

Heart risks of glucose-lowering drugs being overlooked in clinical trials

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Why is heart failure not more rigorously assessed in clinical trials of antidiabetes drugs? In a Personal View, published in *The Lancet Diabetes & Endocrinology* journal, Professor John McMurray of The University of Glasgow and colleagues review evidence that hospitalization for heart failure is one of the most common and prognostically important complications of diabetes. Moreover, increasing evidence shows that some glucose-lowering drugs increase the risk of heart failure. Yet, heart failure is rarely considered as a key outcome, or even part of composite cardiovascular outcomes, in clinical trials of glucose-lowering drugs.

Previously, the ability of an antidiabetes [drug](#) to lower glucose was used in clinical trials accepted as a surrogate of its ability to reduce the risk of microvascular disease, and possibly cardiovascular risk. Recent evidence has suggested, however, that some antidiabetes drugs may increase patients' cardiovascular risk, despite their ability to effectively lower blood glucose. These findings have prompted the FDA and EMA to make new regulations requiring [cardiovascular outcomes](#) trials for new antidiabetes drugs.

Such cardiovascular outcomes trials have typically used so-called major adverse cardiovascular events (MACE) as a primary outcome. This combined outcome usually includes cardiovascular death, heart attack, and stroke. However, as McMurray and colleagues explain, [heart failure](#) can be more common than any of these other cardiovascular outcomes, especially in patients with advanced diabetes, and it is also more closely associated with premature death. Thus, its omission as a key endpoint in

clinical trials could mean that important cardiovascular effects of the glucose-lowering drugs being tested are being overlooked.

According to Professor McMurray, "Fortunately, some trials in progress are taking heart failure into account as a secondary outcome. But many others are neglecting to report this important complication as a key trial outcome. Until heart failure is systematically evaluated in [clinical trials](#), the cardiovascular safety of antidiabetes drugs will remain uncertain."

More information: Study paper: [www.thelancet.com/journals/lan.../s0140-6736\(14\)70031-2/abstract](http://www.thelancet.com/journals/lan.../s0140-6736(14)70031-2/abstract)

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