Patient Selection Key for Monitor/Pump Success

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CHICAGO — Findings from a recent study suggest that the combined real-time continuous glucose monitor/insulin pump system reduces glycemic variability and improves glucose control in selected insulin pump users with type 1 diabetes, Dr. Irl B. Hirsch reported at the annual scientific sessions of the American Diabetes Association.

A significant finding of the 6-month study was that the benefits of real-time continuous glucose monitoring (RT-CGM) were realized only among patients who wore the sensor device consistently. "A key point is that while we're learning to use this new technology, we have to choose our patients carefully," said Dr. Hirsch, professor of medicine and medical director of the Diabetes Care Center at the University of Washington, Seattle.

In the study, 138 adolescents and adults with poorly-controlled type 1 diabetes (defined as having a hemoglobin A_{1c} of 7.5% or greater) despite 6 months or more of insulin pump therapy were randomized to either wear the combined pump/RT-CGM device (MiniMed Paradigm 722 System) and to perform self-monitoring of blood glucose (SMBG) four or more times per day, or to perform SMBG while wearing the MiniMed pump by itself. All insulin adjustments were based on SMBG values. Clinical staff made contact with all the patients on a weekly or biweekly basis throughout the study period. The study was funded by Medtronic, maker of the devices.

The group was 90% white, nearly two-thirds female, and had a mean diabetes duration of 18 years. There were 40 adolescents with a mean age of 14 years, and 98 adults with a mean age of 41 years. Mean hemoglobin A_{1c} (HbA_{1c}) levels did not differ between the two groups at baseline.

At 13 weeks, mean HbA_{1c} levels had dropped significantly and to a nearly identical degree in both groups, from 8.4% to 7.8% in the controls and from 8.5% to 7.7% in the CGM group. There were no further significant drops in either group, and by week 26, both groups had a mean HbA_{1c} of 7.8%. However, the proportion reaching the HbA_{1c} target of less than 7% was significantly greater in the CGM patients, at 38%, versus just 19% of the controls. Similar results were seen when the adults were analyzed separately: There were no differences in HbA_{1c} lowering between the two groups overall, but a significantly better 39% of the CGM group reached an HbA_{1c} of less than 7%, compared with 25% of the controls.

Benefits were realized only among patients who wore the sensor device consistently.

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Among the adolescents, only the CGM group had a significant drop in HbA_{1c} from baseline, from 8.8% to 8.0% at 26 weeks, with 35% reaching an HbA_{1c} below 7%, compared with just 9% of controls. Dr. Hirsch reported.

Differences in the amount of hypoglycemia—but not hyperglycemia—could help explain why the proportion dropping below 7.0% between the two groups was significantly different, whereas the overall HbA_{1c} values were not. While there were no differences in the time and amplitude of exposure (in mg/dL per minute) for hyperglycemia between the two groups, the controls spent significantly more time at glucose levels below 70 mg/dL than did the CGM group (0.8 vs. 0.3 mg/dL per minute), suggesting that they had more glucose variability. "The A_{1c} and the hyperglycemic exposure were the same, but hypoglycemia was less with the sensor group. That means there had to be more variability in the controls and the A_{1c} isn't sensitive enough to pick that up," Dr. Hirsch surmised.

Compliance strongly predicted the results among the CGM patients. With "compliance" defined as wearing the sensor 6 days per week (meaning it was possible to be more than 100% compliant) HbA_{1c} levels among the patients with 100% or greater compliance dropped from 8.6% at baseline to 7.7% at 26 weeks. Those with 80%-100% compliance dropped similarly, from 8.4% to 7.7%, as did those with 60%-80% compliance, 8.2% to 7.5%. All of those reductions were significant. However, when compliance dropped below 60%, mean HbA_{1c} actually rose slightly (but not significantly), from 9.5% to 9.6%. ■