‘Low Glucose Suspend’ Reduces Hypoglycemia

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SAN DIEGO – The “low glucose suspend” insulin pump feature reduced hypoglycemia risk without any severe hyperglycemia or diabetic ketoacidosis in study of 21 children with type 1 diabetes.

Medtronic’s sensor-augmented insulin pump, the Paradigm Veo system, comprises an insulin pump, a continuous glucose monitor, and a component that first issues a “pre-alarm” if the sensor detects a reading below a preset level. If there is no response by the patient and the glucose level continues to drop to a second preset level, the pump then alerts again and stops the basal insulin infusion for 2 hours or until there is a response. At 2 hours, the basal infusion resumes. If the glucose level is still too low at 4 hours after resumption, the cycle begins again.

The patient can interrupt the low glucose suspend (LGS) feature at any time, said Dr. Thomas Danne, head of the diabetes center for children and adolescents at the Kinderkrankenhaus auf der Bult in Hanover, Germany.

The Veo system is sold in 45 countries, including Canada and countries in Europe, but it is not currently available in the United States. The Food and Drug Administration recently issued a guidance for manufacturers developing LGS, specifying the testing that must take place to address safety issues, including a concern that the device might overcorrect the hypoglycemia, resulting in hyperglycemia and/or diabetic ketoacidosis (DKA).

The Medtronic-sponsored study, conducted in Germany, initially enrolled 24 patients aged 1-21 years (mean, 10.8 years) who had type 1 diabetes and had been on insulin pump therapy for an average of 3.6 years. After patients wore the Veo without the LGS and pre-alerts for 2 weeks, those features were then turned on for the subsequent 6 weeks. The hypoglycemia alert was set at 75 mg/dL, and the LGS alert at 70 mg/dL. Complete data were available for 21 of the children.

There were 1,298 alerts, of which 66% were shorter than 5 minutes because the patients reacted immediately. The frequency of alerts was 2.56 per patient per day, of which 78% occurred during the day (6:00 a.m.–10:00 p.m.). The frequency of insulin delivery disruptions was more common at night (0.175 vs. 0.032 per patient per day), said Dr. Danne.

During the time of the LGS suspension, glucose levels rose an average of 35 mg/dL per hour, totaling 68.4 mg/dL per hour for the entire 120-minute period. The mean blood glucose level during the 6-week LGS period was 148 mg/dL, which was nearly identical to the 145 mg/dL recorded during the initial 2-week phase without the LGS. The time spent with hyperglycemia also was not significantly different (639 vs. 651 minutes). There were no cases of DKA during either time period, he reported.

But hypoglycemia rates did differ significantly. The amount of time spent with blood glucose levels less than 70 mg/dL was 58 minutes per day with the LGS, compared with 101 minutes without. Excursions of hypoglycemia below 40 mg/dL were also much lower with the LGS (0.13 vs. 0.28 per patient per day) during both the daytime and overnight hours. The LGS cut the time spent with blood glucose levels lower than both 70 mg/dL and 40 mg/dL by about 50%. ■

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Major Finding: Mean blood glucose levels were nearly identical with and without the LGS (148 vs. 145 mg/dL, respectively), whereas the amount of time spent with blood glucose levels of less than 70 mg/dL and excursions of hypoglycemia below 40 mg/dL were reduced by about 50% with the LGS.

Data Source: A study of 21 children at three German pediatric diabetes centers.

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