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ORIGINAL ARTICLE

Acceptability and Utility of the mySentry Remote Glucose Monitoring System

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Abstract

Background:

The mySentry system (Medtronic Inc.) is the first to amplify and relay continuous glucose monitoring (CGM) and insulin pump data to a remote site within the house. Its usability and acceptability were evaluated in families having a child with type 1 diabetes.

Methods:

Each enrolled family included a child (age 7–17 years) who used a Paradigm REAL-Time Revel sensor-augmented insulin pump (Medtronic). After a 1-week run-in phase, families set up and used the mySentry system for a 3-week study phase. Opinion surveys were completed by parents, and pump and CGM data were collected and analyzed retrospectively. No formal hypothesis testing was performed, and the study was not powered to detect changes in nocturnal glycemia.

Results:

Thirty-five families completed the study. Enrolled children (61.1% female) had a mean (± standard deviation) age of 11.9 ± 2.70 years and a mean age at initiation of pump therapy of 7.1 ± 3.19 years. Baseline survey results indicated that most parents were fearful of their unawareness of their children's nocturnal glucose excursions. The mySentry system met the predefined acceptability criteria for general experience, product usability, and training materials. There were no unanticipated device-related adverse effects. Among children who experienced nocturnal hypo- or hyperglycemic episodes in both phases of the study, there was a trend toward less frequent and less prolonged episodes during mySentry use.

Conclusion:

The mySentry system met all predefined criteria for acceptability and did not demonstrate safety issues. Alerting parents to abnormal glucose values or trends may attenuate nocturnal hypoglycemia and hyperglycemia by prompting appropriate and timely intervention.

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Abbreviations: (AUC) area under the curve, (CGM) continuous glucose monitoring, (RF) radio frequency, (SD) standard deviation, (SG) sensor glucose, (SMBG) self-monitored blood glucose

Keywords: continuous glucose monitoring, nocturnal hypoglycemia, remote glucose monitoring, sensor-augmented therapy

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Introduction

Avoidance and management of hypoglycemia and hyperglycemia are difficult tasks for children with type 1 diabetes and their parents. Because awareness of abnormal glucose values or trends can prompt appropriate interventions before symptoms develop, continuous glucose monitoring (CGM) systems that provide real-time information have found a place in the management of many patients who take insulin.

Personal CGM systems allow for programmable alarms that sound when a prespecified threshold glucose value is reached. These alarms may be especially useful and potentially lifesaving for people with hypoglycemia unawareness. Such CGM-based alarms may assist parents of children with diabetes, especially at night, which is when most severe hypoglycemic reactions occur[1] and management of their child's diabetes seems to be most difficult.[2] Unfortunately, it is often difficult to hear alarms when a child and the child's parents have separate bedrooms. To address these concerns, the mySentry system (Medtronic Inc., Northridge, CA) was developed and became commercially available in the United States in January 2012 to allow for remote monitoring.

The mySentry system is compatible with the Paradigm REAL-Time Revel sensor-augmented insulin pump system (Medtronic Inc.) and includes an outpost and a monitor (**Figure 1**). The outpost is placed in the child's bedroom to receive and retransmit radio frequency (RF) signals from a single Revel insulin pump and CGM device. The monitor receives the RF signals from the outpost in a different room, such as the parents' bedroom. The monitor can also receive signals directly from the pump in the same room. Pump and CGM information are displayed by the monitor, and the monitor will sound an alert or alarm if one is sounded by the pump. The monitor does not allow remote operation of the pump or remote dismissal of alarms.

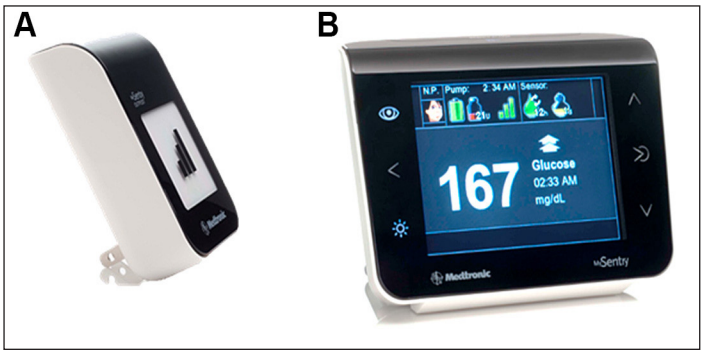

Figure 1. The outpost (**A**) and monitor (**B**) of the mySentry system.

Prior to its commercial availability, we evaluated the mySentry system's usability, acceptability, and impact on nocturnal glycemic consequences in families with a child or adolescent with type 1 diabetes. Surveys were completed by parents and investigators, and CGM data collected before and during mySentry use were used for retrospective exploratory data analysis.

