Flash Continuous Home Glucose Monitoring to Improve Adherence to Self-Monitoring of Blood Glucose and Self-Efficacy in Adolescents With Type 1 Diabetes

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Adolescents with type 1 diabetes face self-management challenges that make it difficult for them to achieve good glycemic control. In our population of adolescents with poorly controlled type 1 diabetes, the use of continuous glucose monitoring (CGM) improved patients' glycemic time in range (TIR) and identified hypoglycemia more frequently than with intermittent self-monitoring of blood glucose throughout a 4-week interval. However, the adolescents were unable to synthesize this information to problem-solve or reduce the frequency of hypoglycemic events. Setting SMART (specific, measurable, achievable, relevant, and time-bound) diabetes management goals and providing intensive diabetes education and support could increase adolescents' TIR and prevent hypoglycemia.

Recommendations for the management of type 1 diabetes include recording and interpreting blood glucose measurements, counting carbohydrates to calculate appropriate insulin doses, and communicating with the diabetes care team as necessary between visits. These demanding tasks continue to be a challenge for adolescents even with advanced diabetes technologies. Both low treatment adherence and withdrawal from involvement in diabetes self-management, including self-monitoring of blood glucose (SMBG) tasks, were found among adolescents in a recent study conducted by pediatric diabetes services at KK Women's and Children's Hospital (KKH) in Singapore (1).

The period of adolescence involves changes in hormones, cognitive processing, and social relationships. Barriers to communication, defiant behavior, and family dysfunction can interfere with diabetes self-care (2). When self-care is compromised, frequent hospital admissions are more likely. A 2018 chart audit noted that, of 47 adolescents admitted to KKH for diabetes ketoacidosis (DKA), 32 (70%) had an A1C >8.5%. Further analysis revealed a mean age of 14.3 years (SD 3.3) for these patients and a general low rate of adherence to SMBG.

DKA requires admission to an intensive care or high dependency inpatient unit. Ying et al. (3) reported that adolescence, older age of pediatrics patients, and an A1C >8.5% were strong predictors of higher diabetes-related direct costs and hospitalizations (4,5). Members of this cohort often experience a higher risk for and rapid progression to vision-threatening retinopathy early in life compared with adults with diabetes (6). The Epidemiology of Diabetes Interventions and Complications study, the long-term follow-up of the Diabetes Control and Complications Trial, reported a higher likelihood of microvascular and macrovascular disease in adolescents who had up to 6 years of suboptimal diabetes control (7). Furthermore, poor diabetes self-management behaviors and associated chronic suboptimal glycemic control can persist into adulthood (8–10).

Evidence: Literature Review and Synthesis

Self-efficacy is defined as "an individual's belief in his or her capacity to execute behaviors necessary to produce specific performance" (11). Reduced frequency of SMBG

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is related to lower treatment adherence, self-efficacy, and quality of life and to worsening glycemic control in adolescents (8,12).

Technologies in glucose monitoring have evolved from an inpatient and clinic-based point-of-care tool using glucose meters to continuous glucose monitoring (CGM) for personal use. CGM devices are biosensor systems that automatically measure interstitial glucose levels every 5 minutes and store glucose data every 15 minutes, with validated accuracy and reliability (13). CGM systems can store 2 weeks of glucose readings, enabling a more comprehensive analysis of glycemic excursions to modify treatment or lifestyle factors (14). More recently in Singapore, a sensor-enabled intermittent, or "flash," CGM (flash glucose monitoring [FGM]) system (FreeStyle Libre, Abbott Diabetes Care) has become available. The FGM system uses LibreView software to generate and share glucose profile reports so that patients and health care professionals can identify glucose patterns and trends, assess the risk of hypoglycemia, and monitor glucose variations to better inform clinical decision-making (15). CGM and FGM have also been shown to improve glycemic control (as indicated by lower A1C levels), reduce hypoglycemic excursions, and improve self-efficacy (12,15).

Adolescents with improved self-efficacy would have increased confidence in their ability to manage their diabetes care, adhere to a diabetes care regimen, and lower their odds of hospitalization (3,16,17). The purpose of this pilot project was to implement FGM use in adolescents with poorly controlled type 1 diabetes. Specific aims were to:

- Improve self-efficacy through the use of FGM compared with home SMBG, as measured by the Confidence in Diabetes Self-Care (CIDS) survey.
- Increase the amount of time in range (70–140 mg/dL [4–8 mmol/L]) through the use of FGM
- Reduce the number of hypoglycemic (<70 mg/dL [4 mmol/L]) events recorded on the FGM system

Research Design and Methods

This project was a prospective, single-cohort, pre- and posttest design study conducted at the KKH pediatric diabetes clinic. A convenience sample of adolescents were offered the FGM system if they met the following criteria: *1*) age 13–18 years, *2*) diagnosed with type 1 diabetes and on a basal-bolus multiple daily injection insulin regimen, and *3*) A1C >8.5%. A grant obtained from the KKH Health Fund Endowment paid for 50 sensors and 40 FGM devices for this pilot project. This project was approved by the Singhealth Central institutional review board. Signed informed consent was obtained from adolescents and their parents to allow for virtual data-sharing.

