

## Statin RX may be overprescribed in healthy people without evidence of diseased arteries

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Rolling back suggestions from previous studies, a Johns Hopkins study of 950 healthy men and women has shown that taking daily doses of a cholesterol-lowering statin medication to protect coronary arteries and ward off heart attack or stroke may not be needed for everyone.

In a study to be presented Nov. 16 at the American Heart Association's (AHA) annual Scientific Sessions in Chicago, the Johns Hopkins team found that nearly 95 percent of all heart attacks, strokes or heart-related deaths occurred in the half of study participants with some measureable buildup of artery-hardening calcium in the blood vessels; hence, only this subgroup might have benefited from preventive drug therapy. Seventy-five percent of all heart emergencies occurred in the quarter with the highest calcium scores.

The 47 percent of study participants with no detectable levels of calcium buildup in their blood vessels suffered about 5 percent of heart-disease related events during the six-year study, meaning that drug therapy may not have offered any coronary protection.

"Our results tell us that only those with calcium buildup in their arteries have a clear benefit from statin therapy, and those who are otherwise healthy and have no significant calcification should with their physician focus on aggressive lifestyle improvements instead of early initiation of statin medications," says study lead investigator Michael Blaha, M.D., M.P.H.



"While statin therapy can benefit healthy men and women with normal or even low <u>cholesterol levels</u>," adds Blaha, a cardiology fellow at the Johns Hopkins University School of Medicine and its Heart and Vascular Institute, "it certainly is not the case that all adults should be taking it to prevent heart attack and stroke, because half are at negligible risk of a sudden <u>coronary event</u> in the next five to 10 years."

Results of the study underscore the importance of measuring <u>coronary</u> <u>artery calcium</u> deposits, Blaha says, in predicting who is really at risk of suffering a heart attack. High levels of C-reactive protein in the blood, a CRP score at or above 2 milligrams per liter, offered no predictive value after established risk factors are taken into account, including age, gender, ethnicity, hypertension, blood cholesterol levels, obesity, diabetes, smoking and a family history of heart disease. Study participants in the new analysis had varying blood levels of the inflammatory byproduct, believed by some to be a predictor of all kinds of coronary disease.

The latest findings from the Johns Hopkins-led Multi-Ethnic Study on Atherosclerosis, or MESA, are believed to be the first to pinpoint precisely who among the more than 6 million healthy American adults with normal blood-cholesterol levels and, thus, potential candidates for preventive statin therapy, would benefit from a statin's cardio-protective effects. Rosuvastatin, marketed as Crestor, is one particular statin drug effective in preventing heart attack and stroke in some individuals, according to results of the landmark JUPITER trial published in 2008.

In the JUPITER trial, short for the Justification for the Use of Statins in Primary Prevention: An Interventional Tool Evaluating Rosuvastin, daily doses of 20 milligrams per liter of blood per day halved the number of potentially fatal coronary blockages in some 18,000 adults, all with high CRP levels.



To check these findings, the Johns Hopkins team selected MESA study participants who met the same criteria set for the JUPITER study. The MESA subgroup came from a pool of 7,000 ethnically diverse adults, including African Americans, Chinese Americans, Caucasians and Hispanics – all monitored at Johns Hopkins and five other medical centers in North America.

A statistical comparison of results showed that few if any heart attacks or strokes would have been prevented within five years had anyone taken the medication, unless there was already some calcium buildup in their blood vessels. In people with moderate calcium buildup, one heart attack would have been averted in every 94 people treated, and one stroke in every 54.

For people with higher coronary calcium scores, the numbers of patients one needed to treat to prevent a <u>heart attack</u> or stroke were 24 and 19, respectively, which Blaha says were superior numbers to those in the JUPITER study or any prior statin trial.

According to study co-investigator and cardiologist Roger Blumenthal, M.D., a professor and director of the Ciccarone Preventive Cardiology Center at Johns Hopkins, "statin therapy should not be approached like diet and exercise as a broadly based solution for preventing coronary heart disease.

These are lifelong medications with potential, although rare side effects, and physicians should only consider their use for those patients at greatest risk, especially those with high coronary calcium scores."

Blumenthal points out that as many as 5 percent of people on statins develop serious side effects, such as muscle pain. One in 255 will develop diabetes.



Blumenthal recommends that all people monitor their risk factors for heart disease, according to their age and gender, diabetes, bloodcholesterol levels, hypertension and smoking, and if recommended by their physician, get a coronary calcium CT scan to gauge their actual risk.

Coronary heart disease remains the nation's leading cause of death, responsible for one in five deaths in adults in the United States.

## Provided by Johns Hopkins Medical Institutions

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