Type 2 Self-Monitoring Improves Glucose Control

BY BRUCE JANCIN

FROM A CONFERENCE ON THE MANAGEMENT OF DIABETES IN YOUTH

KEYSTONE, COLO. – When it comes to self-monitoring of blood glucose, it's not the quantity that matters, it's the quality of the testing.

This was the central lesson of the Structured Testing Program (STeP) study, a 12-month, randomized, multicenter trial conducted in poorly controlled, non–insulin-treated type 2 diabetes patients. STeP

VITALS

Major Finding: Mean HbA$_{1c}$ fell from 8.9% to 8.0% over 12 months in controls and dropped significantly more, to 7.7%, in the structured self-monitoring of blood glucose group.

Data Source: A randomized, multicenter trial in 483 poorly controlled, non–insulin-treated type 2 diabetes patients.

Disclosures: The STeP study was funded by Roche Diagnostics. Dr. Polonsky has worked as a consultant for the company.

showed that self-monitoring of blood glucose (SMBG) has clinical value in such patients, provided the testing is done in a structured way that facilitates timely treatment decisions by their primary care physician.

Patients assigned to the structured SMBG intervention showed a significantly greater reduction in their mean glycosylated hemoglobin at 12 months than did active controls. They also evidenced significantly more shrinkage in their mean amplitude of glycemic excursions and greater quality of life improvement as reflected in depression and diabetes-related emotional distress scores, William H. Polonsky, Ph.D., reported at the conference.

"The most interesting thing is how the study impacted physicians," said Dr. Polonsky at the conference sponsored by the University of Colorado Denver and the Children's Diabetes Foundation at Denver. "Use of the testing form to create a blood glucose snapshot for quarterly review contributes to more aggressive treatment intensification."

The improvements documented in the STeP study were achieved using a relatively modest but carefully considered intervention: That is, patients randomized to structured SMBG were asked to measure their blood glucose seven times a day on 3 consecutive days within 2 weeks prior to the quarterly diabetes-focused visit with their primary care physician.

Patients recorded and graphed these 21 blood glucose readings using the Roche Diagnostics Accu-Chek 360 View analysis system. They brought the form with them to the quarterly office visit.

Patients could do as much or as little testing as they wanted during the rest of each 3-month period. It was only those 21 measurements obtained on 3 consecutive days once every 3 months that served as the basis for physician/patient discussion and treatment modifications. In fact, patients in the intervention arm achieved greater improvement in HbA$_{1c}$ than did controls while using significantly fewer blood glucose test strips, said Dr. Polonsky, founder and CEO of the Behavioral Diabetes Institute and a psychologist at the University of California, San Diego.

The STeP study involved 483 poorly controlled patients with type 2 diabetes in 34 primary care practices. Their mean baseline HbA$_{1c}$ was 8.9%, with a body mass

Patients recorded and graphed their readings for quarterly review.

index of 35.1 kg/m^2 and a 7.6-year disease duration. Patients in the intervention and active control/usual care arms received a free blood glucose meter and test strips and were instructed in their use at the baseline visit.

Primary care physicians in practices assigned to the intervention received 2 hours of training in how to interpret and make lifestyle and/or medication changes based on their patients' structured SMBG charts; the patients themselves got a DVD explaining their task. All STeP participants met with their physician in a diabetes-focused visit at months 1, 3, 6, 9, and 12.

Mean HbA$_{1c}$ fell from 8.9% to 8.0% over the course of 12 months in controls and dropped significantly more, to 7.7%, in the structured SMBG group. Moreover, among the 130 patients in the intervention arm who adhered to the intervention protocol by completing at least 80% of their quarterly forms, the mean HbA$_{1c}$ at 12 months was 7.6%, while in nonadherent patients, the final HbA$_{1c}$ was the same as that of control patients. A significant drop from months 1 to 12 was seen in preprandial and postprandial glucose excursions at all meals in the structured SMBG group.

Scores on the Patient Health Questionnaire depression screening instrument (PHQ-8) dropped significantly in both study arms over the 12 months, but the reduction was significantly greater in the structured SMBG arm. Moreover, when the analysis was restricted to subjects having an elevated baseline depression score of greater than 10 on the PHQ-8, the intervention group showed a dramatic, nearly 6-point reduction over the study period, a 2.4-point greater drop in depressive mood and symptoms than that seen in controls. ∎

Ped Type 1 Diabetes Cases Often Misdiagnosed as Type 2

BY DOUG BRUNK

FROM THE ANNUAL SCIENTIFIC SESSIONS OF THE AMERICAN DIABETES ASSOCIATION

SAN DIEGO – More than a third of type 1 diabetes cases in a large pediatric Medicaid population were misdiagnosed as having type 2 early in management, results from a 10-year analysis showed.

