

Type 2 diabetes medication rosiglitazone associated with increased cardiovascular risks and death

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A new study published online today by *JAMA* shows that among patients age 65 years and older, rosiglitazone (a medication for treating Type 2 diabetes) is associated with an increased risk of stroke, heart failure, and all-cause mortality (death) when compared with pioglitazone (another medication for diabetes). The study was published online today in advance of an upcoming Food and Drug Administration meeting that will review the safety of rosiglitazone. The paper will appear in the July 28 print issue of *JAMA*.

"Rosiglitazone and pioglitazone are the only thiazolidinediones (a class of drugs for treating diabetes) currently marketed in the United States," the authors provide as background information. "Studies have suggested that the use of rosiglitazone may be associated with an increased risk of serious cardiovascular events compared with other treatments for type 2 diabetes."

David J. Graham, M.D., M.P.H., from the Center for Drug Evaluation and Research, U.S. <u>Food and Drug Administration</u>, Silver Springs, MD and colleagues, evaluated data from 227,571 Medicare beneficiaries (average age, 74.4 years) who started treatment with rosiglitazone or pioglitazone through a Medicare Part D prescription drug plan from July 2006 through June 2009. The patients were followed for up to three years after the initiation of the medications.



"During follow-up, there were 1,746 acute myocardial infarctions [heart attacks] (21.7 percent fatal), 1,052 strokes (7.3 percent fatal), 3,307 hospitalizations for heart failure (2.6 percent fatal), and 2,562 deaths for all causes among cohort members," the authors report. Analysis showed no differences in the risk for heart attack between rosiglitazone and pioglitazone, but "...our study found that rosiglitazone was associated with a 1.25-fold increase in risk of heart failure compared with pioglitazone," and "...these data suggest that rosiglitazone was associated with a 1.27-fold increased risk of stroke and a 1.14-fold increased risk of death compared with pioglitazone," according to the authors.

In conclusion, the authors write: "...in a population of more than 227,000 patients 65 years or older who initiated treatment with a thiazolidinedione, we found that, compared with pioglitazone, rosiglitazone was associated with an increased risk of stroke, heart failure, and death and the composite of AMI (heart attack), stroke, heart failure or death."

More information: JAMA.doi:10.1001/jama.2010.920.

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