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Psychological Aspects of Continuous Glucose Monitoring in Pediatric Type 1 Diabetes

The Diabetes Research in Children Network (DirecNet) Study Group *

Abstract

Clinical use of near-continuous glucose monitors (CGM) could have substantial impact on family management of pediatric type 1 diabetes and could generate both beneficial and adverse psychological reactions. In addition to glycemic benefits, CGM could possibly yield educational and motivational benefits. Conversely, CGM may also lead to information overload and increased treatment burden. Further, patients and families with certain affective, behavioral, and cognitive characteristics might derive greater benefit from CGM use. Since information about these processes could facilitate optimal clinical use of CGM, the Diabetes Research in Children Network (DirecNet) included measurement of selected psychological variables in a recent randomized trial of the GlucoWatch G2[®] Biographer (GW2B). A multi-center sample of 200 youths with type 1 diabetes was randomized to 6-mo of either continued usual care (UC) using a conventional home glucose meter for diabetes or to supplementation of standard care with use of the GW2B. Diabetes treatment adherence, diabetes-specific quality of life and diabetes-related anxiety were measured at baseline and end of study. Satisfaction with use of the GW2B was measured at end of study. The results indicated neither adverse nor beneficial psychological effects of CGM use. More frequent GW2B use over the 6-mo study was found among youths whose parents reported higher scores for treatment adherence and diabetes-related quality of life at baseline. The study illustrates the empirical assessment of the psychological context of CGM use and establishes methods that are applicable to new CGM devices as they emerge.

Keywords

diabetes; continuous glucose monitoring; psychological aspects

Introduction

The impact of the Diabetes Control and Complications Trial (1) on diabetes management has elevated the importance of achieving tight glycemic control without increased risk of severe hypoglycemia (2,3). The search for tools to achieve these difficult and competing goals has led to the development and testing of continuous glucose monitoring systems as supplements to conventional self-monitoring of blood glucose (SMBG) in the management of type 1 diabetes mellitus (T1DM). Recently, several continuous glucose monitors (CGM) have received FDA approval for such applications (4-9). These devices read the patient's blood glucose level frequently and automatically, providing a nearly continuous glucose profile that can be used to supplement the results from conventional SMBG. Two CGM devices, the GlucoWatch G2[®] Biographer ("GW2B", Cyngus, Inc., Redwood City, CA) and the Continuous Glucose Monitoring System, CGMS[™] (Medtronic Minimed, Northridge, CA), currently have FDA approval for use as a supplement to conventional SMBG and the

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technology may eventually evolve to replace conventional SMBG. It is conceivable that future CGM devices will be sufficiently accurate and reliable to be used to adjust insulin administration via an insulin pump automatically and continuously, effectively providing an artificial pancreas. Although accuracy of currently approved CGM devices relative to laboratory glucose determinations is lower than that achieved by conventional home glucose meters (10-12), their accuracy levels may still be sufficient to enable clinical benefit from their use. Moreover, there is little doubt that existing CGM devices will be refined and that new and improved products will be introduced (13-17). Careful evaluation of the psychological, as well as medical, outcomes of CGM use, and of the predictors of those outcomes, would be very valuable at this early point in the emergence of this technology. However, these issues have not yet been explored empirically.

Use of CGM devices in the management of type 1 diabetes in children has the potential to yield positive psychological and behavioral effects (18), such as reinforcement of concepts taught in diabetes education, increased salience of glycemic effects of meticulous or careless self-management, enhanced diabetes self-efficacy, decreased anxiety about unexpected hypoglycemia, increased flexibility in daily living, and enhanced motivation for improved glycemic control.

However, CGM use also carries the potential for adverse psychological and behavioral effects such as increasing the overall burden of diabetes management; serving as an excuse to decrease SMBG; generating unrealistic expectations about its benefits; aggravating parent-adolescent conflict about glycemic control; yielding an overwhelming amount of glucose data; promoting over-reaction to transitory glucose fluctuations; or increasing the salience of diabetes in school and social settings, possibly increasing social stigma.

