

Study compares risk with 2 diabetes drugs

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In contrast to previous reports, the risks of the composite endpoint of heart attack, heart failure, both, or death were the same - about 4 percent - for patients taking the diabetes drugs rosiglitazone or pioglitazone, according to a study published in the American Heart Association journal *Circulation: Cardiovascular Quality and Outcomes*.

"This study provides patients and their doctors with another source of information about rosiglitazone and pioglitazone (sold as Avandia and Actos, respectively) as they determine the best therapy for diabetes patients," said Debra Wertz, Pharm.D., lead author and outcomes research manager at HealthCore, Inc., the research subsidiary of health insurance company WellPoint, Inc.

This study evaluated more than 36,000 diabetes patients. Of the 28,938 patients who were propensity-score matched, a methodology used to provide an estimation of treatment-effects that is as unbiased as possible, 602 patients taking rosiglitazone and 599 taking pioglitazone over a 33-month period suffered either a heart attack, heart failure, both, or died. This translates to about 4 percent of all patients taking either medication. The individual specific adverse events were also not significantly different between the two groups, and were:

- Heart attack - 96 patients on rosiglitazone and 121 patients on pioglitazone;
- Heart failure - 265 patients taking rosiglitazone and 243 taking

pioglitazone;

- Heart attack and heart failure - 24 patients on rosiglitazone and 18 on pioglitazone; and
- Death - 217 patients taking rosiglitazone and 217 taking pioglitazone.

The study included 36,628 patients who had submitted insurance claims to WellPoint affiliates for either of the two [diabetes medications](#) between 2001 and 2005. Patients' average age was 54, and 58 percent were male. Wertz and her team obtained death records from the National Death Index, a central database administered by the National Center for Health Statistics.

The investigators divided patients into two equal groups, one receiving rosiglitazone and the other, pioglitazone. After adjusting the data for (removing/minimizing the effect of) age, gender, prior heart and blood vessel diseases and diabetes-related complications and severity indicators, they compared the incidence of heart attack, [heart failure](#) and death for an average 14 months of treatment and 19 months of post-treatment follow-up.

Diabetes is a disease in which the body cannot adequately produce the hormone insulin or uses it improperly. The disease can cause a potentially dangerous buildup of sugar in the blood and also increases the risk of heart and blood vessel diseases, which are the main causes of death for people with diabetes.

Rosiglitazone, sold under the trade name Avandia by GlaxoSmithKline, and pioglitazone, sold as Actos by Takeda Pharmaceuticals, belong to the same class of drugs, called TZDs or thiazolidinediones. They help the body use insulin more effectively by boosting the body's sensitivity

to the hormone and thus help control blood sugar.

This study has results different from earlier ones that found a greater risk of [heart attack](#) among rosiglitazone users compared to patients on other treatments or placebo. In 2007, the Food and Drug Administration decided that the benefits of rosiglitazone outweighed the risks, and it remained on the market although its use decreased significantly. In July 2010, an FDA advisory committee again reviewed numerous studies, including this study, and recommended that rosiglitazone remain on the market, although with additional warnings or restrictions. The FDA has not yet ruled on this latest recommendation.

"Besides its findings that rosiglitazone and pioglitazone have comparable risks, what distinguishes this latest study from other claims-based analyses is its analysis of death records, which include out-of-hospital deaths," Wertz said. The study also followed patients for a longer period of time than some of the earlier research, according to the investigators.

"One of the reasons we embarked on this analysis was to see if there were any differences in effect that we could identify between these two agents," said Mark J. Cziraky, Pharm.D., study co-author, and vice president of research development and operations at HealthCore. "We did not find that with the approach and methods we took within this population."

More information: Link to public comment on FDA advisory committee recommendation:

www.newsroom.heart.org/index.php?s=43&item=1081

Provided by American Heart Association

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