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Avandia

Diabetes Drug Avandia: Heart Risk?
Study Shows 43% More Heart Attacks With Avandia; Drugmaker Says Study Is Flawed
By Daniel J. DeNoon
WebMD Medical News
Reviewed by Louise Chang, MD
May 21, 2007 – The diabetes drug Avandia may increase a person's risk of heart attack and death due to heart disease, a new study warns.

Avandia maker GlaxoSmithKline says the study is flawed and that better data -- some already submitted to the FDA, some from an ongoing clinical trial -- show Avandia poses no significant risk to patients' heart health.

The FDA says that based on this "contradictory evidence about the risks in patients treated with Avandia," patients taking the drug -- especially those who have had heart attacks or who have underlying heart disease -- should talk with their doctors about whether to continue taking the drug.

The new warning comes from an analysis of publicly available, short-term clinical studies comparing Avandia to other diabetes treatments. It shows that Avandia increases heart attack risk by 43% -- and increases risk of death from heart disease by 64%.

However, the overall risk was small. Among the 15,560 Avandia patients there were 86 heart attacks and 39 deaths, compared with 72 heart attacks and 22 deaths among the 12,283 patients not taking Avandia.

"In susceptible patients, [Avandia] therapy may be capable of provoking myocardial infarction [heart attack] or death from cardiovascular causes after relatively short-term exposure," suggest study investigators Steven Nissen, MD, and Kathy Wolski, MPH. Nissen chairs the Cleveland Clinic's department of cardiovascular medicine; he is past president of the American College of Cardiology.

The Nissen/Wolski report will be published in The New England Journal of Medicine. The journal today made the report public under its early-release policy.

Avandia is sold by itself and, as Avandamet and Avandaryl, in pills that combine Avandia with other diabetes medications. The findings do not appear to immediately affect Actos (made by Takeda Pharmaceuticals), a diabetes drug in the same class as Avandia.

Avandia Benefit, Avandia Risk

The FDA in 1999 approved Avandia on the basis of clinical trials showing that the drug could reduce blood-sugar levels in people with type 2 diabetes. Diabetes has been linked to both microvascular problems (problems of tiny blood vessels) such as blindness, kidney failure, and loss of circulation in the extremities. It has also been linked to heart disease.

But none of the trials on which Avandia was approved showed that the drug actually prevented the greatest threats to people with diabetes: microvascular problems, heart disease, or heart death.

In a strongly worded editorial accompanying the study, University of Washington researcher Bruce M. Psaty, MD, PhD, says the Nissen study means there's no good reason for most patients to take Avandia.

"There is little evidence for using this drug," Psaty tells WebMD. "The purpose of reducing blood sugar is to prevent cardiovascular events. Now the possibility of cardiovascular benefit associated with Avandia appears remote -- indeed, it appears linked to harm. So the rationale for prescribing it at this time is just not clear."

Psaty warns patients taking Avandia not to just stop using it. They should continue taking the drug until they can discuss the matter with their doctor.

"This is not an immediate risk. It is the absence of an expected benefit and the possibility of harm over the years," he says. "Patients should talk with their doctors and see if they are getting the benefit they expected. Doctors can look at the data and say whether there is a compelling reason for them to prescribe this drug. I don't think there is."

Avandia Safe, GlaxoSmithKline Says

GlaxoSmithKline has done its own analysis of Avandia's heart safety data. Using techniques similar to those used in the Nissen study, the GSK study showed about a 30% increase in heart risk to patients taking Avandia.

But a study of 33,000 patients in a managed-care database showed no increased heart risk in patients taking Avandia. Both this study and the GSK analysis were given to the FDA in August 2006.

Ongoing, long-term studies also support Avandia safety, says GSK chief medical officer Ronald Krall, MD.

"I want to be very clear that we are confident in the benefit/risk profile for Avandia. We believe that if it is used according to the directions incorporated into U.S. and European labels, it is an important treatment for patients with type 2 diabetes," Krall says in a news release. "We believe that important evidence coming from long-term studies supports the safety of Avandia."

Are you taking Avandia?Are you concerned about your heart? Discuss this important diabetes development in the WebMD Diabetes community.
SOURCES: Nissen, S.E. and Wolski, K. The New England Journal of Medicine, early release, May 21, 2007. GlaxoSmithKline (GSK) news conference with Ronald Krall, MD chief medical officer, and Lawson McCartney, vice president of cardiovascular, metabolic and neurology marketing, GlaxoSmithKline. FDA news conference with Robert J. Meyer, MD, Center for Drug Evaluation and Research (CDER), and Gerald Dal Pan, MD, director, CDER Office of Surveillance and Epidemiology, CDER, FDA. Bruce M. Psaty, MD, PhD, professor of medicine and epidemiology, University of Washington, Seattle.

Article Link: http://diabetes.webmd.com/news/20070521/diabetes-drug-avandia-heart-risk?ecd=wnl_nal_052107