Validation of Measures of Satisfaction with and Impact of Continuous and Conventional Glucose Monitoring

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group

Abstract

Background: The evaluation of patient-reported outcomes (e.g. impact, satisfaction) is important in trials of continuous glucose monitoring (CGM). We evaluated psychometric properties of the CGM Satisfaction Scale (CGM-SAT) and the Glucose Monitoring Survey (GMS).

Methods: CGM-SAT is a 44-item scale on which patients ($n = 224$) or parents ($n = 102$) rated their experience with CGM over the prior 6 months. GMS is a 22-item scale on which patients ($n = 447$) or parents ($n = 221$) rated the blood glucose monitoring system they were using (home glucose meter with or without CGM) at baseline and 6 months.

Results: The alpha coefficient for the CGM-SAT was ≥ 0.94 for all respondents and for the GMS was ≥ 0.84 for all respondents at baseline and 6 months. Parent–youth agreement was 0.52 for the CGM-SAT at 6 months and 0.24 and 0.20 for the GMS at baseline and 6 months for the Standard Care Group, respectively. Test–retest reliability of the GMS at 6 months for controls was $r = 0.76$ for adult patients, 0.63 for pediatric patients, and 0.43 for parents. Factor analysis isolated measurement factors for the CGM-SAT labeled Benefits of CGM and Hassles of CGM, accounting for 33% and 9% of score variance, respectively. For the GMS, two factors emerged: Glucose Control and Social Complications, accounting for 28% and 9% of variance, respectively. Significant correlations of CGM-SAT with frequency of CGM use between 6 months and baseline and GMS with frequency of conventional daily self-monitoring of blood glucose at baseline support their convergent validity.

Conclusions: The CGM-SAT and GMS are reliable and valid measures of patient-reported CGM outcomes.

Introduction

CONTINUOUS GLUCOSE monitoring (CGM) provides frequent, real-time feedback about glucose levels and retrospective 24-h glucose profiles.¹ Incorporating CGM into the treatment of type 1 diabetes (T1D) provides potential advantages over conventional self-monitoring of blood glucose (SMBG).^{2–5} Real-time use of CGM results could equip people with T1D and parents of youths with T1D to respond promptly to untoward glycemic excursions, minimizing both hyperglycemia and hypoglycemia. Retrospective use of CGM profiles can reveal recurring glycemic fluctuations that are not apparent with conventional SMBG, permitting regimen adjustments to better stabilize glucose control.

Recent CGM studies have confirmed some of these benefits. The Diabetes Research in Children Network pilot studies with the Abbott Diabetes Care (Alameda, CA) Navigator™ CGM device showed that CGM use decreased hemoglobin A1c (HbA1c) in youths on insulin pump⁵ or multiple daily injection regimens.^{6,7} The European GuardControl trial showed that near-daily CGM use yielded significant glycemic benefits

over conventional SMBG and less frequent (3 days/week) CGM use.⁸ The Juvenile Diabetes Research Foundation (JDRF) CGM Study Group randomized 451 patients with HbA1c $< 10\%$ to either Standard Care (based on conventional SMBG) or CGM (based on conventional SMBG and CGM use) over 6 months.^{9–11} This trial showed that CGM use yielded glycemic benefits for adults and, to a lesser extent, children under 15 years of age, but little or no benefit for adolescents and young adults.¹⁰ For patients with HbA1c $< 7.0\%$, CGM use was associated with significant improvements in certain indices of hypoglycemia and maintenance of target HbA1c levels.¹¹ One other small study¹² suggested that, after CGM use, adult patients reported increased treatment satisfaction.