Data on the psychological implications of CGM technology may therefore enhance its clinical use. Such information could assist clinicians in selecting and preparing candidates for this change in diabetes management and guide diabetes educators in teaching and coaching families in its use. Recently, the Diabetes Research in Children Network (DirecNet) completed a 6 month randomized trial comparing management of T1DM based on conventional SMBG alone versus conventional SMBG supplemented with concurrent use of the GW2B with 200 youths age 7-17 years old with T1DM (19). As part of that trial, several measures of psychological variables were obtained at baseline and at the end of the study. The purposes of this aspect of the clinical trial were to:

1. Evaluate the psychological impact of clinical use of the GW2B.
2. Provide a conceptual framework for the empirical assessment of selected psychological aspects of continuous glucose monitoring that might guide future studies of other CGM devices.

Methods

The study was conducted by DirecNet, an NIH-funded research consortium consisting of five pediatric diabetes clinical centers and a coordinating center. An external Data and Safety Monitoring Board and the Institutional Review Boards at each of the centers approved the study protocol, informed consent form and assent form. A parent or guardian gave written consent and each subject gave written assent prior to the performance of any study procedures. The protocol, which has been detailed in a separate publication (19), is summarized below.

Participants and randomization:

To be eligible for the study, a subject had to be between 7 and 18 years old, have T1DM with use of insulin for at least one year, have a glycosylated hemoglobin (HbA1c) level in the range

of 7.0% to 11.0% inclusive, and be on a stable insulin regimen (either an insulin pump or at least 2 injections per day) for the prior two months with no plans to switch modality of insulin administration during the next 6 months. Exclusion criteria included prior home use of a GW2B, skin abnormalities that would prevent use of the GW2B, current or past use of corticosteroids in the last 6 months, or presence of another chronic illness. Patients and their parents or other legal caregivers were invited to participate based on the attending endocrinologist's assessment that they were interested in incorporating CGM technology into daily diabetes management and capable of completing the various behavioral and cognitive requirements of the study procedures. Hence, the sample was highly selected.

Between July 2003 and January 2004, 200 subjects entered the trial (40 at each of the five clinical centers), with 99 randomly assigned to the GW2B group and 101 to the usual care (UC) group with conventional SMBG monitoring alone. The average age of the subjects in the GW2B group was 12.3 ± 2.7 years; 45% were female and 85% were white. Mean duration of diabetes was 5.3 ± 3.4 years. Insulin modality was multiple daily injections for 54% of the patients and insulin pump therapy for 46%. The mean baseline HbA1c was 8.0%, with 41% of subjects having an HbA1c level $\geq 8.0\%$.

Procedures:

Subjects in the GW2B group were provided with a GW2B and an unlimited number of sensors. The GW2B resembles a large wristwatch that adheres to the skin via a sensor that draws interstitial fluid through the skin and displays an estimate of the patient's glucose level every 10 minutes for up to 13 hours. The device provides audible alarms for high, low and rapidly falling glucose levels. The data are stored in memory for computer download and analysis, which was the source of data on GW2B use and results that are reported in this paper. Subjects were encouraged to use sensors as often as desired and instructed to use a minimum of four sensors during the first week and then at least two sensors a week thereafter (with use of at least one sensor a week that covered the overnight period).

Subjects in both groups were provided with a One Touch[®] Ultra[®] Meter (Lifescan, Inc., Milipitas, CA) and an unlimited number of test strips. They were asked to measure finger stick blood glucose levels at least four times daily (i.e. prior to meals and bedtime). The study also provided all subjects with a personal computer to download the Ultra and GW2B data and view the glucose results on a weekly basis. All subjects used the computer to complete a weekly questionnaire on episodes of symptomatic hypoglycemia. The GW2B group was also asked to download the GW2B glucose data and report any problems that were encountered with use of the device.

Phone contacts were made after 1, 2, and 4 weeks and then monthly through 6 months to review diabetes management. Follow-up visits were conducted at three and six months. At each visit, HbA1c was measured and information was elicited on the frequency of GW2B use, problems encountered with its use, and episodes of hypoglycemia. A standardized assessment of skin reactions attributable to GW2B use was performed.

