

ORIGINAL ARTICLE

Salient Characteristics of Youth with Type 1 Diabetes Initiating Continuous Glucose Monitoring

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Abstract

Objective: Consistent continuous glucose monitoring (CGM) use is a challenge in youth with type 1 diabetes. This study aimed to investigate patient and family behavioral and clinical characteristics associated with interest in implementing CGM.

Research Design and Methods: In a cross-sectional study, we compared 120 youth interested in starting CGM (the CGM group) with a general sample of 238 youth with type 1 diabetes (the Standard group). Youth and their parents completed validated surveys assessing adherence to diabetes management, diabetes-specific family conflict, parent involvement in diabetes management, and youth quality of life. Demographic and clinical data were obtained from chart review and interview.

Results: Youth participants had a mean age of 13.0 ± 2.8 years, diabetes duration of 6.3 ± 3.4 years, and hemoglobin A1c (HbA1c) level of $8.2 \pm 1.0\%$ (66 ± 11 mmol/mol). Youth in the CGM group performed more frequent blood glucose monitoring, had lower HbA1c levels, and were more likely to be treated by continuous subcutaneous insulin infusion (CSII) and to be living in two-parent homes than youth in the Standard group. Compared with the Standard group, youth interested in wearing a CGM device and their parents reported greater adherence to diabetes management, less diabetes-specific family conflict, and higher youth quality of life. No differences were found between groups with respect to parent involvement in diabetes management by both youth and parent reports.

Conclusions: In efforts to enhance CGM uptake, it is important to address factors such as blood glucose monitoring frequency, CSII use, adherence, and diabetes-specific family conflict when considering youth with type 1 diabetes for CGM implementation.

Introduction

THE MANAGEMENT OF TYPE 1 DIABETES places substantial physical demands on both patients and family members. The burdens are heightened owing to emotional demands such as fear of hypoglycemia and hyperglycemia. There are opportunities for potentially reducing these burdens with the use of new technologies, such as continuous glucose monitoring (CGM), which can assist in optimizing blood glucose levels.¹ The advancements achieved in recent years with CGM provide substantial potential benefits for diabetes outcomes.² Studies have identified that use of CGM improves

glycemic control in patients with type 1 diabetes when the device is worn consistently³⁻⁵; however, sustained CGM use has been shown to be difficult in pediatric patients.^{6,7} The recently published American Diabetes Association position statement on type 1 diabetes noted that CGM can reduce glycemic excursions in children; however, glycemic improvements are correlated with frequency of CGM use across all ages.⁸

Despite opportunities afforded by CGM use, only 6–9% of youth appear to use CGM.^{9,10} There is a need to identify factors associated with successful CGM implementation as well as barriers to CGM use. Sustained use of technologies

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for diabetes management remains dependent on the patient's active engagement and adherence to a complex management plan.¹¹ One might expect that children versed in insulin pump therapy who perform frequent blood glucose monitoring may be ideal candidates for CGM use, as shown in one cross-sectional study.¹² Diabetes-specific family stress and conflict may also be both potential drivers for and consequences of increasingly complex and demanding therapies such as CGM.^{13,14} However, there are likely many other factors that may be associated with CGM adoption by pediatric patients and families related to quality of life,^{2,15} fear of hypoglycemia,¹² diabetes-related distress,^{6,16} and other behavioral barriers.^{11,14} Before exploring youth and family factors associated with sustained CGM use, it is important to gain improved greater understanding of the characteristics of youth and families preparing to begin CGM. Such knowledge may enhance opportunities to implement CGM in greater numbers of youth with type 1 diabetes.²

In this study, we sought to investigate additional patient and family characteristics associated with interest in implementing CGM. We designed a cross-sectional study to explore differences between youth interested in using CGM and a general sample of youth with type 1 diabetes at the same diabetes clinic. We hypothesized that the percentage of youth and their families who are already engaged in intensive insulin therapy such as continuous subcutaneous insulin infusion (CSII) would be higher in the group preparing to begin CGM than in the general sample of youth with type 1 diabetes. We also hypothesized that youth interested in starting CGM would be more adherent and would report more parent involvement in diabetes management tasks than the general sample of youth with type 1 diabetes.

