New Anti-Clotting Medication Not More Effective than Standard Care; Hint of Other Clinical Benefits

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(PhysOrg.com) -- Two large studies confirmed that an investigational, reversible anti-clotting medication failed to show greater effectiveness than clopidogrel or a placebo for patients undergoing a procedure to open blocked coronary arteries, according to researchers at the Duke Clinical Research Institute.

However, some data in the study suggest the potential for a different, more targeted use for cangrelor.

The findings were released today at the American Heart Association's Scientific Sessions 2009 and simultaneously published online in the New England Journal of Medicine.

Researchers found the new drug did not reduce rates of death, heart attack, or a procedure that restores oxygen to areas of the heart, known as ischemia-related revascularization, better than standard therapy, but may provide other potential benefits.

The Phase III studies were conducted at 200 sites in 18 countries to determine if the new anti-clotting drug, cangrelor, was more effective than either placebo or clopidogrel (Plavix) when administered to patients undergoing percutaneous coronary intervention (PCI).

Enrollment in the studies was terminated on May 13, 2009, after an

interim review concluded that the ability to demonstrate cangrelor was superior to clopidogrel was low.

"While the primary endpoints in this study were clearly not met, we observed some potentially interesting data for some secondary endpoints that, if confirmed in prospective studies, could suggest a clinical application for this agent," said Robert A. Harrington, MD, director of the Duke Clinical Research Institute, who co-led the studies and presented the findings in collaboration with Deepak L. Bhatt, chief of cardiology for the VA Boston Healthcare System.

PCI involves clearing clogged arteries with a balloon and then propping them open with stents. Clinical guidelines recommend clopidogrel be given to patients to help avoid the development of dangerous blood clots that can result from the procedure.

Harrington said that while clopidogrel can be effective, patients vary in their response to it, some having bleeding and other cardiovascular events. Cangrelor is the first in a new class of intravenous anti-clotting medications designed to be both fast-acting and reversible.

In the first study, CHAMPION PLATFORM, patients were given either cangrelor or placebo when the PCI procedure began, followed by the maximum dose of clopidogrel (600 mg).

The study included 5,362 patients and studied the combined rates of death, heart attack, or ischemic-related revascularization at 48 hours, which occurred in seven percent of patients on cangrelor and eight percent on placebo.

In the cangrelor group, mortality and stent thrombosis, or blood clots in the stent, were reduced after two days (.7 percent to .2 percent and .6 percent to .2 percent, respectively). One measure of major bleeding was

increased with cangrelor (3.5 percent to 5.5 percent).

The second study, CHAMPION PCI, was conducted among 8,820 higher-risk patients and also studied the combined rates of death, heart attack or ischemia-related revascularization but compared to clopidogrel.

In the cangrelor group, patients with acute coronary syndrome were given the drug 30 minutes prior to PCI and continuously for two hours. After the procedure, they were given clopidogrel (600 mg).

Patients in the clopidogrel group, received the maximum dose (600 mg) 30 minutes before their PCI. Patients in both groups continued use of clopidogrel (75 mg) and aspirin (75 mg to 325 md/day) for 30 days.

Researchers did not observe a statistically significant difference between the drugs after two days.

Among cangrelor patients, 7.5 percent experienced death, heart attack, or ischemia-related revascularization, versus 7.1 percent on clopidogrel.

Minor bleeding was more common with cangrelor, and one measure of major bleeding trended towards an increase with cangrelor over clopidogrel.

"When we took an early look at the results of both studies combined, some important secondary endpoints got our attention and which may suggest that further study could be considered for potentially viable alternative applications for cangrelor, such as a short-acting antiplatelet agent or for patients who require platelet blockage but can’t be on oral therapy," Harrington added.

Provided by Duke University (news : web)