Methods

For this study, a convenience sampling technique was used. Eligibility for this study included a paired child or adolescent aged 7–17 years with type 1 diabetes who currently used a Paradigm sensor-augmented pump system and a parent living in the same home. The home layout was to have no more than 100 ft. separating the bedrooms of the child and parent (by verbal report), the sensor-augmented pump system was to have been initiated at least 4 weeks prior to study enrollment, and its use must have been continued throughout the study. Exclusion criteria included pregnancy; impairments in vision or hearing that, in the opinion of the investigator, would compromise the handling of the mySentry unit; and participation in an investigational drug or device study (other than an observational, noninterventional study). In this study, "parent" denotes a biological or adoptive parent or a caregiver. In households with two parents, surveys were to be completed by the same parent throughout the study. There were five investigational centers (Billings, MT; Sacramento, CA; Stanford, CA; Torrance, CA; and Aurora, CO) and the protocol was approved by each site's institutional review board. All children provided informed assent, and a parent or guardian provided informed consent.

The study included a 1-week run-in phase of routine pump and sensor use, followed by a 3-week study phase of mySentry use. The families set up the system and determined appropriate alert settings at home, without investigator assistance. Surveys were conducted before and after use of the mySentry system in which parents or caregivers rated their concerns about nocturnal glucose control and their agreement with statements related to acceptability and usability

of mySentry on a 7-point Likert scale. No attempt was made to validate the survey because of its product-specific focus and the study's short duration. Narrative comments regarding mySentry were also solicited from participants and the pediatric diabetes specialists involved in the study. Parents were asked to complete daily night logs during the period of mySentry use to record the occurrence of audible alarms and details of any interventions based on the alarm. Retrospective analysis was performed on pump and sensor data uploads. Continuous glucose monitoring data from 10:00 PM to 8:00 AM were considered nocturnal. The study was neither intended nor powered to detect differences in nocturnal glycemia between the run-in and mySentry phases, and no formal hypothesis testing was performed on the user evaluation data or the CGM data.

Results

Thirty-six children enrolled, and 35 completed the study. One subject withdrew because of parental time constraints. Enrolled children (61.1% female) had a mean [± standard deviation (SD)] age of 11.9 ± 2.70 years, mean age at diagnosis of 5.4 ± 3.21 years, and mean age at initiation of pump therapy of 7.1 ± 3.19 years. The median family size was four, and most families lived in homes with three or four bedrooms. Bedrooms were typically located on the same floor of the house, and the median distance between the bedrooms of the parents and the child using the mySentry system was 20 ft. Most children's capillary glucose levels were checked one or two times per night.

Throughout the run-in and study phase, sensor use was consistently high. During the 1-week run-in phase, sensors were worn for 68.5% ± 15.5% of daytime hours (8:00 AM to 10:00 PM) and 71.9% ± 15.9% of nighttime hours (10:00 PM to 8:00 AM). During the 3-week study period, sensors were worn for 71.9% ± 16.3% of the daytime hours and 77.8% ± 16.6% of the nighttime hours. The false positive rates for hypoglycemia occurring within 15 or 30 min were 34.7% and 33.9%, respectively. The false positive rates for hyperglycemia occurring within 15 or 30 min were 15.3% and 15.2%, respectively.

At baseline, surveys completed by parents indicated that most of the children had nocturnal low or high blood sugars, with the most frequent response being 6 (out of a possible 7) to this specific question (**Table 1**). Most parents were fearful of their unawareness of these excursions and were frequently dissatisfied with the night-time monitoring of their child's sensor glucose (SG) levels (**Table 1**). All respondents found the mySentry initialization and setup procedures easy and found the user guide to be helpful (**Table 2**). Questionnaire responses at the midpoint of the study phase indicated that the alerts were helpful, the display was easy to read, and the alarms were easier to hear (**Table 2**). At the end of the study, questionnaire responses indicated that the parents had a high level of satisfaction with the system, that it allowed parents to better manage their child's diabetes at night, and that the user guide was easy to understand. All participants would recommend the system to other parents or caregivers (**Table 3**).

Surveys completed by the clinical investigators (all specialists in pediatric diabetes) showed that mySentry could be expected to provide parents and caregivers with increased comfort at night and assist them in successfully managing their child's diabetes. Narrative comments included suggestions to allow for more extensive adjustment of the screen's

Table 1.
Baseline Questionnaire Responses (General Experience)[a]

Question	Mean (SD)	Median (range)	Mode
My child experiences nighttime low/high blood sugar levels.	5.5 (1.3)	6 (3–7)	6
I am satisfied with nighttime monitoring of my child's SG levels using CGM.	3.8 (1.6)	4 (1–7)	3
I am able to sleep soundly at night, without fear of my child going low/high at night.	3.1 (2)	3 (1–7)	1
At night, I am fearful of being unaware that my child might experience low/high blood sugar levels.	5.4 (2)	6 (1–7)	7
I can hear my child's pump and SG alarms from where I am sleeping at night.	2.5 (2.1)	2 (1–7)	1
I feel I can successfully manage my child's diabetes at night.	4 (1.6)	4 (1–7)	4

[a] Allowable responses ranged from 1 (strongly disagree) to 7 (strongly agree).

