

Study points to more individualized treatment options for youth with onset type 2 diabetes

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New results from the Treatment Options for Type 2 Diabetes in Youth study (TODAY) examined predictors of the outcomes in youth with onset type 2 diabetes (T2D) based on early characteristics at diagnosis, and suggests the need for specific criteria for adolescents that are different from those in adults. The findings indicate that if youth with T2D have an A1C greater than 6.3 percent three months after beginning treatment with metformin, the drug generally accepted as the first drug to be used in the treatment of T2D, they have nearly four times the risk for losing glucose control, within a median time of 11 months.

The TODAY study, the largest clinical trial to study the <u>treatment</u> of youth-onset T2D to-date, randomly assigned youth with T2D to one of three treatment groups to examine optimal approaches for disease management: <u>metformin</u> alone, metformin and rosiglitazone together, or metformin plus an intensive lifestyle program aimed to help participants lose weight and increase exercise.

TODAY researchers followed participants' <u>blood glucose levels</u> through the A1C test, which measures a person's average levels of blood glucose over a three-month period. Typically, a person without diabetes should have an A1C measurement below 5.7 percent, while an A1C above 6.5 percent is considered diagnostic for diabetes. People who have diabetes often aim for an A1C below 7 percent as a marker of good control, which is considered to be 'in target.'



The primary results of the TODAY study have been previously reported and showed that approximately 50 percent of youth with T2D failed treatment with metformin, the first drug generally used in treatment of T2D. This failure rate is much higher than that seen with metformin therapy in adult patients, suggesting that progression of the disease may be more aggressive in some youth than adults.

At the same time, the study showed that 50 percent of participants were able to maintain <u>glucose control</u> regardless of treatment group. These results suggested that there may be at least two distinct populations of youth with T2D, where one group needs intensive therapy to maintain blood glucose levels and the other does not.

Researchers from the TODAY study group examined the data in an additional analysis to understand if they could predict early on which patients would fall into which group. The ability to predict the outcome early on would allow appropriate treatment measures to be instituted to prevent loss of control of <u>blood glucose</u> in those who will need additional treatment, while avoiding excessive therapy for those who will be able to manage their disease adequately on metformin alone. This analysis indicated that the A1C test is an easily obtained clinical marker that effectively distinguishes the two groups and may provide important treatment information to providers. Furthermore, the A1C cut-off that distinguishes those who will need early intensive therapy of 6.3 percent is lower than expected and lower than the target generally considered to indicate good control.

"These results already have changed my own clinical practice when caring for youth who have A1C values that are 'in target' but above the cutoff we've identified," said Phil Zeitler, MD, PhD, study chair for the TODAY study, chair of the Department of Endocrinology, Children's Hospital Colorado, and professor and head of the Section of Endocrinology, Department of Pediatrics, University of Colorado School



of Medicine. "With the current results, I am much more likely to recommend intensification of therapy among youth in this population group who have not attained a non-diabetic A1C, even if they have reached targets generally recommended for adults by the American Diabetes Association."

Type 2 diabetes has risen in youth along with the rise of childhood obesity, and is one of the most common chronic disorders in adulthood, with an estimated 1.5 million new cases in the U.S. each year. Although the disorder in <u>youth</u> remains much rarer than among adults, with an estimated 5,000 new cases in the U.S. annually, the prevalence has increased dramatically since first recognized by Dr. Zeitler and colleagues in 1996, and is considered a serious emerging public health concern due to the association of T2D with cardiovascular complications, as well as kidney, nerve and eye diseases.

Provided by Children's Hospital Colorado

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