Psychological measures

At baseline and 6-months, the measures described below were obtained separately and independently from parents and youths ≥ 11 years of age. Two families completed the psychosocial measures at baseline, but not at 6-months. Data analyzed for this paper are limited to the 198 youths and parents (101 UC and 97 GW2B) who completed the questionnaires at both time points. The Diabetes Self Management Profile was completed by telephone interview as described below. The other questionnaires were completed independently on a tablet personal computer by parents and youths ≥ 11 years of age using a secure website maintained

by the study coordinating center. The computerized administration of the various questionnaires required entry of a response to every item before submission was possible.

Diabetes Self Management Profile (DSMP): The DSMP (20) is a 25-item structured interview regarding diabetes self management behaviors. Separate, psychometrically equivalent forms of the DSMP have been developed and validated for patients on conventional insulin regimens and for patients on flexible regimens (e.g. insulin pump; “basal-bolus” regimens or any other regimen in which insulin adjustment is guided by carbohydrate counting and a prescribed insulin to carbohydrate ratio). The interview total score was analyzed for the present paper. Scores can range from 0 to 86 and higher scores are indicative of more meticulous diabetes self-management behavior. Parents and youths ≥ 11 years of age were interviewed by telephone using the DSMP form appropriate to their current insulin regimens. Interviews were completed by one of two experienced interviewers either during the scheduled study visits at baseline and end of study or by appointment soon after those visits. Several validation studies have verified the psychometric properties of the DSMP (20).

Diabetes Worry Scale: The Diabetes Worry Scale (DWS) is a 50-item Likert scale that quantifies anxiety related to a variety of diabetes-related concerns and problems (21). Separate parent and adolescent forms have been developed. Scores can range from 50-250 and higher scores indicate greater diabetes-related anxiety. Psychometric analyses of DWS responses obtained in a previous study of intensive diabetes management revealed internal reliability of .97 for youths and .96 for parents. Principle components factor analyses yielded similar factor structures for mothers and youths. For the purposes of the present paper, only DWS total scores entered the data analyses, in an effort to minimize the number of statistical comparisons that were completed.

Peds QL Diabetes Module: The PedsQL (22) is a 28-item scale for the measurement of diabetes-specific quality of life. Separate parent and child report forms of the instrument have been developed and validated. The parent form seeks the respondent's perspective of the child's diabetes-related quality of life. Total scores, with a possible range of 0-112, were analyzed for this paper. Higher PedsQL scores are indicative of less favorable quality of life. Varni and colleagues have verified the psychometric properties of the instrument. For the present sample, alpha coefficients of .89 were obtained for both parent and youth PedsQL total scores.

Continuous Glucose Monitor Satisfaction Scale (CGM-SAT): This measure was completed at the end of the study only by parents and youths ≥ 11 years of age who were randomized to the GW2B group. The questionnaire was designed for this study to provide a quantitative assessment of patients' and parents' perspectives of their satisfaction and their perceived therapeutic impact of CGM use. The CGM-SAT consists of 37 statements related to CGM use, satisfaction and impact and the respondent's task is to rate the degree of their agreement or disagreement with each statement on a 5-point Likert scale. Scores can range from 37-185, with higher scores indicative of greater satisfaction with CGM use. A detailed psychometric analysis of the CGM-SAT is the topic of a separate paper (manuscript under review). Certain portions of the results presented in that paper are also evaluated here for analysis of associations between CGM satisfaction and other study measures.

Statistical Analyses:

Scores for the various measures were summarized with mean $\pm$ 1SD. Analyses of covariance (ANCOVA) were performed with group (UC and GW2B) as the independent variable, the various psychological measures as the dependent variables and the baseline score for each dependent variable as a covariate. In an effort to identify predictors of GW2B benefit, associations between baseline scores on the DSMP, DWS, and PedsQL with HbA1c and frequency of GW2B use were calculated using Pearson correlation for the GW2B group only.

Because of the multiple comparisons performed, p -values $> .01$ were not considered statistically significant.

Results

As described in a separate report (19), there were no statistically significant differences in HbA1c, mean glucose levels, or frequency of hypoglycemia between the GW2B and UC groups during the 6-mo trial. The mean frequency of GW2B use for youths in that group declined steadily during the study from 2.1 ± 0.8 sensors worn per week during month 1 to 1.5 ± 0.6 sensors worn per week during month 6. By the end of the study, 27 (27%) of the GW2B subjects had stopped using the device altogether.

