

Experimental Drug Shows Promise in Reducing Heart Damage

A single dose of an experimental Roche biotech drug that blocks inflammation reduced damage to the heart during artery clearing angioplasty procedures, according to data from a midstage trial presented on Sunday.

The drug, inclacumab, was significantly better than a placebo in decreasing levels of molecular markers, or enzymes, that are used to diagnose heart attacks and heart damage in patients also taking standard drugs, such as cholesterol lowering statins, researchers said.

“It was exciting to see that a single administration of inclacumab would yield clinical benefit,” said Dr. Jean-Claude Tardif, who led the study and presented the data at the American College of Cardiology (ACC) scientific meeting in San Francisco.

“This is huge potentially,” said Tardif in an interview. “A drug that blocks the inflammatory process on top of statins holds a lot of potential.”

The main goal of the study was a decrease in levels of troponin I—a protein found in the blood when heart damage has occurred after angioplasty—at 16 hours and 24 hours after the procedure. Researchers also measured another heart damage biomarker called CK-MB.

The study involved 530 patients who had experienced a type of heart attack that required artery-clearing procedures. Patients received one of two doses of the Roche drug—20 milligrams/kilogram of weight or 5 mg/kg—or a placebo one hour before undergoing angioplasty.

For the higher dose of the drug, troponin I levels had decreased 22.4 percent more than placebo at 16 hours and 24.4 percent more at 24 hours.

At 24 hours after the procedure, 18.3 percent of the placebo patients had CK-MB levels increase more than three times the upper limit of what is considered normal—a level clinical studies often use to define a post angioplasty heart attack, researchers said. That compared with 8.9 percent of patients getting the higher dose of inclacumab.

“They found a very striking difference in these markers,” said Dr. Miguel Quinones, chairman of the 2013 ACC meeting who was not involved in the study.

The lower dose of the Roche drug had no significant effect on the cardiac markers.

Inclacumab works by blocking an antibody called p-selectin found in blood platelets and cells that line blood vessels. It is associated with inflammation that can destabilize plaque in the arteries and lead to a heart attack.

Patients who received the higher dose of inclacumab had p-selectin levels drop 19.2 percent compared with placebo, which was highly statistically significant, researchers said.

One of the most important frontiers in addressing heart disease is blocking inflammation as a cause of instability of arterial plaque, said Tardif, director of the Research Centre at the Montreal Heart Institute.

More than 1 million coronary artery angioplasty procedures are performed in the United States each year with a risk of damage to heart tissue, according to the ACC.

“The first step was to demonstrate the effect of this drug on myocardial damage immediately after angioplasty,” Tardif said. “The bigger question will be is this a drug that can provide

benefit not only for those who are undergoing angioplasty but to the much larger population of patients coming in with Acute Coronary Syndrome.”