OBSERVATIONS

Extended 6-Month Follow-Up of A Randomized Clinical Trial to Assess the Efficacy and Safety of Real-Time Continuous Glucose Monitoring in the Management of Type 1 Diabetes in Young Children Aged 4 to <10 Years

In a 6-month randomized trial of continuous glucose monitoring (CGM) in children 4–9 years of age with type 1 diabetes (1), the DirecNet Study Group reported no difference in change in A1C between the CGM and usual care groups, although parents expressed high satisfaction with use of CGM. In a 6-month posttrial phase, the CGM group continued to use CGM and the control group was started on CGM. This observation provides a summary of the findings for both groups during this posttrial phase.

Sixty-four of the 69 children in the CGM group who completed the trial participated in the extension phase; all 64 completed the 12-month visit. Baseline A1C was 7.9 ± 0.8 and 7.8 ± 0.8% at the beginning of the extension phase and 7.9 ± 0.8% at 12 months. During the extension phase, A1C decreased ≥0.5% in 14% and increased ≥0.5% in 25%. Sensor use dropped from a median of 92 h/week at 6 months to 60 h/week at 12 months; 33% of subjects were wearing the sensor ≥6 days/week at 12 months, compared with 44% at 6 months. There was no correlation between sensor use and change in A1C during the extension phase and no significant differences in glycemic profiles between the initial 6 month and extension phases. Severe hypoglycemia rate dropped from 9.5 events/100 person-years in the first 6 months to 3.3 in the extension phase, with no seizures or loss of consciousness. On the CGM Satisfaction questionnaire, parents continued to endorse feeling safer with use of CGM and that CGM made adjusting insulin easier.

Of the 68 children in the control arm who completed the initial 6-month trial, 66 initiated CGM in the posttrial phase; 61 completed the 12-month visit. Mean A1C was 7.8 ± 0.8% at CGM initiation and 7.8 ± 0.7% 6 months later ($P = 0.54$). A decrease in A1C ≥0.5% was seen in 21% and an increase in A1C ≥0.5% was seen in 31%. CGM wear decreased from a median of 95 h/week during the first month to 32 h/week at the end of the study. Only 16% of subjects were using CGM ≥6 days/week by study end. Significant improvements from 6 to 12 months were observed for the percentage of sensor values ≤70 mg/dL (median 2.2 vs. 1.4%; $P = 0.001$) and the coefficient of variation (41 vs. 37%; $P < 0.001$), but the percentage in the target range 71–180 mg/dL was similar (52 vs. 54%). Severe hypoglycemia rate was 13.3/100 person-years (four events in 61 participants). The CGM Satisfaction questionnaire completed by parents indicated high benefit and low hassles with CGM despite the lack of improvement in glycemic indices.

Despite parental reports of great satisfaction with CGM, glycemic control did not improve in these young children, and sensor use progressively decreased. Identifying barriers to improved glycemic control will be important in future studies of young children with type 1 diabetes who use CGM. Meaningful improvement in control and reduction in hypoglycemia in this group may require closed-loop insulin delivery.

MICHAEL TANSEY, MD[1]
STUART WEINZIMER, MD[2]
ROY BECK, MD, PHD[3]
KATRINA RUEDY, MSPH[3]
PEIYAO CHENG, MPH[3]
WILLIAM TAMBORLANE, MD[2]
CRAIG KOLLMAN, PHD[3]
NELLY MAURAS, MD[4]
LARRY FOX, MD[4]
JULIE COFFEY, ARNP[1]
NEIL H. WHITE, MD[5]
FOR THE DIABETES RESEARCH IN CHILDREN NETWORK (DIRECNET) STUDY GROUP

From the [1]Division of Pediatric Endocrinology, University of Iowa, Iowa City, Iowa; the [2]Section of Pediatric Endocrinology, Yale University, New Haven, Connecticut; the [3]Jaeb Center for Health Research, Tampa, Florida; [4]Pediatric Endocrinology, Nemours Children's Clinic, Jacksonville, Florida; and the [5]Department of Pediatrics, Washington University, St. Louis, Missouri.

Corresponding author: Katrina Ruedy, direcnet@jaeb.org.

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