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ORIGINAL ARTICLE

Analysis of a Remote System to Closely Monitor Glycemia and Insulin Pump Delivery—Is This the Beginning of a Wireless Transformation in Diabetes Management?

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Abstract

Episodes of hypoglycemia and hyperglycemia in between blood glucose checks—especially during sleep—can go unrecognized for children and adolescents with type 1 diabetes mellitus (T1DM). Continuous glucose monitoring (CGM) systems have introduced a new tool to monitor glucose levels for people with diabetes in real time and to alert them when glucose levels are above or below target range. However, many of the alarms are not heard at night by the children or adolescents or by their parents who oversee their treatment. The mySentry™ system is a device that is designed to relay real-time insulin pump and CGM data for display elsewhere in the house. In this issue of *Journal of Diabetes Science and Technology*, Kaiserman and coauthors report on the acceptability, usefulness, and user friendliness of the mySentry for families with children and adolescents with T1DM, which was determined by survey results during a 3-week study period. Based on the results, the mySentry system met all predefined criteria for acceptability without safety issues in this small-scale, short-term study and as an example of wireless systems integration in diabetes management.

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Hypoglycemia and hyperglycemia in children with type 1 diabetes mellitus (T1DM) create tension for both the children and their parents and carry with them an increased risk of morbidity and mortality for millions of people with diabetes. Fear of hypoglycemia has been well established by various studies as a stressful fact of life in families with children with diabetes.[1–3] The short-term goal of avoiding hypoglycemia can take precedence over good glycemic control, leading to long-term complications. Moreover, impaired awareness of hypoglycemic symptoms may be present in up to 30% of youth with T1DM, increasing the risk of severe hypoglycemic episodes.[4–6] The ramifications of exposure to hyperglycemia in the pediatric population, in addition to leading to high hemoglobin A1c levels, have been gaining importance. Data from studies have demonstrated that hyperglycemia can be associated with anatomic as well as cognitive alterations in central nervous system morphology and function and is worsened with exposure to neuroglycopenia.[7,8]

Continuous glucose monitoring (CGM) systems have introduced a new tool to monitor glucose levels for people with diabetes in real time and to alert them when glucose levels are above or below target range. However, many of the alarms are not heard at night by the children or adolescents or by their parents who oversee their treatment.

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Abbreviations: (CGM) continuous glucose monitoring, (SAP) sensor-augmented insulin pump, (T1DM) type 1 diabetes mellitus

Keywords: children, continuous glucose monitoring, diabetes, hyperglycemia, hypoglycemia, insulin pump, technology

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The technological solution to this problem is a remote monitoring system for CGM and insulin pump devices that allows parents to monitor the CGM readings from different rooms of a home and to intervene as needed. The mySentry™ system (Medtronic, Inc., Northridge, CA) is designed to help parents monitor their children's CGM readings remotely and to relay a steady stream of data to a monitor that can be placed 50 feet away from the sensor. mySentry interfaces with the MiniMed Paradigm® REAL-Time Revel™ sensor-augmented insulin pump (SAP) system (Medtronic, Inc.) and consists of an outpost and a monitor. The outpost receives and transmits radiofrequency signals from a single insulin pump and sensor from one room and transmits the signals to the monitor that is located in the parents' (or other caretaker's) room, enabling remote monitoring of the SAP system. Data that are relayed by the system include current and recent CGM values, remaining insulin, battery life, and alarm conditions. In this issue of *Journal of Diabetes and Scientific Technology*, Kaiserman and coauthors[9] report the usability and acceptability of the mySentry system by the primary user—parents of children (ages 7–17 years old) with T1DM—during a 3-week study period. Thirty-six families with children and adolescents with T1DM who were using the Paradigm Revel insulin pump were enrolled from five investigational centers, with one family withdrawing from the study because of parental time constraints. After a 1-week run-in period, the parents set up a mySentry system in their homes without any assistance from the research staff. They also completed a questionnaire by rating their concerns about nocturnal hypoglycemia and the acceptability and usability of the mySentry system on a 7-point Likert scale at the beginning, midpoint, and end of the 3-week study phase.

The parents' responses to the baseline questionnaire clearly demonstrated that their anxiety was related to their children's nocturnal blood glucose monitoring and fear of unawareness of nocturnal blood glucose excursions. The parents' responses with regard to the ease of initial system setup were overwhelmingly favorable; however, one can speculate that the families who agreed to participate in this study could have been tech-savvy families to begin with. Based on the mid-study survey, the respondents found the display easy to read and the alerts loud enough to hear and helpful. The questionnaire responses at the end of the study suggested that the mySentry system allowed the respondents to gain more confidence in managing their children's diabetes at night and gave them peace of mind regarding nocturnal blood glucose monitoring. The surveys that were completed by the subjects' diabetologists supported the findings from the parents' surveys. Although study duration was short and the questionnaire nonvalidated, the results demonstrating user friendliness and acceptability of the device remain promising. It is difficult to comment on the change in frequency of nocturnal hypoglycemia and hyperglycemia during the run-in and study periods because of the short study duration and also because the study was not powered to test such variables. The impact of the educational levels of the parents who were enrolled in the study on the successful use and acceptability of the mySentry system is not clear but may potentially play an important role.

The integration of wireless technology for remote monitoring in medicine, such as with the mySentry system, has received interest for use in chronic diseases other than diabetes. Systems that continuously monitor and transmit electrocardiogram readings and breathing rates to patients' smartphones and to physicians have been approved by the Food and Drug Administration.[10] The mySentry system could be the first remote monitoring device to be used in the management of diabetes and is not likely to be the last. There are applications in use and in progress that are available for mobile information and communication to assist patients with diabetes, and various companies are exploring methods to transmit glucose sensor data to smartphones for remote access.[11] Interestingly enough, such technology has the potential to end some of the diabetes-related tension between teenagers and their worried parents by giving parents remote access to SAP data without directly invading their child's privacy. However, the long-term effects of these systems on parent–child interactions and on the development of age-appropriate autonomy in adolescents have yet to be established.

For years, many parents in my practice used baby monitors to hear their children's CGM or pump alarms, and my teenage patients would have to explain to their friends why they had baby monitors in their bedrooms. It is about time that we have a more sophisticated approach to relay and monitor data from SAP systems in the homes of children with T1DM. Nevertheless, it will take long-term, well-powered clinical studies to demonstrate whether use of the mySentry system in homes, daycare centers, and diabetes camps will lead to improvement in glycemic control and/or quality of life for children with diabetes. In the meantime, the mySentry system seems to be a user-friendly device that could appeal to families of children with diabetes who have a fear of nocturnal hypoglycemia or hyperglycemia.

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