Research Design and Methods

We compared characteristics of youth with type 1 diabetes beginning CGM (the CGM group) with a separate general sample of youth with type 1 diabetes (the Standard group) from the same pediatric diabetes clinic. In the CGM group, youth with type 1 diabetes and their caregivers were recruited to participate in a CGM family-focused teamwork intervention study designed to optimize CGM use. In the Standard group, youth with type 1 diabetes and their caregivers were recruited from the general clinic population at the same center to complete questionnaires at a single visit and did not receive intervention. In both groups, the data from only one parent were included in this analysis.

All participants included in these analyses met the following inclusion criteria: 8–17.9 years of age; type 1 diabetes duration of ≥ 1 year at enrollment; and documentation of daily insulin dose of ≥ 0.5 units/kg and hemoglobin A1c (HbA1c) level of 6.5–10% at a screening visit prior to enrollment. In addition, if a family enrolled multiple siblings with type 1 diabetes, data from the child with the longer diabetes duration were used. Entry criteria were harmonized between the two study samples. The electronic medical record and a parent–youth interview provided demographic and clinical data, all obtained by trained research staff. Glycemic control was assessed by HbA1c, which was performed in a clinical laboratory using a Diabetes Control and Complications Trial standardized assay (reference range, 4.0–6.0%). Uniform study procedures were used for collection of data

regarding insulin regimen and daily insulin dose using pump downloads when available; if not available, both participant and clinician reported data were used. Blood glucose monitoring data were self-reported from parent–youth interviews.

The local Institutional Review Board approved the study protocols, and all youth/parents signed informed assent/consent forms before beginning any study procedures. CGM group participants needed to complete a 1-week run-in period for inclusion in this analysis; however, all the data reported here were obtained during baseline assessment, prior to intervention group assignment and CGM implementation.

Measures

Youth and their caregivers independently completed the following previously validated assessment instruments. For all of the surveys, the total scores were adjusted to account for any missing responses.

Diabetes Management Questionnaire. The 20-item Diabetes Management Questionnaire (DMQ)¹⁷ measures adherence to different diabetes management tasks on a 5-point response scale, with responses ranging from 1 = almost never to 5 = almost always. Scores range from 0 to 100. Higher scores indicate greater adherence.

Diabetes Family Conflict Scale. The 19-item Diabetes Family Conflict Scale (DFCS)¹⁸ assesses diabetes-specific family conflict on a 3-point response scale, ranging from 1 = almost never to 3 = almost always. Previously published scoring methods for this survey result in total scores ranging from 19 to 57; however, in order to better calibrate the score to the other surveys used in this study, we normalized the total scores to a 0 to 100 scale. Higher scores indicate more diabetes-specific family conflict.

Diabetes Family Responsibility Questionnaire. The 17-item Diabetes Family Responsibility Questionnaire (DFRQ)¹⁹ measures parent involvement in different diabetes management tasks. This questionnaire assesses who has primary responsibility for each task (1 = child, 2 = equal, or 3 = parent). Previously published scoring methods for this survey result in total scores ranging from 17 to 51; however, we normalized the total scores to a 0–100 scale in order to better calibrate the results against the other measures. Higher scores indicate more parent involvement in diabetes management tasks.

Pediatric Quality of Life Inventory Generic Core Scales. The 23-item Pediatric Quality of Life Inventory (PedsQL)^{20,21} measures youth self-report of generic quality of life and the caregiver's perception of the youth's quality of life in four domains: physical, emotional, social, and school functioning. The 5-point response scale ranges from 0 = never a problem to 4 = almost always a problem. Responses were linearly transformed and reverse-scored according to published scoring methods.^{20,21} Scores range from 0 to 100; higher scores indicate higher youth quality of life.

