Predictors of Parental Interest in Continuous Glucose Monitoring for Children with Type 1 Diabetes

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Abstract

Background: Optimal control of type 1 diabetes (T1D) in children minimizes long-term complications, but increases hypoglycemic events. A continuous glucose monitor (CGM) can provide real-time information about glucose levels and trends. Little has been published on the characteristics of patients most willing to use CGM.

Methods: Online survey software was utilized to administer a 50-item questionnaire to parents of children with T1D. The primary outcome was whether the parent expressed a high level of interest in CGM. The proportion of parents who expressed a high level of interest was compared across demographic and clinical variables via χ^2 tests ($\alpha = 0.05$).

Results: Analysis was performed on 457 surveys. The mean $\pm$ SD age of the children was 10 ± 4.1 years. Mean reported hemoglobin A1c (HbA1c) was $7.8 \pm 1.3\%$. Of the respondents, 70% used continuous subcutaneous insulin infusion (CSII). Parents reported an average of eight blood glucose (BG) checks daily. Over 90% of the parents indicated a high level of interest in having their child use a CGM. Primary variables related to interest in a CGM were use of CSII ($P = 0.002$), checking BG more than six times daily ($P = 0.005$), and parental worry about high or low BG ($P = 0.0012$ and $P = 0.02$, respectively). Age of the child and HbA1c were not related to parental interest in a CGM.

Conclusions: Overall parental interest in CGM was high. Use of CSII, frequent BG checks, and parental worry, but not age of the child or diabetes control, were associated with parental interest in using a CGM.

Introduction

CHILDREN WITH TYPE 1 DIABETES (T1D) are at significant risk for the micro- and macrovascular complications of hyperglycemia, as well as the short-term and long-term effects of hypoglycemia.^{1,2} Attempting to control the blood glucose (BG) to near normal levels can lower the hemoglobin A1c (HbA1c) and minimize long-term complications, but also considerably increases the number of hypoglycemic events.³⁻⁵ Frequent self-monitoring of BG (SMBG) is associated with good control. But, SMBG gives children, parents, and practitioners only glimpses of the glycemic excursions that children with T1D experience in daily life.

A continuous glucose monitor (CGM) can provide near real-time information about glucose levels and trends, as well as alarms for projected dangerous glucose levels. With a very small sensor that is inserted just under the skin and worn for 3-7 days, the sensor transmits the interstitial glucose values to

a receiver that displays this information. Currently, CGMs are not Food and Drug Administration-approved to *replace* SMBG. However, preliminary clinical data show that the information provided by CGM technology enables patients to decrease wide fluctuations in BG, as well as time in hypo- and hyperglycemic ranges.⁶ This decrease in BG variability may have important implications for decreasing the long-term morbidity and mortality of diabetes.⁷⁻¹⁰ CGM will also be an integral component to closed-loop insulin delivery in a successful artificial pancreas.

There remain some issues with accuracy and with the time lag between the interstitial fluid glucose and the BG reading. Practical considerations also initially prevented widespread acceptance. A randomized, controlled study using an early CGM version reported no improvement in glucose control or severe hypoglycemia compared to usual care, and there were significant problems with skin irritation, frequent skips, excessive alarms, and inaccurate readings.¹¹ A survey of the

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treatment arm of this 200-subject trial revealed satisfaction ratings of "less favorable than 'neutral'" in 73% of the children and 81% of the parents.¹² These trials, however, used the GlucoWatch™ (Cygnus Inc., Redwood City, CA), an older and much more difficult-to-use form of continuous sensing technology. Recent studies with the most up-to-date CGM versions have reported much higher accuracy¹³ and satisfaction¹⁴ and have even had promising results in "closing the loop."¹⁵

Although some might assume that most people with T1D would be highly interested in using a CGM, little has been written about the level of acceptability of these devices in different subgroups and families. Research in the United Kingdom has shown that certain patient groups, including those who do not trust physicians and those who question the benefits of scientific research, are more reluctant to use medical technology.¹⁶ Which factors predict the degree of interest in using CGM in parents of children with T1D remain unknown.

The present study investigated the level of interest, as well as variables associated with more or less parental interest in using a CGM. Our hypotheses were that the age of the child and the degree of diabetes control would be associated with the level of parental interest in CGM.

