Continuous Glucose Monitor for Kids Is Approved

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Medtronic's real-time continuous glucose monitoring devices will be available for use in children aged 7-17 years later this year.

The company's REAL-Time Continuous Glucose Monitor (CGM) systems, previously approved by the Food and Drug Administration only for adults, will be available in specifically designed pediatric models of both the stand-alone Guardian Real-Time CGM system and the Paradigm REAL-Time system, which combines an insulin pump with a continuous glucose monitor in a single unit.

The REAL-Time systems display glucose values every 5 minutes, along with trend graphs and directional arrows. They also issue alarms when glucose levels rise too high or drop too low. The pediatric alarm threshold is set at a minimum of 90 mg/dL, while the adult CGM low-glucose threshold is set at 50 mg/dL. Patients can adjust those thresholds higher, but not lower. In both adult and pediatric versions, the high-alert threshold default is 280 mg/dL, which can be adjusted up or down.

Dr. Daniel Einhorn, secretary of the American Association of Clinical Endocrinologists, was enthusiastic about the availability of these devices for children. "This is very exciting technology, and it's most exciting when it comes to kids," he said. "For one thing, they can have some of the most erratic blood glucose swings. They are not the easiest group to get to do frequent blood glucose monitoring. . . . For parents, it's very reassuring to have alarms for high and low blood sugar."

Pivotal data for FDA approval of Medtronic's current CGM technology came from a 12-week international study of 162 patients with type 1 diabetes, including 81 children aged 8-18.9 years (median 14.4 years) and 81 adults aged 19-59.5 years (median 39.1 years). At baseline, all subjects had hemoglobin A_{1c} levels of 8.1% or greater despite adhering to intensive insulin therapy with either a pump (78 patients) or multiple daily injections (84 patients).

Patients were randomly assigned for 3 months to one of three groups: CGM either always or for a 3-day period every other week, or conventional self–blood glucose monitoring (SBGM) via fingerstick, performed 4-5 times a day. Treatment adjustments based on the respective readings were made by physicians and patients. Patients were instructed to perform confirmatory SBGM measurements prior to either therapeutic interventions or corrective actions if the high or low alarm sounded, or if they had symptoms (Diabetes Care 2006;29:2730-2).

A total of 156 patients completed the evaluation. Hemoglobin A_{1c} values at 1 month dropped in the continuous CGM group by 0.6 percentage points from a baseline mean of 9.5%, compared with just 0.2 from a baseline mean of 9.7% in the SBGM-only (control) group. At 3 months, the reductions were 1.0% vs. 0.4%. Reductions in HbA_{1c} in the group using CGM intermittently did not differ significantly from either of the other groups.

At 3 months, 50% of the patients using CGM continuously had HbA_{1c} reductions of 1 percentage point or greater, compared with 37% in the intermittent CGM group and 15% of the controls. One-fourth of the continuous CGM group had reductions of 2 percentage points or greater, compared with 9% and 4%, respectively.

Total insulin doses did not differ significantly among the three groups at 3 months. Severe hypoglycemia occurred once each in two CGM patients, but one of them, from the intermittent use group, was not wearing the device at the time.

Currently, the information obtained from CGM devices is meant to illustrate patterns, not to make therapeutic decisions. Patients still need to perform SBGM fingersticks for that, as well as for twice-daily calibration of the machines.

Dr. Einhorn, who is medical director of the Scripps Whittier Institute for Diabetes, in San Diego, acknowledged that the current CGM devices still have some shortcomings that need to be worked out, including the fact that patients sometimes feel overwhelmed by the amount of data the devices generate.

However, he added, the American Association of Clinical Endocrinologists is enthusiastic about the technology and is urging insurance companies and Medicare to begin reimbursing for continuous glucose monitors. "This technology, even though first generation, is definitely ready for prime time." ■