

Study results leave search for new diabetes and heart disease treatments unresolved

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Treatment with the anti-hypertensive drug valsartan (Diovan) led to a modest reduction in the development of type 2 diabetes but did not significantly reduce cardiovascular events in patients with impaired glucose tolerance, according to researchers at Duke University Medical Center and the University of Oxford. They jointly reported results at the American College of Cardiology meeting today from the world's first study designed to find ways to control the progression to diabetes and cardiovascular disease in people at risk.

The study also showed the blood sugar lowering drug nateglinide (Starlix) used to treat diabetes, proved ineffective at halting progression to diabetes, and had no significant impact on reducing cardiovascular events.

"This is a sobering confirmation of the need to continue to focus on lifestyle improvements while also accelerating the efforts to develop new treatments for the exploding epidemics of diabetes and [cardiovascular disease](#) around the world," said Robert M. Califf, MD, Vice Chancellor for Clinical Research at Duke University School of Medicine, and Director of the Duke Translational Medicine Institute. He presented the results of the NAVIGATOR trial today with Rury Holman, MD, Professor of Diabetic Medicine and Director of the Diabetes Trials Unit, Oxford.

Simultaneous publication of the results appears online today in the [New England Journal of Medicine](#).

"The diabetes epidemic is a major challenge for all healthcare systems," Holman said. "We have effective treatments for lowering [high blood sugar](#) and high blood pressure, but we urgently need pharmacologic interventions that will minimize the likelihood of diabetes and heart disease in high risk populations."

More than 150 million people worldwide have diabetes - 90 percent of which is type 2. Global forecasts predict an increase in disease incidence of almost 50 percent by 2025. Heart disease incidence will rise too as patients with diabetes are up to 10 times more likely to have higher rates of coronary artery disease, stroke and peripheral arterial disease than people without diabetes.

The NAVIGATOR trial was designed to address whether established treatments for diabetes and blood pressure could also prevent the onset of diabetes and cardiovascular events in patients aged 50 or more who had impaired glucose tolerance and cardiovascular risk factors or cardiovascular disease. Researchers analyzed data from more than 9,300 patients at 806 centers in 40 countries who were randomized to the two study drugs or placebo. All participants received a lifestyle modification program aimed at reducing body weight and dietary fat intake while increasing physical activity.

After about five years of follow-up, the researchers found nateglinide, an insulin secretion enhancer, did not reduce the incidence of diabetes. The disease developed in 36 percent (1674) of the nateglinide group and 34 percent (1580) of the placebo group. Nateglinide also had no significant effect on cardiovascular outcomes.

The angiotensin receptor blocker valsartan had a moderate effect on diabetes progression, with a 14 percent relative risk reduction (equating to 38 fewer cases of diabetes per 1000 participants treated for 5 years), but no significant impact on cardiovascular outcomes.

Califf and Holman say that administration of the oral [glucose tolerance test](#) (OGTT) without the study drug created difficulties in interpreting the diabetes outcome for nateglinide.

Regardless, the researchers say the trial confirms the high risk of diabetes in the population studied, and reinforces the need to apply the known benefits of lifestyle modification and to continue the search for successful and safe medications.

"We must continue to develop new therapies while encouraging people to exercise and pay attention to what they eat," said John McMurray, MD, Professor of Medical Cardiology at the University of Glasgow, Scotland, and a member of the NAVIGATOR Trial's executive committee. "Losing as little as five percent of body weight has been shown to make a dramatic difference in other studies. NAVIGATOR participants lost weight on average showing that a relatively simple lifestyle program can make a difference." However, stated, McMurray, "In patients with hypertension in need of drug therapy, clinicians might consider an agent that demonstrated evidence to delay or prevent progression to diabetes, and not increase this risk, as may be the case with some antihypertensive treatments."

"Until just a few years ago, drugs for [diabetes](#) were approved each year on the basis of nothing more than symptomatic relief or effects on putative surrogate markers of disease," Califf said. "The new FDA and EMEA requirements are now forcing studies of new drugs to modulate blood sugar to show whether or not they have an impact on cardiovascular disease prevention or development, and NAVIGATOR gives us a lot of information about issues in these long term studies. I commend the sponsor for having the courage to conduct this study before it was required and hope others will look closely at NAVIGATOR and incorporate the lessons into their trials."

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