Subjects and Methods

Parents of children attending the University of Virginia Children's Hospital (Charlottesville, VA) and the Cincinnati Children's Hospital (Cincinnati, OH) diabetes clinics were asked to participate in an anonymous online survey. In addition, a link to the online survey was provided at www.childrenwithdiabetes.com, a website viewed by parents of children with diabetes across the United States and around the world. The survey was administered from February 2007 through June 2007. The introduction page to the survey stated that consent to participate would be implied if the questionnaire were completed. The following page of the survey asked if the respondent's child had diabetes and if so, what type. If the answer was "type 2" or "unknown," the program terminated the survey, and the participant was thanked for his or her time.

The questionnaire consisted of 50 items that were rated on a Likert scale, where 1 = strongly disagree and 5 = strongly agree. The survey explored parental attitudes regarding using a CGM, as well as parental concerns about different aspects of their child's diabetes. Items assessed level of interest, perceived benefits and costs of a CGM, and degree of worry about various aspects of their child's diabetes, including long-term complications and fear of hypoglycemia. Parents provided demographic information including the child's age, gender, and country of residence. Diabetes-specific information was also provided, including years since diagnosis, use of continuous subcutaneous insulin infusion (CSII) (yes/no), frequency of daily SMBG, and most recent HbA1c. The survey also assessed level of parental interest in using a CGM if the cost of the equipment were covered by insurance, as well as level of interest if insurance did not cover the device. This analysis focuses on those with high interest if insurance were to pay for a CGM, as this seems to be where the market is trending.

The primary outcome measure was whether or not the parent expressed high interest in using a CGM if insurance were to cover the device, with high interest defined as a score

of 4 or 5 on the Likert scale response for that question. The proportion of respondents who expressed high interest was compared across different clinical and demographic groups, as well as parent opinions, using χ^2 tests when sample size was sufficiently large ($\alpha = 0.05$). When comparisons involved groups with small expected sample sizes, Fisher's exact test was used. The Cochran-Armitage test was used to assess for any trend in the proportion with high interest for increasing categories of age and number of times blood sugar was checked. Mean HbA1c levels were compared between the two interest groups (high vs. low) via a *t* test (not assuming equal variances).

Results

A total of 503 parents of children (51% boys, 49% girls) with T1D responded to the online survey. Of these, 46 questionnaires were incomplete, leaving 457 completed questionnaires for data analysis. The mean $\pm$ SD age of the children was 10 ± 4 years, and their average duration of diabetes was 4 ± 3 years. Average reported HbA1c was $7.8 \pm 1.3\%$; values ranged from 5.2% to 14.5%. Only 46% of parents believed that their child's T1D was in "good control." Parents reported that SMBG was performed an average of eight times daily; 70% of the children used CSII therapy. Ninety-six percent of parents had heard of continuous glucose sensors, and 12% of the children had previously used such a device. The great majority (>95%) of respondents were from the United States and Canada.

Over 90% of the parents indicated a strong interest in having their child use a CGM, if insurance covered it. Without insurance coverage, however, only 50% of those interested thought that they would be able to afford the technology. In the 12% of parents whose child had previously used a CGM, 96% continued to be interested in using a device. The vast majority of parents believed that a CGM would benefit their child in several ways. More than 90% of parents believed that CGM would improve control of their child's diabetes and help to decrease complications, and 95% of those studied thought that a CGM would help them better see the effects of food and exercise on glucose levels. However, only 80% indicated that they would want their child to wear a CGM device all of the time, as opposed to intermittently.

Only a very few parents (6%) believed that using a CGM would increase their diabetes-related stress. Less than 2% of parents indicated believing that they would be overwhelmed by the large number of glucose readings provided by the technology. Some (7%) were concerned that they would give too much or too little insulin if they saw glucose readings continuously.

Several variables influenced the level of parental interest in using a CGM (Table 1), including current treatment regimen. Ninety-six percent of families who used CSII were interested in a CGM, compared to 91% of those on multiple daily injections (MDI) who wanted to start using CSII; this dropped to 84% in families who were not interested in using CSII ($P = 0.0002$). Ninety-six percent of families who checked BG more than six times daily indicated high interest in CGM, compared to 82% of families who checked BG three times or less a day ($P = 0.005$).