While these studies suggest promise for CGM, questions remain regarding the potential effects of its incorporation into diabetes management on psychosocial and patient-reported outcomes.^{13,14} The extent to which CGM exerts positive or negative psychosocial effects could influence patients' frequency and persistence of CGM use.^{13,14}

Evaluation of these possibilities requires the development and validation of measures of psychosocial effects of CGM

The members of the Group are given in the Appendix.

use. In the JDRF CGM Trial, we further evaluated the measurement properties of the CGM Satisfaction Scale (CGM-SAT), an instrument developed for previous CGM studies (see Supplementary Appendix at www.liebertonline.com/dia).¹³ We also constructed and evaluated a new measure, the Glucose Monitoring Survey (GMS) (see Supplementary Appendix at www.liebertonline.com/dia), that elicits participants' perceptions of the blood glucose monitoring systems they were currently using (meter-only or meter plus CGM) both cross-sectionally and longitudinally.⁹ The objectives of the present article were to report:

1. Internal consistency of these two measures
2. Parent-youth agreement and test-retest reliability for GMS from baseline to 6 months
3. Analysis of treatment group effects on GMS change scores at 6 months
4. Principal components factor analysis to isolate the primary measurement factors that are assessed by each instrument
5. Validity of the two measures via associations with frequency of CGM use/SMBG and HbA1c change over 6 months

Subjects and Methods

Participants and setting

There were 451 patients with T1D who were enrolled in the JDRF CGM Trial who were assigned to conventional SMBG using a home glucose meter only (Standard Care group) or SMBG augmented with CGM (CGM group). The trial has been described in detail elsewhere⁹⁻¹¹; a brief summary appears here. Participants signed Institutional Review Board-approved consent forms (adult patients and parents) or assent forms (youths). Enrollment criteria were designed to determine who might be likely to benefit from CGM use, including HbA1c <10.0%. With a nurse's guidance, those randomized to CGM selected the MiniMed Paradigm[®] REAL-Time Insulin Pump and Continuous Glucose Monitoring System (Medtronic MiniMed, Inc., Northridge, CA), the FreeStyle Navigator (Abbott Diabetes Care), or the DexCom[™] SEVEN[®] (DexCom, Inc., San Diego, CA). Demographic characteristics of the sample have been summarized elsewhere.^{10,11} At each visit, glucose data from the CGM devices were downloaded, and HbA1c level was measured at a central laboratory at the University of Minnesota (Minneapolis, MN) using the Tosoh (Kanagawa, Japan) A1C 2.2 Plus Glycohemoglobin Analyzer method.¹⁵ The CGM-SAT Scale was completed by the indicated participants at 6 and 12 months, and the GMS was completed at baseline and 6 months.

CGM-SAT

This 44-item questionnaire was designed to measure the impact of using CGM on diabetes management and family relationships and on satisfaction with emotional, behavioral, and cognitive effects of CGM use.¹³ Adult patients, pediatric patients (at least 8, but not yet 18, years old), and parents of youth <18 years old rated their agreement or disagreement on a 5-point Likert scale (1 = strongly agree; 5 = strongly disagree) with each of 44 potential positive or negative effects of use of the rated CGM device (see Supplementary Appendix at

www.liebertonline.com/dia). Higher scores reflect more favorable impact of, and satisfaction with, CGM use. Completion of the CGM-SAT took 10–20 min.

GMS

This is a 22-item scale constructed for this trial that quantifies respondents' satisfaction with and therapeutic impact of the glucose monitoring systems that they were currently using (SMBG alone or with CGM). The 22 two-part items ask the respondent to evaluate "Is this a problem now?" and then "How has it changed in the past 6 months?" Response options for the "Problem" questions range from 1 = "a lot" to 4 = "not at all," while those for the "Change" questions range from 1 = "worse" to 3 = "better." Higher scores on the "Problem" questions indicate more positive views of the rated glucose monitoring system. Higher scores on the "Change" questions indicate greater perceived improvement over the 6-month interval. Adult patients, pediatric patients ≥8 years old, and parents of youth <18 years old completed the survey (see Supplemental Appendix at www.liebertonline.com/dia). Completion took 10–15 min.

Statistical methods

Separate analyses were conducted for adult patients (≥18 years), pediatric patients, and parents except where noted. Some children <11 years old were unable to complete the GMS ($n=4$) and CGM-SAT ($n=3$) independently, and their data were not analyzed.

Descriptive statistics. Mean and SD values of item scores on the CGM-SAT and GMS were calculated for each administration of these scales.

