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## Large U.K. database shows sulfonylurea mortality link

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BARCELONA – Treatment of type 2 diabetes with a sulfonylurea drug was tied to a significantly increased risk of death in two large U.K. epidemiology studies with a total of more than 100,000 patients.

These and other recent findings that raised questions about the safety and efficacy of sulfonylurea drugs for type 2 diabetes highlight the need for regulatory reassessment of the sulfonylurea drug class, Craig J. Currie, Ph.D., said at the annual meeting of the European Association for the Study of Diabetes.

"The safety of sulfonylureas needs urgent evaluation," said Dr. Currie, professor of applied pharmacoepidemiology at Cardiff (Wales) University. "Regulatory agencies have to take this seriously." He noted that current [U.K. recommendations](#) from the U.K. National Institute for Health and Care Excellence (NICE) cite sulfonylurea drugs as the top second-line drug treatment for patients with type 2 diabetes if monotherapy with metformin fails. Last year, management guidelines from the American Diabetes Association and the EASD listed sulfonylurea drugs as candidate second-line agents after metformin along with several other drug classes ([Diabetes Care 2012;35:1364-79](#)).



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### Dr. Craig J. Currie

But others cautioned of the risk for unrecognized confounding when using observational data to gauge

drug safety. "I'm not sure they can get rid of all the confounders; the patients [treated with a sulfonylurea] may just be fundamentally different. In most clinical trials we did not see harm" from sulfonylureas, commented Dean T. Eurich, Ph.D., a pharmacoepidemiologist at the University of Alberta in Edmonton.

Both studies reported by Dr. Currie and his associates used data collected by the [Clinical Practice Research Datalink](#), an observational database of the U.K. National Health Service that routinely collects data from a representative sample of British patients. [In one study](#), they focused on patients who began initial therapy for type 2 diabetes during 2000-2012 with metformin monotherapy, 76,811 patients, or sulfonylurea monotherapy, 15,687 patients. During an average 3-year follow-up, the all-cause mortality rate was roughly 14 deaths/1,000 patient-years for those on metformin, and about 45/1,000 patient-years for those on a sulfonylurea. [After adjustment for many potential confounders, including age, sex, body mass index, duration of diabetes, serum creatinine, and hemoglobin A<sub>1c</sub> level, the analysis found a relative 58% increased risk for death in the sulfonylurea patients compared with those taking metformin,](#) a statistically significant difference, reported Christopher L. Morgan, a researcher at Cardiff University.



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### Christopher L. Morgan

[The second study](#) compared patients who began a two-drug combination regimen during 2007-2013, comprising 33,983 patients who began metformin plus a sulfonylurea and 7,864 who began metformin plus a dipeptidyl peptidase-4 inhibitor. The adjusted rate of [all-cause mortality was a relative 36% higher among patients treated with a sulfonylurea, compared with those treated with a DPP-4 inhibitor,](#) Dr. Currie reported.

[Metformin plus a sulfonylurea is the most commonly used drug combination for treating type 2 diabetes worldwide,](#) Dr. Currie noted.

[He speculated that sulfonylureas may boost mortality by increasing insulin levels and thereby causing more episodes of severe hypoglycemia than other oral diabetes drugs.](#)

The study was funded by Astra Zeneca and Bristol-Myers Squibb. Dr. Currie said he owns a drug-assessment company that has done work for several drug companies. Mr. Morgan and Dr. Eurich said they had no relevant financial disclosures.

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