In contrast to our hypotheses, parent-reported HbA1c level was not associated with interest in CGM. Those with a high

TABLE 1. CHILD/FAMILY CHARACTERISTICS AND THEIR ASSOCIATION WITH HIGH PARENTAL INTEREST IN A CGM

Child/family variable	n	Percentage indicating high interest ^a	P value ^b
Age			0.4746 ^c
0–5 years	60	95%	
6–11 years	217	94%	
12–18 years	180	93%	
Gender			0.4860
Male	232	93%	
Female	225	95%	
Years since diagnosis			0.1043 ^c
Less than 2	101	91%	
2–5	216	94%	
6 or more	140	96%	
Checks blood sugar			0.0069 ^c
1–3 times/day	11	82%	
4–6 times/day	177	91%	
>6 times/day	269	96%	
Uses insulin pump			0.0014
Yes	319	96%	
No	138	88%	
Parent has heard of a CGM			<0.0001 ^d
Yes	438	95%	
No	19	58%	
Child has worn a CGM			0.7406
Yes	53	96%	
No	375	95%	

^aHigh interest = score of 4 or 5 on question regarding interest in using a CGM if insurance were to cover the device.

^bUnless noted, χ^2 P value.

^cCochran-Armitage trend test (exact P value).

^dFisher's exact test P value.

interest in CGM had a mean $\pm$ SD HbA1c level of $7.8 \pm 1.3\%$, whereas those with a low interest had a mean level $\pm$ SD of $7.6 \pm 0.8\%$; this difference was not clinically nor statistically significant (*t* test, $P = 0.13$). There were also no significant differences in parental CGM interest based on child's gender, years since diagnosis, or previous use of a device (Table 1). Additionally, the age of the child did not influence parental interest in using a CGM; however, parents' perception of their child's level of maturity did. For children 6–11 years old, 97% of parents who believed that their child was mature enough to wear a CGM were interested in trying one. Conversely, for parents who did not believe their child in this age group was mature enough to use CGM, only 68% were interested in using it ($P < 0.0001$). Similarly, in the 12–18-year-old age group, 95% of parents who believed that their child was mature enough to wear a CGM were interested in using one, compared to 56% of parents who did not believe that their adolescent was mature enough ($P = 0.0017$).

Parental level of concern or worry about their child's diabetes and blood glucose control was significantly associated with interest in using a CGM (Table 2). Ninety-five percent of parents who indicated a high level of worry about the effects of elevated BG on their child's health were interested in CGM, compared to 67% of parents who indicated a lower level of worry ($P = 0.0012$). Ninety-five percent of parents who indicated a high level of worry about hypoglycemia were interested in using a CGM, compared to 89% who indicated a

lower level of worry ($P = 0.02$). In addition, nearly all (98%) parents whose child had problems with nocturnal hypoglycemia indicated high interest in using a CGM, compared to 92% of families for whom this was not a problem ($P = 0.0065$).

Discussion

This study demonstrates that there is a high level of interest in CGM in families of children with T1D. Although overall interest was high, there were some variables that are associated with greater interest in this technology. First, familiarity and interest in diabetes technology in general seem to predict interest in using a CGM. Interest in using a CGM was highest in parents whose children used CSII. The group next most likely to want a CGM device were those parents whose children used MDI but wanted to use CSII. Finally, the group that was least interested in CGM were those parents of children who used MDI and had no desire to start CSII therapy. To date, most clinical trials in children using CGM have focused on children already using CSII, likely because of an assumption that there may be a technology barrier to overcome in children who have not previously worn a medical device. However, a recent study of children using MDI therapy showed that CSII-naïve children benefit equally in terms of clinical improvements from using a CGM.¹⁴

Families who are currently performing SMBG greater than six times daily were more interested in using a CGM than those who only test one to three times daily, as well as those who test four to six times daily. This may initially seem counterintuitive. One might assume that those families who test the least frequently would be most interested in a device that has the potential to eventually replace SMBG and possibly simplify patient diabetes management. However, our data suggest that those who test the most frequently desire to obtain even more data about glucose levels. A DirecNet Study found similar results: children whose parents reported higher scores on adherence scales, including BG checking, used their CGM more frequently over the course of a 6-month study.¹⁷ These findings may be somewhat concerning: families who are already having difficulty coping with demands of intensive diabetes therapies, including SMBG, and who may potentially reap the greatest benefits from CGM may not be interested in this technology. This lack of interest may be due to reluctance to receive "negative feedback" about extreme BG values. Thus, there may be some psychological barriers to overcome before certain families can be helped by CGM.

One of the most interesting findings in our study was the impact of parental worry on the parent's interest in using a CGM. Significant differences in the level of interest in using a CGM were found between those that agreed and those that did not agree with the following statements: "I am worried about the effects of high blood sugar on my child's health," "I worry about my child having a low blood sugar reaction," and "My child has problems with low blood sugar in the middle of the night" (Table 2).