Data analysis

Analyses were performed using SAS software (version 9.2; SAS Institute, Inc., Cary, NC). Descriptive data are presented as mean \pm SD values or percentages. Statistical

analyses included an unpaired *t* test for continuous variables and Fisher's exact test for categorical variables. Youth and parent survey scores were compared using Spearman correlations and paired *t* tests. The survey scores were evaluated according to study group (CGM group vs. Standard group). An α level of ≤ 0.05 was used to determine statistical significance.

Results

Participant characteristics

In total, 457 eligible youth were approached to participate in the CGM study, and 130 (28%) agreed to participate and provided written informed consent. Those who agreed were younger (0.7 years; $P=0.01$) and had shorter diabetes duration (1.2 years; $P=0.01$) than youth who declined to participate. HbA1c did not differ by enrollment status. Alternately, in a separate sample, 455 youth with type 1 diabetes were approached as the Standard group, and 302 (66%) agreed to participate and provided written informed consent. Those youth who declined participation in the Standard group had similar age, diabetes duration, and HbA1c as the youth who agreed. Four patients in the CGM group and 64 patients in the Standard group were excluded because they did not meet the harmonized inclusion criteria required for this current analysis. Six patients in the CGM group declined ongoing CGM use during the run-in period and were also excluded from this analysis, yielding a final sample of 120 youth in the CGM group and 238 youth in the Standard group.

Overall, participants in both groups ($n=358$) had a mean age of 13.0 ± 2.8 years, a mean diabetes duration of 6.3 ± 3.4 years, and a mean HbA1c level of $8.2 \pm 1.0\%$ (66 ± 11 mmol/mol); 51% were female, and 93% were white. The CGM and Standard groups were comparable with respect to age, diabetes duration, sex, and race/ethnicity distributions (Table 1). There were differences between the CGM group and the Standard group in the frequency of daily blood glucose monitoring (7.4 ± 2.2 vs. 5.6 ± 2.1 ; $P < 0.0001$), CSII use (84% vs. 70%; $P=0.004$), and percentage of participants living in two-parent homes (92% vs. 84%; $P=0.05$). In addition, HbA1c was lower in the CGM group ($8.0 \pm 0.8\%$ [64 ± 9 mmol/mol]) compared with the Standard group ($8.3 \pm 1.0\%$ [67 ± 11 mmol/mol]; $P < 0.001$). There were no statistically significant differences between groups with respect to parental education (percentage of families with at least one parent with a college degree).

Survey results

Across the entire sample, youth and parent survey scores were significantly correlated for each of the four measures (DMQ, $r=0.48$; DFCS, $r=0.35$; DFRQ, $r=0.75$; PedsQL, $r=0.42$; all $P < 0.0001$). Youth consistently reported lower adherence to diabetes treatment ($P < 0.0001$), less parent involvement in diabetes management tasks ($P < 0.0001$), and more diabetes-specific family conflict than their parents ($P < 0.001$). It is interesting that the youths' report of quality of life was higher than their parents' proxy report of youth quality of life ($P < 0.0001$).

The CGM and Standard groups had substantial differences in both child (Fig. 1) and parent (Fig. 2) scores regarding adherence to diabetes treatment, diabetes-specific family

TABLE 1. DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF STUDY PARTICIPANTS

	CGM group (n=120)	Standard group (n=238)	P value
Age (years)	12.7 ± 2.7	13.1 ± 2.8	0.23
Sex (% female)	49	51	0.74
Race/ethnicity (% white)	95	92	0.50
Age (years) at diagnosis	6.6 ± 3.6	6.7 ± 3.2	0.93
Diabetes duration (years)	6.1 ± 3.6	6.4 ± 3.4	0.38
HbA1c			
%	8.0 ± 0.8	8.3 ± 1.0	<0.001 ^a
mmol/mol	64 ± 9	67 ± 11	<0.001 ^a
Blood glucose monitoring (frequency/day)	7.4 ± 2.2	5.6 ± 2.1	<0.0001 ^a
Daily insulin dose (units/kg)	0.9 ± 0.3	0.9 ± 0.3	0.95
Insulin regimen (% CSII use)	84	70	0.004 ^a
Family structure (% two-parent family)	92	84	0.05 ^a
Parental education (% college graduate)	73	76	0.52

Data are mean ± SD or %.

