

Genetic test for Plavix use may be unneeded: study

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A new study published Wednesday cast doubt on the usefulness of a genetic test for patients taking the anti-coagulant drug Plavix, calling into question last year's FDA warning about the blood thinner.

The study, a new review of 32 previous clinical studies published in the [Journal of the American Medical Association](#), said the genetic test may not help identify those patients more at risk of a heart attack or other cardiac event.

Plavix, one of the world's top selling drugs, is marketed by US-based Bristol-Myers Squibb and France's Sanofi. It reduces the risk of heart attack and stroke by keeping [blood platelets](#) from sticking together to cause clots.

In 2010, the US Food and Drug Administration ordered the manufacturers to add a boxed warning to Plavix packets saying the drug may be less effective in preventing heart attacks in people who cannot metabolize it properly.

The FDA said an estimated two to 14 percent of the US population are poor metabolizers who have a certain variant of the gene that makes the CYP2C19 [liver enzyme](#), which converts Plavix to its active form.

The FDA had recommended that doctors prescribe higher doses of Plavix, or clopidogrel, to those patients who had the genetic test and were found not to produce enough of the enzyme.

But researchers led by Michael Holmes at University College London concluded after their new review of studies involving 42,000 patients that those with the [gene variant](#) did not have more [cardiac events](#) than other patients.

"Despite associations between CYP2C19 genotype, clopidogrel metabolism, and platelet aggregation, this systematic review and meta-analysis does not demonstrate a clinically important association of genotype with [cardiovascular outcomes](#)," researchers led by Michael Holmes at University College London said.

The only notable possible exception was in patients with stent thrombosis, they wrote.

"The FDA's warnings on Plavix were premature and were not based on solid science," said Steven Nissen, a cardiologist at the Cleveland Clinic Foundation, in an editorial published in the Journal of the AMA.

Plavix sales totalled \$5.4 billion in the first three quarters of 2011, as compared with \$4.9 billion in the same period last year.

About 40 million people take the drug worldwide.

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