Journal of Diabetes Science and Technology
Volume 5, Issue 5, September 2011

ORIGINAL ARTICLE

Putting Brakes on Insulin Pump Infusion to Prevent Hypoglycemia

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Abstract

The author provides an analysis of the study published by Agrawal and colleagues, in this issue of *Journal of Diabetes Science and Technology*, which describes usage and effectiveness of the low glucose suspend feature that is integrated into the Medtronic Paradigm® Veo™ sensor-augmented pump system.

J Diabetes Sci Technol 2011;5(5):1142-1143

Hypoglycemia is the sword of Damocles that hangs over the heads of clinicians and patients who are trying to achieve good glycemic control with intensified insulin therapy. Detection and prevention of hypoglycemia becomes even more challenging when hypoglycemia unawareness develops as a result of recurrent episodes of mild hypoglycemia that often accompanies intensive insulin therapy. Overtreatment of hypoglycemia can also result in long periods of hyperglycemia and a vicious cycle of chasing after high and low blood glucose levels. A major focus of current translational research in type 1 diabetes is to put advances in diabetes technology to work to achieve good glycemic control without episodes of hypoglycemia for people with diabetes.

The article by Agrawal and colleagues[1] published in this issue of *Journal of Diabetes Science and Technology* describes the usage and effectiveness of the low glucose suspend (LGS) feature that is integrated in the new Medtronic Paradigm® Veo™ sensor-augmented pump system. This study was made possible by 935 Veo system users who uploaded a total of 49,867 patient days of insulin pump and sensor glucose data to Medtronic's CareLink database. The Veo system utilizes incoming sensor glucose data to suspend basal insulin infusion for up to 2 h if the preprogrammed LGS threshold is reached. The patient can manually abort the LGS at any time point or completely turn off the LGS feature. The hypoglycemic alert threshold can be set at a level higher than the LGS threshold in order to sound an alarm before the LGS threshold is reached.

Due to the alarms that are sounded before and when the low glucose threshold is reached, most LGS events lasted for only 0–5 min (45%). On the other hand, there were nearly 3000 suspend events that lasted longer than 115 min, and 2/3 of these events occurred between 22:00 and 08:00 h. One of the most important intended uses of the Veo system is to protect patients from catastrophic episodes of nocturnal hypoglycemia when they are unable to respond to hypoglycemic alerts and alarms. Consequently, one of the most important findings of the study was that LGS events that lasted for more than 115 min were accompanied by a rise in sensor glucose levels of ~40 mg/dl (i.e., from 59 to 102 mg/dl) without causing marked hyperglycemia in the postsuspend period. In a separate analysis of data from 278 patients who used the Veo system for 3 months or longer, exposure

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Abbreviations: (HbA1c) hemoglobin A1c, (LGS) low glucose suspend

Keywords: diabetes, glucose sensor, insulin pump therapy

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to high and low glucose levels was significantly reduced on days when the LGS was activated compared with days when it was not. It is also noteworthy that findings in this study are in agreement with those of a study presented by Danne[2] during the American Diabetes Association 71st scientific session regarding use of the Veo system in pediatric patients with type 1 diabetes.

The CareLink database contained a small number of LGS events caused by sensor glucose levels <70 mg/dl in which there was a contemporaneous blood glucose measurement. A potential concern raised by these data is that blood glucose levels were ≥100 mg/dl in 17% of these events and ≥180 mg/dl in 4%. Whether a 2 h interruption of the basal insulin infusion due to artifactually low sensor values has any adverse consequences remains to be established.

While CareLink provided a wealth of information to evaluate a number of aspects of the real-life use of the Veo system, the database is devoid of any clinical information such as the patients' demographic data, hemoglobin A1c (HbA1c) levels, history of episodes of hypoglycemia, and duration of diabetes and insulin pump therapy. Similarly, analyses of sensor data provide little insight into the ability of the Veo system to reduce the frequency of symptomatic hypoglycemic events. Additional studies are needed to assess the patient-perceived benefits and burdens of the use of this system as well. This issue is important because a potential secondary benefit of the Veo system is that the added protection against nocturnal hypoglycemia that the system provides will encourage patients to wear a sensor on a nearly daily basis, which, in turn, should lead to better daytime control of glycemia and lowering of HbA1c levels.[3]

Technology is integrated into our daily lives with devices controlled by artificial intelligence, from air conditioning systems to airplanes, enhancing the safety and functionality of such systems by putting circuitry between the device and the user. However, adaptation of technology to diabetes management has not been very swift. Studies such as this one are encouraging and should be followed by other well-designed studies with an aim to demonstrate efficacy, reliability, and safety of sensor-augmented pump systems that are aimed at preventing episodes of hypoglycemia by suspending basal insulin infusion for a projected glucose level.

In closing, the results of Agrawal and colleagues[1] and other recent free-range clinical-use studies of the Veo system illustrate the wisdom of regulatory authorities in Europe, Canada, and Australia in approving this integrated device for patient use. It also makes it even more frustrating that the Veo system remains unavailable to patients with type 1 diabetes in the United States.

Funding:

This publication was made possible by the CTSA Grant UL1 RR024139 and KL2 RR024138 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), and NIH roadmap for Medical Research. Its contents are solely the responsibility of the author and do not necessarily represent the official views of the NCRR or NIH.

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