Setting

The KKH pediatric diabetes service manages 400 patients with diabetes annually. Routine visits include assessment of glucose logs to inform medication adjustment and efforts to attain a goal A1C. Approximately 120 adolescents with type 1 diabetes are followed by the clinic and typically come in for visits every 6 months. At these visits, the advanced practice nurse (APN) typically conducts a self-care assessment that includes psychosocial, behavioral, and physiological measures to identify barriers to glucose control.

Implementation

The project involved three interactions with the APN; one was face to face, and two were via telehealth (Supplementary Appendix 1). The three encounters unfolded as follows.

- Visit 1. The APN offered the FGM system to eligible adolescents during a routine visit. Once a patient and family agreed to use the system, the patient completed a preintervention CIDS survey (Supplementary Appendix 2). The APN provided education on the FGM system using the teach-back method to ensure comprehension and inserted the patient's first sensor or provided guidance while the patient inserted the sensor. Patients received educational materials about using FGM created by the pediatric diabetes service (Supplementary Appendix 3) and contact information for reaching the APN via telephone and e-mail.
- Visit 2 (first telehealth session). After 14 days of wearing a sensor, patients uploaded their FGM data to the data management software program to be viewed and discussed during the first telehealth session. The APN documented any adjustments to insulin, meals, and exercise and any hypoglycemic events requiring treatment. Patients inserted their second sensor with supervision by the APN via video conference. In the event of a patient's failure to engage in video telehealth services, either a phone consultation or a face-to-face clinic visit was arranged.
- Visit 3 (second telehealth session). After 14 days of wearing their second sensor, the adolescents uploaded data to the software program for review and discussion during the second telehealth session. The APN documented any adjustments to insulin, meals,

or exercise and any hypoglycemic events requiring treatment. Patients completed a second CIDS survey.

Measures

Demographic data included the adolescents' age, ethnicity, sex, education streams (from Singapore education system), duration of diabetes, and prior use of FGM. Glucose profile reports specifically included the percentage of TIR (70–140 mg/dL [4–8 mmol/L]), the number of hypoglycemic events (<70 mg/dL [4 mmol/L]), and daily scans obtained from the data management software.

CIDS is a 20-item self-report questionnaire validated in individuals with type 1 diabetes to measure changes in self-efficacy. The CIDS scale has a high test-retest reliability (Spearman's $r = 0.85$, $P < 0.001$). Each item is preceded by, "I believe I can . . .," with the strength of this belief rated on a 5-point Likert scale ranging from 1 to 5. An example item was, "I believe I can . . . adjust my insulin for exercise, traveling, or celebrations." A total CIDS score was calculated by summing all item scores, with higher scores indicating greater self-efficacy.

Data Analysis

All data were de-identified and entered directly into and analyzed in IBM SPSS, version 25, statistics software. Descriptive statistics (mean ± SD) were used to summarize demographics and calculate the percentage of TIR, the number of hypoglycemic events, and the number of daily sensor scans. A paired *t* test was used to determine changes in CIDS score, percentage of TIR, and sensor scanning frequency between visit 2 and visit 3. A one-way ANOVA with Bonferroni post hoc test was used to compare the change in number of hypoglycemic events and average glucose levels throughout the three time points of visits 1, 2, and 3.

Results

Participants

Of the 64 adolescents approached in routine clinic consultation, 34 (53%) declined participation, and 22 (73%) completed use of the FGM system for 4 weeks (Figure 1). Table 1 summarizes demographic information for both completers and noncompleters.

Of the 22 adolescents who completed the 4-week pilot, 15 (68.2%) had used FGM before this project when offered a free FGM device by the manufacturer. These individuals ceased use of FGM because of the cost of associated equipment. The mean age was 15.3 years (SD 1.6), and the mean duration of diabetes was 7.0 years (SD 3.5). There were more females ($n = 14$, 63.7%) than males ($n = 8$, 36.3%). Chinese ethnicity dominated comprising 50% of the group ($n = 11$). More participants were in the express education stream (college preparatory) ($n = 11$, 50%) than in the normal academic/technical stream (skill-based) ($n = 10$, 45.4%). The mean A1C was 10.3% (± 2.0).

The noncompleter group had similar demographics except for a higher percentage (62.5%) of participants who had not previously used FGM. There were no reported skin reactions to the FGM sensor adhesive among all participants.

