

Common Gene Mutation Linked to Statin Side Effects

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(PhysOrg.com) -- Common genetic mutations may help explain why some people develop side effects that lead to discontinuing the use of cholesterol-lowering statins. Duke University Medical Center researchers who identified the mutations say they might be used to help doctors match a medication with their patient's genetic makeup.

Statins are used by millions of Americans to reduce high cholesterol and prevent a <u>heart attack</u> or stroke.

While they are potentially life-saving, anywhere from 25 to 50 percent of people prescribed these drugs stop using them after one year. Side effects, especially muscle aches, are believed to be a primary reason.

The new findings suggest that people with the mutation are more likely to have muscle aches, the risk increases if they have more copies of the mutation, and the muscle effects differ depending on the statin they were prescribed. The study is published online in the <u>Journal of the American College of Cardiology</u>.

"This study is the first to suggest that a common genetic variant in the SLCO1B1 gene may affect adherence to medication," said Geoffrey Ginsburg, MD, PhD, director of Duke University's Center for Genomic Medicine in the Institute for Genome Sciences & Policy.

"Following further validation, these findings could be used to design a pharmacogenetic test to predict how an individual will respond to a statin



and possibly to assist with compliance to this important class of drugs."

The study included 509 people with high <u>cholesterol</u> randomly assigned to receive treatment with atorvastatin (Lipitor), simvastatin (Zocor) or pravastatin (Pravachol). Following eight weeks of treatment, the doses for all three groups were increased for an additional eight weeks.

The Duke team analyzed the genetic makeup of people who discontinued their medication due to side effects, developed muscle aches and had elevated levels of an enzyme indicating muscle damage.

"We were attempting to answer a difficult diagnostic question -- is a patient experiencing simple muscle aches or are these aches due to the medication?" said Deepak Voora, MD, a cardiologist at Duke and the lead author of the study.

The findings replicate and expand on research published last year by another group which found the same mutation was associated with a more severe, but much less common type of muscle problem in patients taking simavstatin.

The Duke team found that people with the mutation were more likely to have muscle aches, even if they did not have abnormally high levels of the enzyme. They also observed variations based on the dose of the medication and the specific statin administered.

The majority of side effects occurred when patients were taking the lower doses of the medications. Simvastatin was associated with the most side effects among people with the mutation while patients taking pravastatin reported the least muscle aches.

"If a genetic test can be developed to determine who will experience side effects that will likely make patients go off their medication, we can



target these individuals for counseling about common side effects, monitor them more closely or tailor their medication accordingly," Voora said.

While the presence of the genetic variant was the characteristic most closely linked with side effects, gender also played a role: women were significantly more likely to report muscle aches. Other factors that contributed to an increased risk of side effects included older age, lower body mass and hypothyroidism.

The investigators plan to conduct a study among the general population to determine if the genetic variant is associated with higher rates of nonadherence to medication. The next step would entail conducting a study where <u>statin</u> therapy would be personalized based on the presence of the mutation to learn who remains on their medication over time.

Other members of the research team included Svati H. Shah, Ivan Spasojevic, and Shazia Ali of Duke and Carol R. Reed and Benjamin A. Salisbury of Clinical Data, Inc.

Provided by Duke University (<u>news</u> : <u>web</u>)

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