

Diabetes drug linked to increased risk of bladder cancer

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a drug used to treat type 2 diabetes - is associated with an increased risk of bladder cancer, finds a study published on *BMJ* today.

The results show that more than two years daily exposure to [pioglitazone](#) doubles the risk of [bladder cancer](#). However, the authors stress that, in absolute terms, the risks are low – up to 137 extra cases per 100,000 person years.

No [increased risk](#) was seen for a similar drug (rosiglitazone).

Pioglitazone and rosiglitazone belong to a class of drugs called thiazolidinediones that help to control blood sugar levels in patients with type 2 [diabetes](#). Both drugs are known to increase the risk of heart failure but, after carrying out a safety review, the European Medicines Agency decided to keep pioglitazone on the market.

However, there is now some evidence suggesting that pioglitazone may be associated with an increased risk of bladder cancer.

So a team of researchers based in Canada set out to determine if the use of pioglitazone was associated with an increased risk of bladder cancer in people with [type 2 diabetes](#).

Using data from the General Practice Research Database (GPRD), which contains anonymised patient records from more than 600 UK general practices, they studied 115,727 patients newly treated with

diabetes drugs from 1988 to 2009. Cases of bladder cancer were identified and matched to up to 20 healthy control patients.

Results showed that 470 patients were diagnosed with bladder cancer during the average 4.6 years of follow-up (a rate of 89 per 100,000 person years). The rate of bladder cancer in the general UK population aged at least 65 years is 73 per 100,000 person years.

The analysis involved 376 cases, matched to 6,699 controls.

If patients had ever taken pioglitazone they were at an 83% increased risk of bladder cancer. This corresponds to 74 per 100,000 person years. This increased to 88 per 100,000 person years for patients who had taken the drug for two years or more and increased further to 137 per 100,000 years for patients who had taken 28,000mg or more.

These findings remained consistent in several further analyses designed to check the results.

The authors conclude that their results "provide evidence that pioglitazone is associated with an increased risk of bladder cancer, whereas no increased risk was observed with the thiazolidinedione rosiglitazone."

They suggest that such associations may have been underestimated in previous observational studies and say doctors, patients and regulatory agencies "should be aware of this association when assessing the overall risks and benefits of this therapy."

In an accompanying editorial, Dominique Hillaire-Buys and Jean-Luc Faillie from the Department of Medical Pharmacology and Toxicology in Montpellier, France say "it can confidently be assumed that pioglitazone increases the risk of bladder cancer. It also seems that this

association could have been predicted earlier."

Considering that the benefit of pioglitazone in reducing cardiovascular events is questionable, they suggest that "prescribers who are ultimately responsible for therapeutic choices can legitimately question whether the benefit-risk ratio of pioglitazone is still acceptable for their patients with diabetes."

Provided by British Medical Journal

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