VITALS

Major Finding: Some 61% of children and adolescents initially diagnosed with type 2 diabetes maintained a diagnosis of type 2 diabetes over a median of 7 years, while 39% were reclassified as having type 1 diabetes.

Data Source: A study of 4,070 subjects aged 17 years and younger enrolled in the South Carolina State Medicaid Program who had at least two initial service encounters with an ICD-9 diagnosis of type 2 diabetes in 1996-2006.

Disclosures: Dr. Tripathi said that he had no relevant financial disclosures.

Such misclassification "may be associated with significantly increased risk of life-threatening, but potentially preventable, acute complications such as diabetic ketoacidosis," Dr. Avnish Tripathi said at the meeting. "These findings have implications for primary health care of diabetes and reiterate the importance of performing laboratory tests such as autoantibody titers and C-pep-

tide levels for establishing type 1 diabetes pathology earlier in the clinical management process," said Dr. Tripathi, a doctoral candidate in public health at the University of South Carolina, Columbia.

Misclassification can occur both ways, he added. Pediatric diabetes is usually assumed to be type 1, so "it may be diagnosed as such even if characteristics point to type 2 diabetes." But increased awareness of type 2 diabetes in the pediatric population means that "type 1 diabetes in overweight or obese patients may be diagnosed as type 2 diabetes."

The researchers analyzed data from 4,070 subjects aged 17 years and younger enrolled in the South Carolina State Medicaid Program who had at least two initial service encounters with an ICD-9 diagnosis of type 2 diabetes in 1996-2006. They also evaluated ICD-9 codes for comorbid medical complications such as obesity and dyslipidemia, and for vascular and other complications such as diabetic ketoacidosis.

Of the 4,070 children and adolescents, more than half (57%) were female, 56% were non-Hispanic black, their median age was 8 years, and they were followed for a median of 7 years. Dr. Tripathi re-

ported that 2,489 of the subjects (61%) maintained a diagnosis of type 2 diabetes over time, whereas 39% were later reclassified as having type 1. After adjustment for variables, older age at diagnosis increased the risk of misclassification (odds ratio, 1.66), while being obese or overweight decreased the risk of being in the misclassification group (OR, 0.79).

Compared with those who maintained a type 2 diagnosis, a significantly higher proportion of misclassified youth were

treated with insulin (82% vs. 2%, respectively), and went on to develop dyslipidemia (P less than .001) and hypertension (P = .0001). Misclassified youth also had a 50-fold increased risk of at least one incidence of diabetic ketoacidosis (OR, 49.5), nearly a 4-fold increased risk of developing cumulative diabetic neuropathy (OR, 3.75), a higher risk of cumulative renal complications (OR, 1.27), and a lower risk of developing cardiac conditions (OR, 0.81). ∎

New Criteria Needed for Type 2 Dx

VIEW ON THE NEWS

This concept is not new, and there have been a number of publications over the past decade regarding the difficulty in clinically separating type 1 and type 2 diabetes, as at least one-third of type 1 patients in our series are overweight or obese at diagnosis (Pediatr. Diabetes 2003;4:110-3; Diabetes Care 2003;26:2876-82; Diabetes Care 2003;26:2871-5). These findings have since been confirmed by the TODAY (Treatment Options for Type 2 Diabetes in Adolescents and Youth) study and the SEARCH for Diabetes in Youth study. In the current study, I found it difficult to evaluate what the criteria for the reclassification were.

The message to pediatricians, general practitioners, and diabetologists should be that being obese does not protect the patient from type 1 diabetes, and thus, there need to be other criteria to make the diagnosis of type 2 in children.

DOROTHY BECKER, M.D., *is professor of pediatrics and director of endocrinology and diabetes at Children's Hospital of Pittsburgh and the University of Pittsburgh, who was asked to comment on Dr. Tripathi's findings. Dr. Becker said she had no relevant financial disclosures. Her 2003 series of diabetes studies was funded by the National Institutes of Health.*