Internal reliability. Cronbach's alpha coefficients were calculated for the 6-month administration of the CGM-SAT and for the baseline and 6-month administrations of the GMS (Standard Care group only). This statistic measures a scale's internal consistency, analogous to an average inter-item correlation, and yields an estimate of the extent to which the items comprising a scale are related to one another. Values may range from 0 to 1, and coefficients above 0.70 are commonly interpreted as demonstrating adequate reliability.

Parent-youth agreement. Spearman rank-order correlation coefficients between parent and youth scores were calculated for the CGM-SAT at 6 months (CGM group) and the GMS at baseline (treatment groups pooled) and 6 months (Standard Care group).

Test-retest reliability. Test-retest reliability of the GMS in the Standard Care group was calculated using Spearman rank order correlations between baseline and 6-month scores and between the 6-month and 12-month scores. The CGM group was excluded from these analyses because their GMS scores were likely to change over the 6-month study.

Treatment effects on GMS. Comparison of CGM and Standard Care between-group effects on GMS scores assessing change at 6 months was completed using an analysis of covariance model adjusting for the baseline score.

Principal components analyses. Principal components analysis is a method of identifying the primary measurement “factors” within a given scale, consisting of clusters of scale items that are correlated with each other but not with items loading on other factors. Initial principal components analyses using varimax rotation and with a minimum eigenvalue of 1.0 were completed separately for parents, adults, and youths on the baseline GMS results and the 6-month CGM-SAT results. Because these initial analyses yielded highly similar results from all three groups, the analyses were repeated on the combined sample of pediatric and adult patients.

Convergent validity. For the CGM-SAT at 6 months, associations were calculated with frequency of CGM use and change in HbA1c from baseline to 6 months. For the GMS, associations were calculated with the frequency of self-reported daily blood glucose meter measurements at baseline (treatment groups pooled) and the change in HbA1c from baseline to 6 months (Standard Care group).

Because multiple comparisons were performed, only P values <0.01 were considered statistically significant. Analyses were performed with SAS version 9.1 (SAS Institute, Cary, NC).

Results

Table 1 summarizes the descriptive statistics and reliability estimates for the CGM-SAT and for the baseline and 6-month administrations of the GMS.

Descriptive statistics

Mean ($\pm$ SD) item scores on the CGM-SAT were $3.9 (\pm 0.5)$ for the 120 adult patients, $3.6 (\pm 0.5)$ for the 104 youths, and $3.8 (\pm 0.5)$ for the 102 parents. The mean item scores were above neutral (i.e., 3.0), favoring CGM use for all three subgroups. Mean ($\pm$ SD) item scores on the baseline administration (treatment groups pooled) of the GMS were $2.7 (\pm 0.5)$ for

adult patients, $2.9 (\pm 0.4)$ for youths, and $2.6 (\pm 0.5)$ for parents. Mean ($\pm$ SD) item scores on the 6-month administration of the GMS (Standard Care group only) were $2.8 (\pm 0.5)$ for adult patients, $3.0 (\pm 0.4)$ for youths, and $2.7 (\pm 0.5)$ for parents. GMS scores assessing change in satisfaction and impact over the prior 6 months were significantly higher in the CGM group compared with the Standard Care group for adult patients (2.3 ± 0.3 vs. 2.0 ± 0.2), youth (2.2 ± 0.3 vs. 2.1 ± 0.2), and parents (2.2 ± 0.3 vs. 2.0 ± 0.2) ($P < 0.001$ for all three groups) adjusting for the baseline GMS change score.

Internal reliability

Alpha coefficients for the CGM-SAT exceeded 0.94 for all respondents, whereas those for the GMS exceeded 0.84 at baseline (treatment groups pooled) and 6 months (Standard Care group only).

Parent–youth agreement

Parent–youth agreement was 0.52 for the CGM-SAT and 0.24 and 0.20 for the GMS at baseline (treatment groups pooled) and 6 months (Standard Care group only), respectively. All differences were statistically significant.

Test–retest reliability

Correlations between the baseline and 6-month scores on the GMS (Standard Care group only) were 0.76 for adult patients, 0.63 for youths, and 0.43 for parents. The corresponding correlations between the 6-month and 12-month CGM-SAT scores were 0.76 for adult patients, 0.69 for youths and 0.70 for parents. All differences were statistically significant.

