

Cholesterol drug shows promise to help reverse heart disease

November 15 2016, by Marilynn Marchione



This undated image provided by Amgen Inc. shows the cholesterol-lowering drug Repatha. In a report published Tuesday, Nov. 15, 2016, by the Journal of the American Medical Association, this new drug added to cholesterol-lowering statins has proved able to shrink plaque that is clogging arteries, potentially giving a way to undo some of the damage of heart disease. (Robert Dawson/Amgen via AP, File)

For the first time, a new drug given along with a cholesterol-lowering



statin medicine has proved able to shrink plaque that is clogging arteries, potentially giving a way to undo some of the damage of heart disease.

The difference was very small but doctors hope it will grow with longer treatment, and any reversal or stabilization of disease would be a win for patients and a long-sought goal.

The drug, Amgen Inc.'s Repatha, also drove LDL, or <u>bad cholesterol</u>, down to levels rarely if ever seen in people before. Heart patients are told to aim for below 70, but some study participants got as low as 15.

"There doesn't appear to be any level at which there is harm" from too little LDL, and the lower patients went, the more their <u>plaque</u> shrank, said one study leader, the Cleveland Clinic's Dr. Steven Nissen.

Results were published Tuesday by the *Journal of the American Medical Association* and discussed at an American Heart Association conference.

Statins such as Lipitor and Crestor curb cholesterol production. Repatha and a similar drug, Praluent, block PCSK9, a substance that interferes with the liver's ability to remove cholesterol from the blood. Too much cholesterol, along with other substances, can build up and form plaque in arteries.

The new drugs have drawbacks, though. Statins are pills sold as generics for as little as a dime a day. The new ones are biotech drugs that are expensive to make—Repatha costs \$14,000 a year and insurers often won't pay. They must be given as shots every two weeks or once a month. People can do it themselves with a penlike device.

In the study, about 900 <u>heart disease</u> patients were given a strong statin and monthly shots of either Repatha or a dummy solution. Ultrasound images were taken of an artery with plaque at the start of the trial and 18



months later.

The average for bad cholesterol stayed around 93 for people given only the statin, but dropped to 37 for those on both drugs. The amount of artery plaque stayed about the same for the statin-only group but shrank 1 percent in those also given Repatha. Some people with more dramatic LDL declines saw plaque shrink 2 percent.

"It's small, but it probably took patients 60 years to accumulate that plaque," so to see any change after just 18 months of treatment is good, said a cholesterol expert, Dr. Raul Santos of the University of Sao Paolo.

Dr. Vincent Bufalino, president of Advocate Medical Group, a large cardiology group in suburban Chicago, agreed.

"It sounds small but it's a beginning" and still a win, he said.

Amgen sponsored the study, and Santos has consulted for the company. Nissen said his fees for doing the study were donated to charity.

The best test of the new drugs' value will be large studies underway now to see whether drops in cholesterol will lead to fewer heart attacks and deaths. Results are expected next year.

Also at the conference, doctors gave results of a safety study of an experimental treatment aimed at rapidly removing cholesterol after a heart attack to help prevent a second one.

"When you have a <u>heart</u> attack, your ability to get cholesterol out of plaque is actually worsened. Your plaques grow more plump....the pipes are getting even more clogged," said Dr. C. Michael Gibson, professor of medicine at Harvard University.



He led a study in 1,250 people testing infusions of ApoA-1, the main component of HDL, or good <u>cholesterol</u>, which helps remove the bad kind. The substance is taken directly from human blood, not synthesized in a lab.

An earlier version showed side effects on the liver; this one was modified to try to avoid that, and no safety roadblocks were seen, said Gibson, who consults for the treatment's maker, CSL Behring.

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Citation: Cholesterol drug shows promise to help reverse heart disease (2016, November 15) retrieved 17 April 2024 from

https://medicalxpress.com/news/2016-11-cholesterol-drug-reverse-heart-disease.html

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