^aIndicates significant difference.

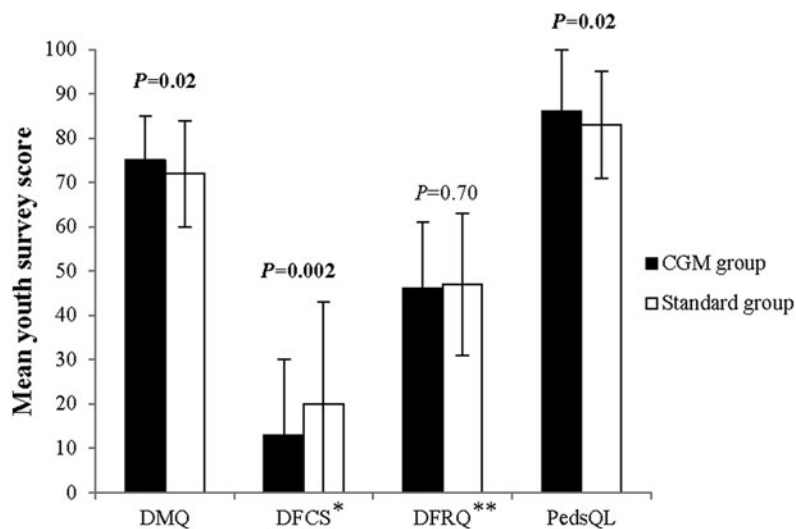
CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; HbA1c, hemoglobin A1c.

conflict, and youth quality of life assessments. Youth interested in wearing CGM and their parents, compared with the Standard group, reported greater adherence to diabetes care (youth, 75 ± 10 vs. 72 ± 12 [$P=0.02$]; parent, 79 ± 11 vs. 75 ± 12 [$P=0.02$]) and higher youth quality of life (youth, 86 ± 14 vs. 83 ± 12 [$P=0.02$]; parent, 83 ± 12 vs. 79 ± 13 [$P < 0.001$]). Similarly, youth and their parents in the CGM group reported less diabetes-specific family conflict than those in the Standard group (youth, 13 ± 17 vs. 20 ± 23 [$P=0.002$]; parent, 11 ± 11 vs. 15 ± 12 [$P=0.003$]). However, as opposed to the other surveys, there were no differences between the CGM and Standard groups with respect to parent involvement in diabetes management, as reported by both children and their parents.

Discussion and Conclusions

Consistent use of CGM may improve HbA1c levels in the absence of severe hypoglycemia.^{4,22,23} Pediatric patients and families may have misconceptions and unrealistic expectations of CGM. In order to promote greater CGM uptake and consistent use for these patients, we sought to evaluate characteristics of pediatric patients and families interested in initiating CGM compared with a general pediatric sample.

In this study, youth interested in wearing a CGM device performed more frequent blood glucose monitoring and had lower HbA1c levels compared with a general sample of youth with type 1 diabetes. Those interested in CGM were also more likely to be treated by CSII than the general sample, even though the CGM device planned for use by the youth was not one that would be integrated into the pump. In addition, youth interested in starting CGM, along with their



parents, reported greater adherence to diabetes management, less diabetes-specific family conflict, and higher youth quality of life. It is not surprising that we uncovered salient differences between the two groups because only 28% of eligible youth who were approached for the CGM study agreed to wear a CGM device compared with 66% of the eligible general pediatric population who were approached and agreed to participate in a nonintervention questionnaire study. The low rate of agreement to participate in the CGM study speaks to the recognized potential burdens related to current CGM technology. Adherence to CGM use appears to be particularly challenging for youth with type 1 diabetes. With the substantial financial and personnel demands required to use CGM technology, it may be opportune to focus efforts on those youth with type 1 diabetes and their families who possess the characteristics associated with CGM uptake. This analysis aimed to identify potentially modifiable diabetes-specific behavioral and clinical characteristics likely to predict uptake of CGM use.

