

Researchers question use of diabetes drug

Heart risk higher with Avandia: study

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New research involving nearly 40,000 Ontario patients is questioning the use of a widely prescribed diabetes drug that an expert in drug safety says should be removed from the market.

The study, published this week by the *British Medical Journal*, found that rosiglitazone -- sold under the brand name Avandia -- is associated with an increased risk of heart failure and death compared to a similar drug, pioglitazone, or Actos.

Both drugs belong to the class of medications known as thiazolidinediones, or glitazones, used to treat type 2 diabetes. The drugs lower blood sugar by making people more sensitive to their own insulin.

Heart failure has been reported with both drugs, and there is debate over whether Avandia also increases the risk of heart attack in some patients.

The Toronto researchers wanted to see whether there's a difference in cardiac safety between the two drugs.

The study involved 39,494 patients, aged 66 and older, who were started on either Avandia or Actos between April 2002 and March 2008.

Compared to Avandia users, patients treated with Actos had a 23 per cent lower risk of being hospitalized for congestive heart failure, and a 14 per cent lower risk of death from any cause.

"It sounds like a small number, but when you think about the millions of patients who have been on these drugs it actually becomes a much bigger number," says principal investigator Dr. David Juurlink, a scientist at the Institute for Clinical Evaluative Sciences in Toronto, and head of the division of clinical pharmacology and toxicology at Sunnybrook Health Sciences Centre.

"If a million patients were treated with rosiglitazone (Avandia) rather than pioglitazone (Actos), these results imply that we would see more than 8,000 excess admissions for heart failure, and more than 3,000 additional deaths from any cause," Juurlink says.

There was no significant difference in the risk of heart attack.

In total, during the six-year study period, 5.3 per cent of patients taking Actos and 6.9 per cent taking Avandia either died or were hospitalized for heart attack or congestive heart failure.

"Given the accumulating evidence of harm with rosiglitazone therapy and the lack of a distinct clinical advantage for the drug over pioglitazone, it is reasonable to question whether ongoing use of rosiglitazone is justified in any circumstance," the researchers report.

Avandia manufacturer GlaxoSmithKline questioned the validity of the findings. The company said data from a large, randomized controlled trial involving more than 4,400 patients found that Avandia "is not associated with an overall increase in cardiac hospitalization or death" compared to patients receiving metformin and sulfonylurea, other commonly used diabetes drugs. GlaxoSmithKline says Avandia "remains an important diabetes medicine for appropriate patients."

Last year, 689,051 prescriptions for Avandia, worth \$81.9 million, were filled by Canadian retail drug stores, according to prescription-drug tracking firm IMS Health Canada.

In a recent statement, the American Diabetes Association and the European Association for the Study of Diabetes recommended against using Avandia.

The Canadian Diabetes Association's 2008 clinical practice guidelines provide recommendations on the use of both drugs. In a statement, a spokesman said the guidelines are based on the "totality of the clinical evidence" which included a number of large trials that did not show any increased risk of heart attacks or death in patients taking Avandia. It said people with diabetes should speak with their doctor if they have questions or concerns.

-- Canwest News Service