There is little in the diabetes literature about parental worry.^{18,19} However, from the time of their child's diagnosis, most parents are aware of the short-term and long-term problems that their child may face as a result of his or her diabetes. Those that worry the most about these problems seem to be seeking additional assistance that might help their child avoid the complications. Similarly, parents' beliefs about

TABLE 2. PARENTAL OPINIONS AND THEIR ASSOCIATION WITH HIGH PARENTAL INTEREST IN A CGM

Parental opinion ^a	n	Percentage indicating high interest ^b	P value ^c
I think that having blood sugar numbers continuously available might be too much information			0.0383 ^d
Agree	22	82%	
Do not agree	435	94%	
I think my child's diabetes is under good control at this time			0.6399
Agree	209	93%	
Do not agree	248	94%	
I am worried about the effects of high blood sugar on my child's health			0.0012 ^d
Agree	440	95%	
Do not agree	15	67%	
I am worried about the effects of low blood sugar on my child's health			0.1206 ^d
Agree	402	95%	
Do not agree	53	87%	
My child has problems with severely low blood sugar			0.3445 ^d
Agree	50	98%	
Do not agree	405	93%	
My child has problems with low blood sugar in the middle of the night			0.0065
Agree	156	98%	
Do not agree	298	92%	
I worry about my child having a low blood sugar reaction			0.0261
Agree	344	95%	
Do not agree	104	89%	
My child worries about having a low blood sugar reaction			0.2083
Agree	167	96%	
Do not agree	281	93%	
I believe my child is mature enough to wear a CGM			<0.0001 ^d
Agree	408	97%	
Do not agree	49	71%	
I don't think my child would be interested in wearing a sensor that is attached to his/her body			<0.0001
Agree	84	85%	
Do not agree	373	96%	

^aFor each statement: agree = score of 4 or 5; do not agree = score of 1, 2, or 3.

^bHigh interest = score of 4 or 5 on question regarding interest in a CGM if insurance were to cover it.

^cUnless noted, χ^2 P value.

^dFisher's exact test P value.

the maturity level of their children were positively related to the level of interest in using a CGM, while absolute age of the child was not.

Our study has several methodological limitations. In using an anonymous online questionnaire, our goal was to facilitate rapid collection of data in an area of pediatric diabetes that is changing rather quickly. However, this method also prevents us from knowing how individual respondents decided to complete the survey, that is, whether they responded to clinic advertisements or discovered the survey independently while searching the Internet for diabetes information. In addition, our data relied on parental recall of variables such as HbA1c levels and history of severe hypoglycemia. However, it was believed that the anonymous nature of the survey would likely facilitate candid responses. Although the survey instrument was not formally validated, we relied on face validity. We focused our analysis on those who were interested in using a CGM, provided insurance covered the device. Currently, most insurance companies have rather strict criteria regarding coverage of CGM devices. Potentially relevant data on socioeconomic levels of the families were not available, although certainly economic

factors currently likely play a large role in whether a family can currently use a CGM. Unfortunately, our study did not query diabetes knowledge, although this may have been an important variable in predicting parental interest in using a CGM.

This study also used a questionnaire accessible only through the World Wide Web, which presumes respondents have access to and familiarity with a computer. This could introduce significant selection bias. The great majority of parents in this study indicated interest in using a CGM, which by itself is an interesting finding with respect to making conclusions about parents who are familiar with a computer. Nonetheless, future studies should attempt to obtain a more representative sample by collecting data via a non-computerized method, such as at a pediatric diabetes clinic or summer camp. Because significant differences in level of parental interest in CGM were found in this motivated and fairly computer-savvy population taking an online survey, we suggest that greater differences are likely in the general population of families with children with T1D.

Recently published research has shown that children and young adults do not obtain the HbA1c-lowering benefits of

using a CGM that their >24-year-old counterparts do.²⁰ The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group also found that 8–14-year-olds and 15–24-year-olds wore their CGM devices 6 out of the 7 days of the week only 50% and 30% of the time, respectively. This is in contrast to those individuals 25 years and older, who wore their sensors 6 out of the 7 days of the week for 83% of the time during the 6-month study. We propose that a level-of-interest survey such as ours may be one tool to assist in selecting those families of young patients who are most interested and ready to fully utilize a CGM.

This study helps to confirm the assumption of many pediatric endocrinologists: there is a high degree of interest in CGM devices in families of children with T1D. More importantly, though, these results suggest that particular populations may be more interested and therefore may be willing to put the most effort into using a new form of diabetes technology. Should using a CGM become the standard of care, our data may also prove useful in helping to identify those groups who are *not* yet ready to initiate new diabetes technology. In identifying barriers to optimal use of a CGM, strategies to overcome these barriers may be developed.

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