clopidogrel platelet reactivity (HCPR) following percutaneous coronary intervention (PCI) was ended early due to relatively few occurrences of cardiac death or myocardial infarction – the primary endpoint – at six month follow up.

Results of the TRIGGER-PCI (Testing platelet Reactivity In patients underGoing elective stent placement on clopidogrel to Guide alternative thErapy with pRasugrel) trial were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

The risk of ischemic events after percutaneous coronary intervention (PCI) is elevated in patients with high on-clopidogrel platelet reactivity (HCPR). Novel P2Y12-receptor antagonists, such as prasugrel, are more potent than clopidogrel and may, thus, improve outcome with respect to ischemic events, but may also increase bleeding risk.

The trial was a multi-center, double-blind, randomized controlled trial. Platelet reactivity was assessed two to seven hours after the first maintenance dose of clopidogrel 75 mg on the day after PCI following loading with clopidogrel 600 mg and randomized to either prasugrel or clopidogrel. TRIGGER-PCI aimed to randomize 2,150 patients to have a 93% power for detecting a 50% relative risk reduction on prasugrel in the primary study endpoint (cardiovascular death or myocardial infarction within six months).

The study was terminated prematurely for futility at March 18, 2011 at which 236 patients completed the six-month follow up. Only one clinical endpoint, a peri-procedural myocardial infarction, was observed.

"High on-clopidogrel platelet reactivity (>208 PRU by VerifyNow P2Y12 test) was observed less frequently than expected," said Dietmar Trenk PhD. Dr. Trenk is Professor and Head of Clinical Pharmacology at Herz-Zentrum Bad Krozingen in Germany.

Dr. Trenk noted that the trial demonstrated that compared with standard-dose clopidogrel 75 mg, prasugrel 10 mg substantially decreased platelet reactivity in patients with high on-clopidogrel platelet reactivity after elective PCI.

"Given the low event rate in elective PCI patients without peri-procedural complications, it was not possible to assess the risk/benefit ratio with prasugrel treatment. Therefore, the study was terminated prematurely for futility," Dr. Trenk said.

Provided by Cardiovascular Research Foundation