Principal components analysis

Table 2 summarizes the results of principal component analyses to isolate CGM-SAT and GMS measurement factors.

TABLE 1. DESCRIPTIVE STATISTICS AND RELIABILITY INDICES FOR THE CONTINUOUS GLUCOSE MONITORING SATISFACTION SCALE AND GLUCOSE MONITORING SURVEY FOR ADULT PATIENTS, YOUTHS, AND PARENTS

	Adult patients ≥ 18 years	Youths 8–<18	Parents
CGM-SAT, 6-month administration (CGM group)			
<i>n</i>	120	104	102
Mean $\pm$ SD item score	3.9 ± 0.5	3.6 ± 0.5	3.8 ± 0.5
Alpha coefficient	0.94	0.95	0.95
Parent–youth agreement	—	0.52	0.52
GMS			
Baseline administration (groups pooled)			
<i>n</i>	228	219	221
Mean $\pm$ SD item score	2.7 ± 0.5	2.9 ± 0.4	2.6 ± 0.5
Alpha coefficient	0.90	0.84	0.90
Parent–youth agreement	—	0.24	0.24
6-month administration (Standard Care group)			
<i>n</i>	106	106	105
Mean $\pm$ SD item score	2.8 ± 0.5	3.0 ± 0.4	2.7 ± 0.5
Mean $\pm$ SD change score	2.0 ± 0.2	2.1 ± 0.2	2.0 ± 0.2
Parent–youth agreement	—	0.20	0.20
Test–retest*	0.76	0.63	0.43

*Comparison of the baseline and 6-month responses for the mean item scale.

CGM, continuous glucose monitoring; CGM-SAT, Continuous Glucose Monitoring Satisfaction Scale; GMS, Glucose Monitoring Survey.

TABLE 2. RESULTS OF PRINCIPAL COMPONENTS ANALYSES OF THE 6-MONTH ADMINISTRATIONS OF THE CONTINUOUS GLUCOSE MONITORING SATISFACTION SCALE AND BASELINE GLUCOSE MONITORING SURVEY FOR COMBINED ADULT AND CHILD PATIENTS

Test	Measurement factor	Items loading	Eigenvalue	% Variance	Alpha coefficient
CGM-SAT at 6 months (<i>n</i> = 224)	Benefits of CGM	Item numbers: 2, 3, 6, 7, 9, 10, 11, 12, 17, 20, 21, 22, 23, 24, 38, 41, 42, 43, 44	14.42	33%	0.93
	Hassles of CGM	Item numbers: 4, 5, 8, 14, 16, 18, 25, 26, 27, 29, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40	4.15	9%	0.93
GMS at enrollment (<i>n</i> = 447)	Glucose Control	Item numbers: 1, 2, 3, 4, 5, 9, 13	6.14	28%	0.80
	Social Complications	Item numbers: 8, 12, 17, 18, 20, 22	1.99	9%	0.77

CGM-SAT, Continuous Glucose Monitoring Satisfaction Scale; GMS, Glucose Monitoring Survey.

Preliminary analyses revealed highly consistent factor structures for both instruments for data obtained from all participants, and so the adults and youth responses were pooled for analysis.

For the CGM-SAT, two factors emerged: Benefits of CGM (19 items; eigenvalue = 14.42; accounting for 33% of variance; $\alpha = 0.93$) and Hassles of CGM (20 items; eigenvalue = 4.15; accounting for 9% of variance; $\alpha = 0.93$). The remaining five items did not load on any factor. After the five items that did not load on a factor were deleted, internal consistency of the total scale was $\alpha = 0.95$.

For the GMS, two factors emerged: Glucose Control (seven items; eigenvalue = 6.14; accounting for 28% of variance; $\alpha = 0.80$) and Social Complications (six items; eigenvalue = 1.99; accounting for 9% of variance; $\alpha = 0.77$). The remaining nine items did not load on any factor. After the nine items that did not load on a factor were deleted, internal consistency of the total scale was $\alpha = 0.83$.