Table 2.
Questionnaire Responses from Initial Setup Experience and Mid-Study Survey

Question	Mean (SD)	Median (range)	Mode
Initial setup and training material questionnaire responses			
It was easy to connect the insulin pump to the mySentry monitor.	6.4 (1)	7 (2–7)	7
It was easy to connect the mySentry outpost to the mySentry monitor.	6.1 (1.5)	7 (1–7)	7
It was easy to navigate through the different mySentry monitor screens.	6.4 (0.7)	7 (5–7)	7
It was easy to understand how to use the mySentry monitor controls during setup.	6.4 (0.7)	6 (5–7)	7
Overall, it was easy to set up the mySentry system.	6.1 (1.3)	6 (1–7)	7
It was easy to understand the "getting started" section of the user guide.	6.1 (0.9)	6 (3–7)	6
The mySentry user guide was helpful during setup.	6.3 (1)	6 (3–7)	7
If I had a problem, there was enough information to solve it myself.	5.5 (1.6)	6 (1–7)	7
When I referred to the mySentry user guide, I was able to find the right section to answer my question.	5.7 (1.4)	6 (1–7)	6
Midpoint questionnaire responses			
The alarms and alerts on the mySentry monitor are helpful.	5.9 (1.5)	6 (1–7)	7
The display of insulin pump and SG data on the mySentry monitor is helpful.	6.4 (0.9)	7 (3–7)	7
The glucose sensor graph(s) displayed on the mySentry monitor are easy to read and understand.	6.5 (1)	7 (2–7)	7
Using the mySentry system, I can better hear my child's pump and SG alarms from where I sleep at night.	6.7 (0.7)	7 (4–7)	7
It is easy to read the pump and SG alarms/alerts on the mySentry monitor.	6.8 (0.5)	7 (5–7)	7

brightness and to provide more robust interdevice communication. Logbook entries showed that the mean (± SD) self-monitored blood glucose (SMBG) value was 181.0 ± 106.5 mg/dl and that the frequency of SMBG measurements increased with adoption of the mySentry system.

Of the 35 subjects who completed the study, 8 experienced one or more nocturnal hypoglycemic episodes (SG ≤ 50 mg/dl) in both phases of the study, and 20 experienced one or more nocturnal hyperglycemic episodes (SG ≥300 mg/dl) in both phases of the study. Nocturnal sensor data for these subjects are summarized in **Table 4**. To allow comparison of run-in and mySentry study phases, data representing the number, duration, and area under the curve (AUC) of glycemic excursions from the 3-week study phase were divided by 3. The weekly average number, duration, and AUC of glycemic excursions were all lower during mySentry use, but the magnitude of the differences was not statistically significant ($p > .05$).

The mySentry system met the predefined acceptability criteria [subject responses ≥4 (neutral or favorable) on the 7-point Likert scale] for general experience after use (97.1%), product usability (98.8%), and training materials (97.1%) as measured by post-questionnaire answers provided by parents. The percentage of responses that were neutral or favorable was ≥75% in all response categories. One severe adverse event occurred (severe hypoglycemia after a subject's mother replaced the insulin pump reservoir and performed a priming operation with the infusion set tubing attached to the subject); this was unrelated to the study device. There were no unanticipated device-related adverse effects. Device performance issues were most often self-limited and related to linking the pump to the monitor during setup or related to RF connection issues. One unit was returned and replaced because of a power-up problem.

Discussion

Avoidance of nocturnal hypoglycemia is an important concern for everyone who takes insulin and for those involved in their care. The prevalence, risk factors, and consequences of nocturnal hypoglycemia have been well-described, and the mySentry system joins other devices aimed at improving diabetes care through communication and teamwork.

Table 3.
General Experience, Product Usability, and Training Material Questionnaire Responses (End of Study)