FIG. 1. Youth survey scores by study group. Youth interested in using continuous glucose monitoring (CGM) (the CGM group), in comparison with a general sample of youth with type 1 diabetes (the Standard group), reported, respectively, greater adherence to diabetes care (Diabetes Management Questionnaire [DMQ], 75 ± 10 vs. 72 ± 12), less diabetes-specific family conflict (Diabetes Family Conflict Scale [DFCS], 13 ± 17 vs. 20 ± 23), and higher youth quality of life (Pediatric Quality of Life Inventory [PedsQL], 86 ± 14 vs. 83 ± 12). There were no differences between the CGM and Standard groups regarding parent involvement in diabetes management (Diabetes Family Responsibility Questionnaire [DFRQ], 46 ± 15 vs. 47 ± 16 , respectively). *DFCS original scores, prior to normalization: 24.0 ± 6.6 (CGM group) versus 26.6 ± 8.9 (Standard group). **DFRQ original scores, prior to normalization: 32.7 ± 5.0 (CGM group) versus 32.9 ± 5.4 (Standard group).

Our findings highlight the observation that technology-assisted diabetes management, such as CGM, that requires user input is dependent on the patient's engagement in diabetes self-care. Indeed, the higher rate of CSII use among those interested in CGM supports the likely comfort of such youth to wear and interface with a diabetes management device. In this study, the percentage of CSII use was high in both CGM and Standard groups; however, it was significantly higher in the CGM group, as hypothesized. Patients who are already wearing CSII may be less reluctant to wear an additional device as they are already familiar with skin care and insertion techniques.²⁴ The value of managing youth with type 1 diabetes from diagnosis using a combination of CSII and CGM, in comparison with CSII and blood glucose monitoring, was previously evaluated, and no differences were found between the two groups in 1 year with respect to HbA1c.²⁵ More studies, however, are needed to better understand the impact of multiple diabetes technologies on diabetes care. In fact, there is an ongoing study aimed at

