



Study: Wider cholesterol drug use may save lives

Study might lead far more Americans to consider taking statin drugs

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NEW ORLEANS - People with low cholesterol and no big risk for heart disease dramatically lowered their chances of dying or having a heart attack if they took the cholesterol pill Crestor, a large study found.

The results, reported Sunday at an American Heart Association conference, were hailed as a watershed event in heart disease prevention. Doctors said the study might lead as many as 7 million more Americans to consider taking cholesterol-lowering statin drugs, sold as Crestor, Lipitor, Zocor or in generic form.

"This takes prevention to a whole new level, because it applies to patients who we now wouldn't have any evidence to treat," said Dr. W. Douglas Weaver, a Detroit cardiologist and president of the American College of Cardiology.

The study also gives the best evidence yet for using a new test to identify people who may need treatment, according to a statement from Dr. Elizabeth Nabel, director of the National Heart, Lung and Blood Institute. The new research will be considered by experts reviewing current guidelines.

However, some doctors urged caution. Crestor gave clear benefit in the study, but so few heart attacks and deaths occurred among these low-risk people that treating everyone like them in the United States could cost up to \$9 billion a year — "a difficult sell," one expert said.

About 120 people would have to take Crestor for two years to prevent a single heart attack, stroke or death, said Stanford University cardiologist Dr. Mark Hlatky. He wrote an editorial accompanying the study published online by the New England Journal of Medicine.

"Everybody likes the idea of prevention. We need to slow down and ask how many people are we going to be treating with drugs for the rest of their lives to prevent heart disease, versus a lot of other things we're not doing" to improve health, Hlatky said.

Top-selling drugs

Statin drugs are the world's top-selling drugs. Until this study, all but Crestor have already been shown to cut the risk of heart attacks and death in people with high LDL, or bad cholesterol.

But half of all heart attacks occur in people with normal or low cholesterol, so doctors have been testing other ways to predict who is at risk.

One is high-sensitivity C-reactive protein, or CRP for short. It is a measure of inflammation, which can mean clogged arteries as well as less serious problems, such as an infection or injury. Doctors check CRP with a blood test that costs about \$80 to have done.

A co-inventor on a patent of the test, Dr. Paul Ridker of Harvard-affiliated Brigham and Women's Hospital in Boston, led the new study. It involved 17,802 people with high CRP and low LDL cholesterol (below 130) in the U.S. and 25 other countries.

One-fourth were black or Hispanic, and 40 percent were women — important because previous statin studies have included few women. Men had to be 50 or older; women, 60 or older. None had a history of heart problems or diabetes.

They were randomly assigned to take dummy pills or Crestor, the strongest statin on the market, made by British-based AstraZeneca PLC. Neither participants nor their doctors knew who was taking what.

The study was supposed to last five years but was stopped in March, after about two years, when independent monitors saw that those taking Crestor were faring better than the others.

Full results were announced Sunday. Crestor reduced a combined measure — heart attacks, strokes, heart-related deaths or hospitalizations, or the need for an artery-opening procedure — by 44 percent.

"We reduced the risk of a heart attack by 54 percent, the risk of a stroke by 48 percent and the chance of needing bypass surgery or angioplasty by 46 percent," Ridker said.

Looked at another way, there were 136 heart-related problems per year for every 10,000 people taking dummy pills versus 77 for those on Crestor.

Remarkably, every single subgroup benefited from the drug.

"If you're skinny it worked, if you're heavy it worked. If you lived here or there, if you smoked, it worked," Ridker said.

AstraZeneca paid for the study, and Ridker and other authors have consulted for the company and other statin makers.

Blood sugar a concern

One concern: More people in the Crestor group saw blood-sugar levels rise or were newly diagnosed with diabetes.

Crestor also has the highest rate among statins of a rare but serious muscle problem, so there are probably safer and cheaper ways to get the same benefits, said Dr. Sidney Wolfe of the consumer group Public Citizen.

"It is highly unlikely that (the benefits are) specific to Crestor," said Wolfe, who has campaigned against the drug in the past.

Crestor costs \$3.45 a day versus less than a dollar for generic drugs.

Drs. James Stein and Jon Keevil of the University of Wisconsin-Madison used federal health statistics to project that 7.4 million Americans, or more than 4 percent of the adult population, are like the people in this study.

Treating them all with Crestor would cost \$9 billion a year and prevent about 30,000 heart attacks, strokes or deaths, they calculate.

"That's pretty costly. This would be a very difficult sell" unless a person also had family history or other heart disease risk factors, said Dr. Thomas Pearson of the University of Rochester School of Medicine and Dentistry.

Pearson was co-chairman of a joint government-heart association panel that wrote current guidelines for using CRP tests to guide treatment.

Researchers do not know whether the benefits seen in the study were due to reducing CRP or cholesterol, since Crestor did both.

Generic alternatives

This study and two other government-sponsored ones reported on Sunday "provide the strongest evidence to date" for testing C-reactive protein, and adding it to traditional risk measures could identify millions more people who would benefit from treatment, Nabel's statement says.

U.S. Crestor prescriptions totaled \$420 million in the third quarter of this year, up 23 percent from a year earlier. In the rest of the world, third quarter sales were \$520 million, up 33 percent.

Sales have been rising even though two statins — Zocor and Pravachol — are now available in generic form.

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