Baseline demographic and psychological comparisons

At baseline, the GW2B and UC groups had similar scores on the DSMP, DWS, and Peds-QL, and for the measures of glycemic control that were obtained. The groups were also similar with respect to age and gender of patients, duration of diabetes and insulin delivery modality.

Between-group analyses of GW2B effects on psychological variables

Analyses of covariance (ANCOVA) were performed treating the 6-month scores on the DSMP, DWS, and PedsQL as the dependent variables and the corresponding baseline score on each measure as a covariate. Table 1 shows that DSMP scores of parents and youths decreased over the 6 months of the study (both $p < 0.001$), indicating deterioration in diabetes self management behaviors over that interval. Mean DSMP scores obtained from parents declined from 63 at baseline to 62 at 6 months for the GW2B group and from 64 to 60 at 6 months for the UC group. There were no meaningful differences between the GW2B and UC groups.

Parents' PedsQL scores were significantly higher than youths' scores at both measurement points, indicating that parents' perceptions of their children's diabetes-related quality of life was less favorable than was the youths' perspectives of their own quality of life. The scores of both parents and youths tended to increase slightly for both groups from baseline to 6 months, suggesting deterioration in quality of life over time, but neither achieved statistical significance ($p = .16$ and $.03$, respectively). Most importantly, there were no significant treatment effects for GW2B on PedsQL scores at baseline or 6 months for parents or youths (Table 1).

Parents' DWS scores were significantly less favorable than those of youths at both measurement points, but there were no between-group differences at baseline or 6 months for parents or youths (Table 1). There were also no significant changes in DWS scores from baseline to 6 months for parents or youths in either group.

Analyses of psychological variables as predictors of GW2B use and glycemic effects

Although the randomized controlled trial showed that GW2B use was not associated with improved glycemic control, there was variability between GW2B subjects relative to glycemic changes during the study. It is possible that subject characteristics may be associated differentially with glycemic benefit from the GW2B. Therefore, additional analyses, limited to participants in the GW2B group, were performed to determine if any of the baseline psychological measures were predictive of the frequency of GW2B use during the study, change in various measures of glycemic control obtained during the study, or satisfaction with the GW2B as measured by the CGM-SAT.

For parents' responses, the DSMP and PedsQL were both significantly associated with frequency of GW2B use ($\rho = .27$; $p = 0.007$ and $\rho = -.29$; $p = 0.004$, respectively). None of the parents' scores on the DSMP, PedsQL, or DWS were associated with the CGM-SAT or

change in HbA1c. Similar trends were observed in youths' scores, but these did not achieve statistical significance.

Discussion

The purposes of this paper were to identify plausible elements of the psychological context of CGM use that may influence its incorporation into T1DM therapy and to illustrate the interactions among these variables during a recently completed randomized trial of one CGM device, the GlucoWatch G2 Biographer. The results of the randomized trial, as summarized in separate publications (19), revealed little glycemic benefit from use of the GW2B, declining use of the GW2B over time and modest satisfaction ratings. In an effort to explore the psychological context of CGM use, selected psychosocial measures were obtained during the trial and their associations with other study measures were evaluated.

In general, the study revealed little evidence that GW2B use resulted in either beneficial or adverse psychological effects on either parents or older youths. None of the changes in scores on the DSMP, DWS, or PedsQL differed significantly between the UC and GW2B groups at the end of the study. As reported elsewhere (manuscript under review), CGM-SAT scores generally indicated minimal benefit from GW2B use, although there was a marginal positive correlation between overall satisfaction and frequency of GW2B use during the study. The absence of adverse psychological effects of GW2B use is also noteworthy, suggesting that the additional treatment burden entailed in its use was not a substantial source of distress among parents or youths.

The study was designed with the assumption that GW2B use would be relatively stable over the 6-mo study period. This was not the case as GW2B use declined steadily during the study. It is possible that psychological effects of GW2B use might have been more discernible earlier in the study had measures been collected at more frequent intervals. Regardless, it is clear that no such effects persisted for 6 months.

