

Avandia Disappoints Again, Doesn't Significantly Reduce Arterial Plaque

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Avandia, GlaxoSmithKline's controversial diabetes drug, does not reduce arterial plaque buildup in any significant way, according to a new study. This news only adds to the uncertainty surrounding Avandia, which has been the subject of safety worries since it was tied to an increased risk of heart attacks by another study in 2007.

Results from this latest Avandia clinical trial were detailed Wednesday at an American Heart Association conference by lead researcher Dr. Richard Nesto of Lahey Clinic in Burlington, Mass. and Brigham and Women's Hospital. The study, which involved 672 patients, compared Avandia's impact on arterial plaque buildup - a condition called atherosclerosis - to glipizide. Glipizide is an older diabetic drug that is available generically.

Though Avandia did seem to reduce plaque buildup slightly better than the older drug, the difference was not statistically significant, and could have happened by chance. After 18 months of treatment, those who took Avandia had an 0.21 percent reduction in plaque at the observed artery, while glipizide patients experienced an 0.43 percent increase in plaque.

Even before this new study was released, Avandia already faced serious questions over its safety. Avandia's trouble started in May 2007, when an analysis of 42 clinical trials published by the Cleveland Clinic showed that patients taking the drug had a 43-percent higher risk of having a heart attack. In November 2007, the Food & Drug Administration (FDA) finally ordered that a black box warning detailing Avandia's heart related risk be added to the drug's labeling.

Late last month, the group Public Citizen said it had identified 14 cases of Avandia-induced liver failure in the FDA's Adverse Event Reporting System. Of the 14 cases of liver failure, 12 resulted in deaths. Those findings prompted Public Citizen to file a petition with the FDA asking that Avandia be removed from the market.

The liver failure associated with Avandia, taken together with the drug's risk of other side effects, including heart failure, fractures and vision loss, was too great to allow the drug to continue to be sold in U.S., the group's petition said.

"The scientific evidence against Avandia is overwhelming," Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, said in a news release. "The timing of these findings should give the FDA the momentum it needs to act swiftly to prevent further needless deaths and health damage by banning this drug."

Public Citizen is just the latest group to criticize Avandia. In October, the American Diabetes Association/European Association for the Study of Diabetes working group dropped Avandia from its treatment guidelines.

James Stein, an expert in cardiovascular imaging technologies at the University of Wisconsin, Madison, told Forbes.com that the findings of this latest Avandia clinical trial raised questions about Avandia's usefulness.

"There's really no reason anybody should be using this medicine," says Stein. "It's time to give this drug a rest. There are better, safer alternatives."