Wider statin use could be cost-effective preventive measure, study finds

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A new analysis suggests that broader statin use among adult patients may be a cost-effective way to prevent heart attack and stroke. The Stanford University School of Medicine study also found that using a popular test - a screening for high sensitivity C-reactive protein, or CRP - to identify patients who may benefit from statin therapy would be cost-effective, but only under certain scenarios.

"If statins are really as safe and effective as they appear to be, broadening the indications for statin therapy would be an effective and cost-effective strategy," said Mark Hlatky, MD, professor of health research and policy and of cardiovascular medicine. "But under different assumptions, targeted CRP screening would be a reasonable approach," Hlatky is the senior author of the findings, which will appear online Sept. 27 in *Circulation*.

The study comes almost two years after a major clinical trial, known as the JUPITER study, showed that millions more people could benefit from taking statins, even if they have low cholesterol. That study involved patients with low cholesterol levels but elevated levels of CRP, which indicates inflammation in the body and suggests a greater risk of heart attack and stroke.

Under current clinical guidelines, statin therapy is recommended for individuals at high risk: those identified as having a 20 percent or more risk of some sort of cardiovascular event in the next 10 years. But heart attacks and stroke also occur in many people at lower risk levels, and the

findings from the JUPITER study suggested that measuring CRP levels might identify patients who would benefit from statin therapy.

Still, that research did not address whether it would be cost-effective to do more screening and/or to give more people statin therapy. Accordingly, Hlatky and his colleagues sought to compare the cost-effectiveness of different strategies to prevent heart disease.

For their study, the researchers developed a model to analyze the cost-effectiveness of three approaches: following current guidelines; doing CRP screening in individuals who don't meet the current guidelines for treatment, with statin therapy for those with elevated CRP levels; and providing statin therapy based on an individual's cardiovascular risk alone, without CRP testing. Their model followed hypothetical patients, starting at 40 years of age, with normal lipid levels and no clinical evidence of heart disease or diabetes.

The researchers then looked at which approaches met the threshold of costing no more than $50,000 per quality-adjusted-life-year, a common metric that takes into account quality of life as well as length of survival. (Therapies costing around $50,000 or less per quality-adjusted life-year are generally considered cost-effective.)

Their conclusion? Assigning statin therapy based on risk alone, without CRP testing, was the most cost-effective strategy. The optimal strategy for men with no risk factors, for example, would be to start a statin at the age of 55.

"Initiation of statin treatment at lower risk levels without CRP testing would further improve clinical outcomes at acceptable cost, making it the optimally cost-effective strategy in our analysis," the researchers wrote in their paper.

The researchers found, however, that the optimal strategy for prevention changed if the assumptions in the model were altered. For instance, if patients with normal CRP levels get little or no benefit from statin therapy, CRP screening would be the optimal strategy. And if harms from statin use are only slightly greater than currently thought, statin therapy would not be reasonable in low-risk individuals, and following current clinical guidelines would be the most cost-effective strategy.

Clearly, there are a lot of unknowns and assumptions - all of which tempered the researchers' conclusion. "This is not a slam-dunk decision in terms of: You should take people at low risk and put them all on treatment," said Hlatky. "If you run the model and change the assumptions even a little bit, you get a different answer. Our model shows that we need better data to be confident about the best approach to drug treatment of lower-risk individuals."

For co-author Douglas Owens, MD, the study points to a high priority for determining whether statins work as well in low-risk people (i.e. those with normal CRP levels) or just high-risk ones. "That's a big uncertainty," he said, and the answer would inform how cost-effective both screening and broad therapy are.

The researchers also said it would be important to know whether high CRP levels do more than identify people who are at risk of developing heart disease, but also identify which people are more likely to have lower risk of heart attack or stroke when treated with a statin. (The test could then spare certain patients from unnecessary treatment.)

"Ideally, a marker would tell us who will benefit from drug treatment and who will not," said Hlatky. "If a test could give us that information, it would be very cost-effective. But there's not good evidence yet that CRP, or any other test, works that well."

Hlatky said a National Heart, Lung, and Blood Institute working group is now updating the clinical guidelines for statin therapy, and he hopes this research will inform their recommendations. "Maybe the threshold for statin treatment ought to be lower than is currently recommended," he said.

In the meantime, the researchers have developed an interactive tool that physicians can reference to determine the most cost-effective approach to statin therapy for individual patients. The calculator can be found at http://med.stanford.edu/hsr/crp-screening/

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