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Cholesterol Drug Zetia Doesn't Cut Heart Attack Risk: Study

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MONDAY, Jan. 14 (HealthDay News)-- The long-awaited results of a trial of Zetia, a cholesterol-lowering drug prescribed to about a million Americans, shows the drug confers no medical benefit to users.

In fact, the pace at which artery-clogging plaques formed within vessels almost doubled in patients taking Zetia (ezetimibe) along with another cholesterol-lowering drug, Zocor (simvastatin), compared to those taking Zocor alone, the study found.

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The two medications -- ezetimibe plus simvastatin -- are also marketed in one prescription pill, called Vytorin. About 60 percent of U.S. patients who are taking Zetia now receive the drug as part of Vytorin.

But the new two-year trial of 720 patients sheds doubt on whether it makes any sense for people battling cholesterol to take Vytorin versus Zocor alone, experts said. The study was funded by the two companies that make Zetia, Merck and Schering-Plough.

"This wraps it up," said Dr. Steven E. Nissen, chairman of cardiology at the Cleveland Clinic. "That's all there is. There just isn't any evidence that adding ezetimibe to simvastatin produces any advantage."

No one is disputing that Zetia can lower levels of LDL "bad" cholesterol by 15 percent to 20 percent -- that had been shown in previous trials. However, whether that reduction led to any greater lowering of heart attack or stroke risk had remained unclear.

The new ENHANCE trial -- which involved patients with a genetic condition that causes abnormally high levels of blood cholesterol -- found no such added benefit. According to a statement released by the two drug companies Monday, researchers found no statistically significant difference in heart attacks or stroke among trial participants who took Zetia plus Zocor, a widely used cholesterol-lower drug, versus those who got Zocor alone.

The study also noted that the speed at which arteries thickened with plaque

almost doubled among those on the two-drug regimen compared to those taking Zocor alone.

Safety profiles were similar for Zetia/Zocor versus Zocor alone, the team added.

"These results are very important considerations on how we treat patients with elevated cholesterol and will very likely impact the way we choose drugs to lower cholesterol and eliminate plaque," said Dr. Howard Weintraub, clinical director of the Center for the Prevention of Cardio-Vascular Disease at New York University Medical Center, New York City, and clinical associate professor at the NYU School of Medicine.

"ENHANCE found that plaque got slightly worse when the drug combination was used," Weintraub noted in a statement. "But, the real take-home message here is that getting LDL down is important, and that's not something that should be lost as a consequence of this study."

The ENHANCE study was completed in April 2006, but the results were only released Monday by Merck and Schering-Plough after continual prodding by medical professionals. According to *The New York Times*, the companies had initially planned to release the findings by March 2007, but then missed several self-imposed deadlines, blaming the delay on the complexities of necessary data analysis.

Now that the results have arrived, Zetia and Vytorin should be viewed as

"drugs of last resort," for patients not helped by standard statin therapy, Nissen said. Only if you can't tolerate full doses of simvastatin should you take ezetimibe, he said.

"This is one of the most widely advertised and widely used drugs out there, so it's obviously good to get these study results," Nissen added.

Another group questioned why patients should be prescribed more expensive cholesterol-lowering drugs, such as Vytorin, versus cheaper, generic statins such as Zocor.

"We already know that millions of people who take these brand drugs probably don't need to; they could be taking a less expensive generic instead. This study lends support to that cost-saving strategy for the health system and for consumers," said Steven Findlay, managing editor of *Consumer Reports Best Buy Drugs*, a public information and education project of Consumers Union, publisher of *Consumer Reports*.

"If there is no apparent clinical benefit, why take a drug that cost three or four times more?" Findlay said in a statement. "Most people do not need that magnitude of cholesterol reduction anyway."

Sales of Zetia and Vytorin totaled \$3.7 billion in the nine months ending Sept. 30, up 33 percent from a year ago. Analysts estimate that about 70 percent of Schering-Plough's earnings depend on the drugs, the *Times* noted.

more information

There's more on lowering cholesterol at the [American Heart Association](#).



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