

Long-term follow-up of diabetes prevention program shows continued reduction in diabetes development

June 16 2014

Treatments used to decrease the development of type 2 diabetes continue to be effective an average of 15 years later, according to the latest findings of the Diabetes Prevention Program Outcomes Study, a landmark study funded by the National Institutes of Health (NIH).

The results, presented at the American Diabetes Association's 74th Scientific Sessions, come more than a decade after the Diabetes Prevention Program, or DPP, reported its original findings. In 2001, after an average of three years of study, the DPP announced that the study's two interventions, a lifestyle program designed to reduce weight and increase activity levels and the diabetes medicine metformin, decreased the development of type 2 diabetes in a diverse group of people, all of whom were at high risk for the disease, by 58 and 31 percent, respectively, compared with a group taking placebo.

The Diabetes Prevention Program Outcomes Study, or DPPOS, was conducted as an extension of the DPP to determine the longer-term effects of the two interventions, including further reduction in diabetes development and whether delaying diabetes would reduce the development of the [diabetes complications](#) that can lead to blindness, kidney failure, amputations and heart disease. Funded largely by the NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the new findings show that the [lifestyle intervention](#) and metformin treatment have beneficial effects, even years later, but did

not reduce [microvascular complications](#).

Delaying Type 2 Diabetes

Participants in the study who were originally assigned to the lifestyle intervention and metformin during DPP continued to have lower rates of type 2 diabetes development than those assigned to placebo, with 27 percent and 17 percent reductions, respectively, after 15 years.

"What we're finding is that we can prevent or delay the onset of type 2 diabetes, a chronic disease, through lifestyle intervention or with metformin, over a very long period of time," said David M. Nathan, MD, Chairman of the DPP/DPPOS and Professor of Medicine at Harvard Medical School. "After the initial randomized treatment phase in DPP, all participants were offered lifestyle intervention and the rates of diabetes development fell in the metformin and former placebo groups, leading to a reduction in the treatment group differences over time. However, the lifestyle intervention and metformin are still quite effective at delaying, if not preventing, type 2 diabetes," Dr. Nathan said. Currently, an estimated 79 million American adults are at high-risk for developing type 2 diabetes.

Microvascular Complications

The DPPOS investigators followed participants for an additional 12 years after the end of the DPP to determine both the extent of [diabetes prevention](#) over time and whether the study treatments would also decrease the small vessel -or microvascular- complications, such as eye, nerve and kidney disease. These long-term results did not demonstrate significant differences among the lifestyle intervention, metformin or placebo groups on the microvascular complications, reported Kieren Mather, MD, Professor of Medicine at Indiana University School of

Medicine and a study investigator.

"However, regardless of type of initial treatment, participants who didn't develop diabetes had a 28 percent lower occurrence of the microvascular complications than those participants who did develop diabetes. These findings show that intervening in the prediabetes phase is important in reducing early stage complications," Dr. Mather noted. The absence of differences in microvascular complications among the intervention groups may be explained by the small differences in average glucose levels among the groups at this stage of follow-up.

Risk for Cardiovascular Disease

The DPP population was relatively young and healthy at the beginning of the study, and few participants had experienced any severe cardiovascular events, such as heart attack or stroke, 15 years later. The relatively small number of events meant that the DPPOS researchers could not test the effects of interventions on cardiovascular disease. However, the research team did examine whether the study interventions, or a delay in the onset of type 2 diabetes, improved [cardiovascular risk factors](#).

"We found that cardiovascular risk factors, such as hypertension, are generally improved by the lifestyle intervention and somewhat less by metformin," said Ronald Goldberg, MD, Professor of Medicine at the University of Miami and one of the DPPOS investigators. "We know that people with type 2 diabetes are at much higher risk for heart disease and stroke than those who do not have diabetes, so a delay in risk factor development or improvement in risk factors may prove to be beneficial."

Long-term Results with Metformin

The DPP/DPPOS is the largest and longest duration study to examine the effects of metformin, an inexpensive, well-known and generally safe diabetes medicine, in people who have not been diagnosed with diabetes. For DPPOS participants, metformin treatment was associated with a modest degree of long-term weight loss. "Other than a small increase in vitamin B-12 deficiency, which is a recognized consequence of metformin therapy, it has been extremely safe and well-tolerated over the 15 years of our study," said Jill Crandall, MD, Professor of Medicine at Albert Einstein College of Medicine and a DPPOS investigator. "Further study will help show whether metformin has beneficial effects on heart disease and cancer, which are both increased in people with type 2 diabetes."

Looking to the Future

In addition to the current findings, the DPPOS includes a uniquely valuable population that can help researchers understand the clinical course of type 2 diabetes. Since the participants did not have diabetes at the beginning of the DPP, for those who have developed diabetes, the data show precisely when they developed the disease, which is rare in previous studies. "The DPP and DPPOS have given us an incredible wealth of information by following a very diverse group of people with regard to race and age as they have progressed from prediabetes to diabetes," said Judith Fradkin, MD, Director of the NIDDK Division of Diabetes, Endocrinology and Metabolic Diseases. "The study provides us with an opportunity to make crucial discoveries about the clinical course of [type 2 diabetes](#)."

Dr. Fradkin noted that the study population held promise for further analyses because researchers would now be able to examine how developing diabetes at different periods of life may cause the disease to progress differently. "We can look at whether [diabetes](#) behaves differently if you develop it before the age of 50 or after the age of 60,"

she said. "Thanks to the large and diverse population of DPPOS that has remained very loyal to the study, we will be able to see how and when complications first develop and understand how to intervene most effectively."

She added that NIDDK had invited the researchers to submit an application for a grant to follow the study population for an additional 10 years.

Provided by American Diabetes Association

Citation: Long-term follow-up of diabetes prevention program shows continued reduction in diabetes development (2014, June 16) retrieved 3 May 2024 from <https://medicalxpress.com/news/2014-06-long-term-follow-up-diabetes-reduction.html>

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