

## The Risk of Bladder Cancer in Korean Diabetic Subjects Treated with Pioglitazone (*Diabetes Metab J* 2012;36: 371-8)

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My colleagues and I thank the comments of Sang-Yong Kim and the emphasis on our study's limitations. We agree entirely with your opinions and also recognize the problems regarding the quality of the data.

Korea has one of the world's highest smoking rates (>40%) [1] and smoking is the greatest risk factor for bladder cancer [2]. Therefore, unlike other countries, the potency of pioglitazone on bladder cancer can be offset by smoking. Furthermore, the medical milieu in our country permits pioglitazone use only after or during concurrent treatment with metformin. Moreover, we are registered as a tertiary referral hospital of the National Insurance System in Korea, so we cannot analyze hazard ratios without checking precise doses. These confounding factors are potentially responsible for the inconsistency of our results with those of previous studies.

Previous large-scale clinical studies regarding pioglitazone use reported the possible increase of bladder cancer rates. However, this observation was meaningful only when pioglitazone dose was quantified, and not from solely its use [3-8]. Our study should be interpreted in the same context. In our study, we suggest that the risk of bladder cancer in Korean diabetics treated with pioglitazone might be different from that of other ethnicities. We could not have concluded that pioglitazone had no effect on bladder cancer risk because the odds of using pioglitazone were relatively high, although it was not significant. In addition, this study was a case-control designed study

that reviewed electronic medical records in a hospital. We could not determine the dose-response relationship of pioglitazone on bladder cancer due to a lack of data and resources. The conclusion of risk stratification under pioglitazone use must be supported with data from National Health Insurance Corporation.

We were unsuccessful in obtaining insurance claims data from the National Health Insurance Corporation (or Health Insurance Review & Assessment Service) in order to analyze the effects of pioglitazone use on bladder cancer on a population-based level. Compared to other developed countries, there are many administrative obstacles for conducting population-based studies using insurance claims data in Korea. The awareness level of our government and/or public institutions, as well as that of the medical community, needs improvement. Without these improvements in awareness and changes in the social atmosphere, academic achievements will be limited.

These circumstances gave us no other choice but to pursue a large, multi-center study using our electronic medical records data. We are currently investigating additional data across the multi-institutional group, but for now, this is most optimal method of evaluating this relationship. We hope improvements in the governmental, medical, and social environments will help us overcome future problems in obtaining high quality data.

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## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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