Convergent validity

Additional analyses examined associations among 6-month CGM-SAT scores with frequency of CGM use, baseline GMS scores with frequency of SMBG, and both CGM-SAT and GMS scores at 6 months with change in HbA1c during the study. CGM-SAT total scores correlated significantly with CGM use (median, 6.6 and 5.9 days/week for adult and pediatric patients, respectively) during the 6-month trial for adult patients ($r = 0.34$; $P < 0.001$) and pediatric patients ($r = 0.27$; $P = 0.005$) with a trend for parents that did not achieve significance ($r = 0.21$; $P = 0.04$). Because treatment goals for those with HbA1c $< 7.0\%$ did not target reduction in HbA1c, analyses of CGM-SAT correlations with change in HbA1c over 6 months included only those with HbA1c $\geq 7.0\%$ at enrollment. Correlations between the CGM-SAT with HbA1c change over the 6-month interval were significant for youths ($r = -0.29$; $P = 0.009$) and for parents ($r = -0.28$; $P = 0.01$) but fell short of significance for adult patients ($r = -0.14$; $P = 0.22$). Lower GMS "Problem" scores (indicating more problems) were associated with a greater frequency of daily blood glucose meter measurements at baseline for adults ($r = -0.22$; $P = 0.002$) but not for children or parents. GMS "Change" scores did not correlate significantly with frequency of glucose meter measurements, and neither GMS

"Problem" nor "Change" scores correlated with change in HbA1c for any subgroup.

Discussion

Mean CGM-SAT and GMS item scores revealed high levels of satisfaction and perceived therapeutic impact from incorporating CGM into T1D management. On both questionnaires, mean item scores of all subgroups converged in the favorable end of the response range. For GMS items measuring change in satisfaction and impact over the prior 6-month interval, mean item scores were slightly but significantly more favorable for the CGM group than for the Standard Care group, indicating that this portion of the GMS was sensitive to CGM intervention effects.

The present results supported several psychometric properties of the CGM-SAT and GMS, including internal reliability (both), parent-youth agreement (CGM-SAT and, to a lesser degree, GMS), and test-retest reliability (GMS). The relatively low estimates of parent-youth agreement on the GMS suggest that parents and youths should complete this measure separately and that parental proxy responses for youths' perspectives of CGM are not valid.

Principal components analyses isolated two primary measurement factors for each questionnaire. For the CGM-SAT, these factors were Benefits of CGM (19 items) and Hassles of CGM (20 items). Perceptions of the positive effects of CGM use and the discomforts or inconveniences associated with it may represent two independent dimensions of people's perspectives of CGM. Because five items did not load on any measurement factor, possibly a condensed version of the CGM-SAT could be as sound psychometrically as the original 44-item questionnaire. Exclusion of the items that did not load on the isolated measurement factors demonstrated acceptable reliability for both the CGM-SAT ($\alpha = 0.95$) and GMS ($\alpha = 0.83$) total scores.

For the GMS, the two primary measurement factors were Blood Glucose Control (seven items) and Social Complications (six items). Two dimensions of satisfaction and impact of blood glucose monitoring appear to cluster together around effects on glycemia and integration of CGM use into one's social context. Because nine items did not load on any factor, a condensed version could represent an alternative to administration of the 22-item original version.

Curiously, among adult patients, higher frequency of blood glucose monitoring at baseline was associated significantly with GMS scores indicative of more problems with glucose monitoring. The same association was not significant for youths or parents. Perhaps adults who were performing frequent blood glucose monitoring entered the study precisely because they were dissatisfied that this effort still did not enable them to achieve desired levels of glycemic control or lifestyle flexibility.

Although some differences among subgroups were evident, CGM-SAT scores were generally associated with frequency of CGM use, and GMS "Problem" scores were associated with frequency of SMBG. These associations support the convergent validity of the CGM-SAT and GMS because both varied significantly with changes in objective indices of relevant patient behavior. While direction of causality, if any, among these measures cannot be ascertained, the consistency of these associations illustrates that subjective and objective measures of CGM benefit are interrelated and that achieving successful outcomes on both dimensions may be necessary in order to optimize therapeutic benefits of CGM.

Appendix: The JDRF Continuous Glucose Monitoring Study Group

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Author Disclosure Statement

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