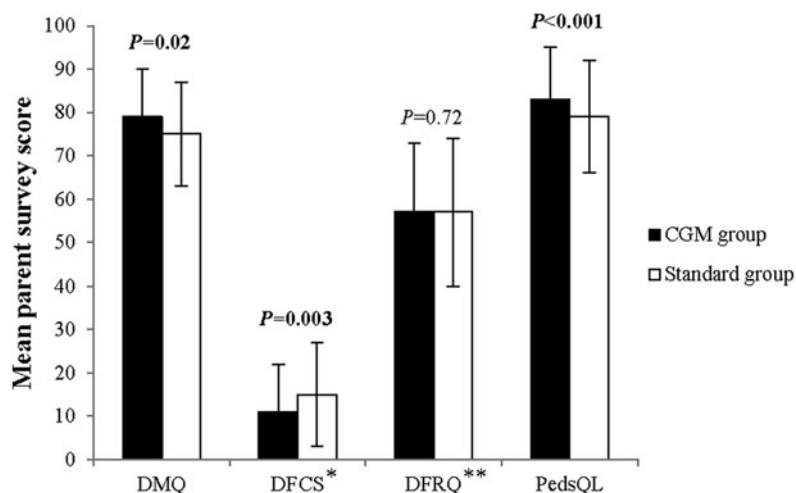


FIG. 2. Parent survey scores by study group. Parents of youth interested in using continuous glucose monitoring (CGM) (CGM group), in comparison with parents of youth in a general sample of youth with type 1 diabetes (Standard group), reported, respectively, greater adherence to diabetes care (Diabetes Management Questionnaire [DMQ], 79 ± 11 vs. 75 ± 12), less diabetes-specific family conflict (Diabetes Family Conflict Scale [DFCS], 11 ± 11 vs. 15 ± 12), and higher youth quality of life (Pediatric Quality of Life Inventory [PedsQL], 83 ± 12 vs. 79 ± 13). There were no differences between the CGM and Standard groups regarding parent involvement in diabetes management (Diabetes Family Responsibility Questionnaire [DFRQ], 57 ± 17 vs. 57 ± 17 , respectively). *DFCS original scores, prior to normalization: 23.1 ± 4.3 (CGM group) versus 24.6 ± 4.7 (Standard group). **DFRQ original scores, prior to normalization: 36.5 ± 5.5 (CGM group) versus 36.3 ± 5.6 (Standard group).

comparing durability of CGM use when implemented at the time of initiating CSII compared with a delay of 6 months for the CGM start.²⁶

It is well documented that lower levels of youth adherence to diabetes treatment correlate with higher levels of diabetes-specific family stress and conflict.^{13,27} In addition, there is growing consensus that youth whose parents are more engaged in diabetes management are more adherent than youth whose parents are less involved in diabetes tasks.^{13,28} These associations, however, have not previously been assessed in patients initiating CGM. In this study, we found lower diabetes-specific family conflict reported by patients and parents interested in starting CGM in comparison with a general population of youth with type 1 diabetes. Contrary to our hypothesis related to family support, although youth interested in starting CGM were more likely to be living in two-parent homes, parent involvement in diabetes management was not associated with motivation to start CGM. This lack of association is possibly due to the observation that youth must wear the CGM sensors and respond to CGM alarms and alerts, independently of their family support.

Perceived youth quality of life may also be associated with adherence to CGM use.^{15,29} In our sample, youth interested in wearing a CGM device reported a higher quality of life in comparison with the general sample. The parents of youth initiating CGM also endorsed higher quality of life for their children than did the parents of the general sample. The higher reported quality of life may be a marker of unmeasured family variables, such as family cohesion, that may aid in the uptake of advanced and complicated diabetes technologies such as CGM.

It is important that we do not overstate our findings. This study involved a cross-sectional research design, and our results represent associations, not causal relationships, between diabetes-specific behavioral characteristics and interest in CGM. Moreover, as occurs frequently in behavioral research, we were reliant on self-report of behaviors and related factors that were not confirmed objectively. Fear of hypoglycemia was also not assessed in this study and could also be an important determinant of CGM uptake. However, previous studies have not consistently found reductions in fear of hypoglycemia with CGM use in the pediatric population.^{6,14} Although we do not have follow-up data to determine if these patients sustained their use of CGM, to our knowledge, this is the first study to assess behavioral characteristics associated with CGM initiation in youth with type 1 diabetes. Longer-term studies will determine the factors that are predictive of sustained CGM use and subsequent benefits on glycemic control.

In summary, the knowledge from this study provides opportunities to identify youth with type 1 diabetes likely to be candidates for CGM technologies based on clinical and behavioral characteristics. Our findings support the International Society for Pediatric and Adolescent Diabetes statement, which recommends that the decision to wear CGM should be made jointly by the youth, who must have a personal interest in using CGM, their parents, and the diabetes team.³⁰ Identifying modifiable factors related to CGM adoption, such as insulin regimen, blood glucose monitoring frequency, adherence to diabetes management, and avoidance of diabetes-specific family conflict, may aid providers as they consider CGM implementation in youth with type 1

diabetes. Further longitudinal studies are necessary to determine if the factors associated with initiation of CGM also predict sustained use of this advanced diabetes technology for youth with type 1 diabetes.

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G.H.T. researched data, analyzed data, and wrote the manuscript. L.K.V. researched data, analyzed data, and reviewed and edited the manuscript. D.A.B. researched data and reviewed and edited the manuscript. L.M.L. researched data, analyzed data, and wrote and edited the manuscript. L.M.L. is the guarantor of this work.

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