Question	Mean (SD)	Median (range)	Mode
General experience			
Overall, I was satisfied with the mySentry system.	6.1 (1.1)	6 (3–7)	7
After using mySentry, I had increased awareness of my child's SG levels at night.	6.3 (1.1)	7 (2–7)	7
The use of mySentry allowed me to sleep soundly, without fear of my child going low or high at night.	5.1 (1.5)	5 (1–7)	6
The use of mySentry gave me increased confidence that my child's pump is functioning appropriately at night.	5.9 (1.1)	6 (2–7)	6
While using mySentry, I had greater confidence in managing my child's diabetes at night.	6.2 (0.8)	6 (5–7)	7
I would recommend mySentry to other parents or caregivers.	6.4 (0.9)	7 (4–7)	7
Product usability			
The alarms/alerts were clear and easy to understand.	6.5 (0.8)	7 (4–7)	7
It was easy to use.	6.5 (0.6)	7 (5–7)	7
The utilities menu was easy to use and understand.	6.6 (0.7)	7 (5–7)	7
While using the system, I was satisfied with the monitoring of my child's SG levels at night.	5.9 (1.2)	6 (2–7)	7
While using the system, I was less fearful at night of being unaware of my child going low/high at night.	6.2 (1.2)	7 (1–7)	7
The alarms/alerts were loud enough to hear from where I am sleeping at night.	6.9 (0.4)	7 (6–7)	7
After using mySentry, I feel I can better manage my child's diabetes at night.	6.3 (1)	7 (3–7)	7
Training materials			
I referred to the user guide(s) often to troubleshoot the mySentry.	3.6 (2.2)	4 (1–7)	1
I had to contact the 24 h help line often to troubleshoot mySentry.[a]	6.1 (1.8)	7 (1–7)	7
I would rather call the 24 h help line than read the user guide if I needed assistance.[a]	5 (1.5)	4 (2–7)	4
The icon table in the user guide was clear and easy to understand.	5.9 (1)	6 (4–7)	7
Overall, the mySentry user guide was easy to understand.	6.2 (1)	6 (3–7)	7

[a] The score was reversed where lower scores were more favorable.

Table 4.
Nocturnal Hypoglycemia and Nocturnal Hyperglycemia (per Week) in the Run-In and mySentry Phases of the Study, Mean ± Standard Deviation

Hypoglycemia (8 subjects)	Run-in	mySentry
Number of excursions to ≤50 mg/dl	3.87 ± 2.69	2.35 ± 1.11
Duration ≤ 50 mg/dl (min)	232.73 ± 397.6	154.5 ± 129.01
AUC ≤ 50 mg/dl (mg/dl/week)	0.13 ± 0.28	0.09 ± 0.11
Hyperglycemia (20 subjects)		
Number of excursions to ≥300 mg/dl	5.76 ± 6.17	4.46 ± 3.25
Duration ≥ 300 mg/dl (min)	619.81 ± 715.1	455.73 ± 510.77
AUC ≥ 300 mg/dl (mg/dl/week)	2.93 ± 4.09	2.06 ± 2.84

While asymptomatic in most cases, hypoglycemic episodes during sleep can be devastating to health and wellbeing and may be fatal.[3] Nocturnal hypoglycemia often contributes to hypoglycemia unawareness, anxiety, poor quality of life,[4] and possibly neurocognitive deficits.[5] Not surprisingly, parents of young children with type 1 diabetes describe daily management as relentless, and nocturnal monitoring contributes to parental fear, anxiety, and stress.[6]

Severe hypoglycemia can be reduced through vigilance in identifying patients at risk, utilization of appropriate therapy, and effective use of glucose monitoring technologies.[7] The mySentry system represents the first device that relays a complete set of insulin pump and CGM data to a remote monitoring station. As such, it can provide parents with a complete picture of pump status and glycemic trends for children sleeping in a different room in the house. The mySentry system is part of an industry-wide trend toward "connected care" that simplifies or automates tasks associated with tracking and sharing data related to insulin delivery and glucose values.

The study was limited by its short duration, small number of enrolled patients, and use of a nonvalidated questionnaire. The convenience sampling technique was chosen for this pilot study, so the families chosen were all under routine care of one of the principal investigators and agreed to participate when given the opportunity. This may limit the study's generalizability. The educational and economic backgrounds of the patients and their families were not considered at entry and were not recorded, so their contribution to the study results cannot be determined. The number of alarms that were missed (not heard) by parents was not recorded as part of the study. Further studies may examine the utility of the mySentry system in other contexts, such as people with diabetes who live alone, and should control for demographic and educational variables in the participants as well as track the number of alarms that were missed by parents. The current study's finding of modest favorable changes in nocturnal hypoglycemia and hyperglycemia were not statistically significant. This is likely due, in part, to the short study length or the small number of participants. Larger prospective studies may demonstrate both statistically and clinically significant improvements in nocturnal glycemia with use of the mySentry system.

Conclusions

The mySentry system, the first to offer remote monitoring of pump and CGM data, was acceptable to both parents and the clinical investigators (all of whom are specialists in pediatric diabetes). The favorable changes in CGM-based estimates of nocturnal hypoglycemia and hyperglycemia are of uncertain clinical significance; larger and longer studies are warranted. No safety issues were identified. In families where a child with type 1 diabetes uses a sensor-augmented pump system, alerting parents to abnormal glucose values or trends may prompt appropriate and timely interventions and thereby reduce the risk of severe or protracted glucose excursions.

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