Long-term use of diabetes drug increases heart attack risk by more than 40 percent

11 September 2007

An analysis of four studies involving more than 14,000 patients found that long-term use of the diabetes drug rosiglitazone (Avandia®) increased the risk of heart attack by 42 percent and doubled the risk of heart failure, according to a new report from researchers at Wake Forest University School of Medicine and colleagues. There was no effect on death from cardiovascular causes.

The analysis, reported in the Sept. 12 issue of the *Journal of the American Medical Association*, is one of the first to evaluate how long-term use of Avandia affects risk of heart attacks, heart failure and mortality. It involved studies that followed patients for at least a year.

The U.S. Food and Drug Administration recently required that Avandia and another drug in the same class carry the agency's toughest "black-box" warning because of an increased risk of heart failure. The agency is currently evaluating whether a warning about heart attack risk should also be included for Avandia. Earlier this year, an analysis of 42 short-term studies found an increased risk of heart attacks.

"The public health impact of potential harm with rosiglitazone is substantial," said Sonal Singh, M.D., lead author and an assistant professor of internal medicine at Wake Forest. "Regulatory agencies should urgently evaluate whether this drug should remain on the market."

Singh said an estimated 3.5 million people in the United States take Avandia. He said that while caution should be taken in estimating event rates based on the analysis, the findings suggest that the drug may cause more than 4,000 excess heart attacks and 9,000 excess cases of heart failure a year.

The researchers pooled data from four studies that randomly assigned participants with type 2 diabetes or impaired glucose tolerance to receive Avandia or either another type of diabetes drug or a placebo, or inactive drug.

Based on the analysis, the researchers estimate that for every 220 diabetic patients treated with Avandia for one year, one will have a heart attack linked to the drug. And, there would be one case of heart failure for every 30 people taking the drug for one year.

"There is no need for physicians, health plans or patients to wait for regulatory action," said Curt Furberg, M.D., Ph.D., a co-author of the report. "On the contrary, they should take prompt action and restrict the use of Avandia, especially since safer alternatives are available."

Avandia received regulatory approval in 1999 and at that time no serious adverse events were recognized. However, since approval, Avandia has been linked to heart failure, vision loss, heart attacks and fractures in women.

The current analysis looked at potential links between the drug and heart attacks, death from cardiovascular causes, and heart failure, which is the inability of the heart to meet the body's demands.

Source: Wake Forest University Baptist Medical Center