

Doctors find insulin dose not a risk factor for cardiovascular mortality

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A NIH-sponsored double-blinded, randomized clinical trial entitled Action to Control Cardiovascular Risk in Diabetes (ACCORD study) came to a halt seven years ago after patients receiving more intensive diabetes therapy were found to have a higher mortality rate, compared to the standard therapy. In 2008, the results were released, puzzling researchers. Subsequent investigations have not been able to clearly identify the exact reason for the increased mortality, although some previous epidemiologic and mechanistic studies did suggest that insulin may be associated with adverse cardiovascular outcomes.

It was with this knowledge that Elias S. Siraj, MD, FACP, FACE, Professor of Medicine at the Lewis Katz School of Medicine at Temple University (LKSOM) and Director of the Diabetes Program at Temple University Hospital (TUH), and Daniel J. Rubin, MD, MSc, FACE, Assistant Professor of Medicine at LKSOM and Chair of the Glycemic Control Taskforce at TUH, joined others in the ACCORD study group to examine whether it was the dose of insulin that could be contributing to increased cardiovascular mortality.

The post-hoc analysis was published online on October 13 by *Diabetes Care*, a leading diabetes journal. "Insulin is a very important medication for patients with diabetes and everyone really wanted to know if insulin could be harmful at higher doses," says Dr. Siraj, lead investigator of the post-hoc analysis.

"Our initial unadjusted analysis showed that an increase in insulin dose

by 1 unit/ kg of body weight increased the risk of cardiovascular death by 83 to 236 percent (Hazards ratio of 1.83 to 3.36). But, we had to adjust the data for various medical conditions and other factors potentially associated with insulin use," says Dr. Siraj.

After appropriate statistical adjustment, the dose of insulin was found not to be associated with increased cardiovascular death, and therefore Dr. Siraj and his team concluded that insulin is not an independent risk factor for [cardiovascular death](#). "This is reassuring for many physicians and their patients. But, our findings won't lay to rest the on-going discussion about insulin use and the potential for increased risk, especially at higher doses. There are still unanswered questions and more studies are needed to answer them definitively," explains Dr. Siraj.

In the United States, diabetes is the leading cause of blindness, kidney failure, non-traumatic amputations, and a major contributor to cardiovascular disease and death. In 2014, more than 29 million Americans were diagnosed with diabetes, up from the previous estimate of 26 million in 2010, according to the U.S. Centers for Disease Control and Prevention. A substantial percentage of patients with diabetes are managed with [insulin therapy](#).

The initial ACCORD study recruited and studied over 10,000 patients with type 2 [diabetes](#) in the US and Canada. It examined whether outcomes, including cardiovascular outcomes, were different when aiming for a lower, near normal blood sugar target (using an intensive therapy approach, which usually leads to more insulin use) compared to a higher (but acceptable) blood sugar target using a standard approach.

"Whether or not [insulin](#) has harmful cardiovascular effects is an important question. We were pleased with the opportunity to be the first group to test our hypothesis in a relatively large and well-characterized population. While this does not end the debate, our results are

reassuring," says Dr. Rubin.

Provided by Temple University

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