Additional analyses were performed to examine psychosocial predictors of GW2B use. Better treatment adherence (DSMP) and quality of life (PedsQL) as reported by parents at baseline was associated with more frequent GW2B use during the study. Patients' reports of these same variables were not associated with frequency of GW2B use. Also, change in HbA1c was not correlated significantly with change in any of the psychosocial measures for either parents or adolescents.

The clinical importance of the present work rests on two points. First no adverse effects of GW2B use on the psychological measures obtained in this study were evident despite the absence of glycemic benefit from its use. Second, the majority of participants (73%) continued using the GW2B throughout the study, although less often. These observations suggest that GW2B use was not unduly burdensome to most patients and families, although presumably those who found it intolerable simply stopped using it.

It should be noted that, relative to recent study samples in which the same psychological measures were obtained, the average characteristics of the enrolled sample indicated rather favorable status at baseline in terms of diabetic control (Mean HbA1c = 8.0%), treatment adherence (Mean DSMP score = 63) and quality of life (Mean PedsQL = 30 for adolescents, 36 for parents). This profile suggests that the study participants tended to be overall in better diabetic control, and to report better adherence and diabetes-related quality of life than might be true of a randomly selected sample of diabetes clinic patients. Given this observation, it is possible that use of the GW2B could not drastically improve these outcomes in this particular sample. Enrollment of a more broadly representative sample of patients could perhaps provide a more sensitive evaluation of the glycemic and psychological effects of CGM use.

The present study illustrates the empirical evaluation of selected psychological variables that were potential predictors of outcomes of GW2B use as well as psychological variables that could conceivably be affected by GW2B use. Additional similar studies could enhance our understanding of how patients and families adapt to this technological advance, assess the degree to which this technology is burdensome or generates adverse psychological effects, and identify variables that differentiate effective from ineffective use of such technology. The present study did not systematically assess how patients and parents used and responded to GW2B data, and investigation of those behaviors may be critical to optimizing the therapeutic benefits of this technology.

Given that the GW2B yielded little discernible therapeutic benefit and that patients tended to use it infrequently, it is not particularly surprising that its use was not associated with pronounced positive or negative psychological effects. Nonetheless, the present report can serve as a basis for comparison for analyses of the psychological context of new CGM devices as they become available and are incorporated into clinical care.

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Appendix

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Table 1
Questionnaire Results (mean $\pm$ SD)

	DSMP ^a	PedsQL ^b	DWS ^c
Youths (N=135)^d			
Baseline	63 $\pm$ 7	30 $\pm$ 13	107 $\pm$ 35
UC (N=69)	61 $\pm$ 8	30 $\pm$ 14	109 $\pm$ 38
GWB (N=66)	64 $\pm$ 6	30 $\pm$ 13	105 $\pm$ 33
6 Months	60 $\pm$ 8	32 $\pm$ 14	105 $\pm$ 33
UC (N=69)	59 $\pm$ 7	32 $\pm$ 14	105 $\pm$ 34
GWB (N=66)	61 $\pm$ 9	31 $\pm$ 13	106 $\pm$ 33
Parents (N=198)^d			
Baseline	63 $\pm$ 8	36 $\pm$ 13	131 $\pm$ 33
UC (N=101)	64 $\pm$ 9	37 $\pm$ 13	131 $\pm$ 36
GWB (N=97)	63 $\pm$ 8	36 $\pm$ 13	131 $\pm$ 30
6 Months	61 $\pm$ 9	37 $\pm$ 12	131 $\pm$ 32
UC (N=101)	60 $\pm$ 9	38 $\pm$ 13	131 $\pm$ 34
GWB (N=97)	62 $\pm$ 8	37 $\pm$ 12	131 $\pm$ 30

^a – Diabetes Self Management Profile: possible range of scores 0-86; higher scores indicate better diabetes adherence.

^b – Pediatric Quality of Life Scale: possible range of scores 0-112; higher scores indicate less favorable quality of life.

^c – Diabetes Worry Scale: possible range of scores 50-250; higher scores indicate more diabetes-related anxiety

^d – Excludes 2 cases where questionnaires were completed at baseline, but not at 6 months.