CIDS Scores

CIDS survey results are summarized in Table 2. The mean total score at visit 3 had increased by 4.09 ± 9.47 points from 78.14 ± 12.91 to 82.23 ± 12.79, and this change was significant ($P = 0.05$). Subgroup analyses showed a significant improvement of 3.00 ± 5.07 points ($P = 0.01$) on questions 1–10, which focused on how to adjust insulin doses for food, exercise, and hypoglycemic events. These scores increased from 39.68 ± 6.38 at visit 1 to 42.68 ± 6.19 at visit 3. Scores on questions 11–20, which focused on self-care activities such as foot care, did not

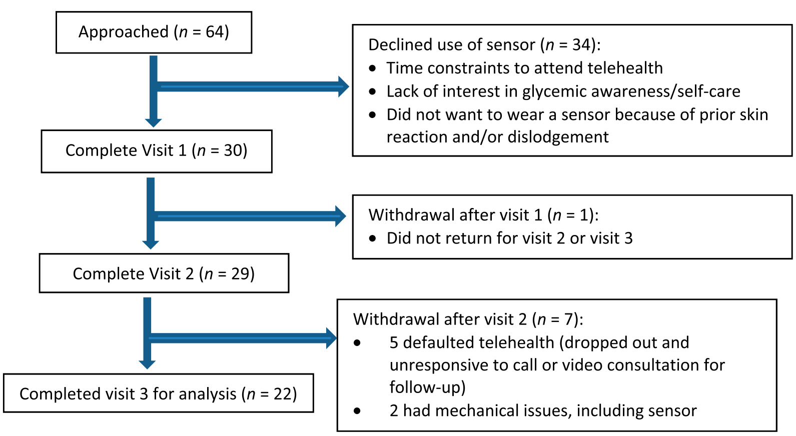

FIGURE 1 Progression of convenience sample of participants.

TABLE 1 Participant Demographics

	Completers (n = 22)	Noncompleters (n = 8)
Age, years	15.3 ± 1.6	15.5 ± 1.6
Duration of diabetes, years	7.0 ± 3.5	6.6 ± 3.2
Baseline A1C, %	10.3 ± 2.0	9.2 ± 1.25
Sex		
Male	8 (36.4)	2 (25)
Female	14 (63.6)	6 (75)
Ethnicity		
Chinese	11 (50)	3 (37.5)
Malay	5 (22.7)	1 (12.5)
Indian	4 (18.2)	2 (25)
Others (Eurasian, mixed)	2 (9.1)	2 (25)
Education stream		
Normal academic/technical (skill-based)	10 (45.4)	4 (50)
Express (college preparatory)	11 (50)	3 (37.5)
International boarding school	1 (4.5)	1 (12.5)
Prior FGM user		
Yes	15 (68.2)	3 (37.5)
No	7 (31.8)	5 (62.5)

Data are mean ± SD or n (%).

significantly change (mean change in score of 1.09 ± 5.38, P = 0.35). These scores were 38.45 ± 7.15 and 39.55 ± 6.95 at visit 1 and visit 3, respectively.

Percentage of TIR

There was an increase of 7.18 ± 15.21% (P = 0.03) in the time spent in this range from 29.82 ± 18.11% at visit 2 to 37.00 ± 21.77% at visit 3 (Table 3).

Hypoglycemic Events

There were higher numbers of hypoglycemic events over 14 days at visit 2 (9.05 ± 6.57, P = 0.001) and visit 3 (8.27 ± 5.48, P <0.001) than at visit 1 (2.45 ± 2.01). There was no significant difference in the number of hypoglycemic events over 14 days between visit 2 and visit 3 (change of 0.77 ± 5.79, P = 1.00) (Table 3).

Glucose Levels

Mean glucose levels (mmol/L) were similar across visit 1 (12.06 ± 2.31; calculated via data in home glucose log), visit 2 as measured by FGM (11.98 ± 3.55), and visit 3 via FGM (11.39 ± 3.05) with no significant differences among the visits (Table 3).

Sensor Scanning Frequency

The frequency of sensor scanning each day was used as a measure of engagement with FGM. Participants had no significant difference in the mean number of daily scans recorded in visit 2 (7.14 ± 6.01) and in visit 3 (7.27 ± 5.71) (P = 0.78) (Table 4).

TABLE 2 Results of CIDS Surveys Measuring Self-Efficacy of Completers (n = 22)

	Overall Score (Mean ± SD)	Overall Change in Score (Mean ± SD)	P
Total score			
Visit 1	78.14 ± 12.91	4.09 ± 9.47	0.05
Visit 3	82.23 ± 12.79		
Total for questions 1–10			
Visit 1	39.68 ± 6.38	3.00 ± 5.07	0.01
Visit 3	42.68 ± 6.19		
Total for questions 11–20			
Visit 1	38.45 ± 7.15	1.09 ± 5.38	0.35
Visit 3	39.55 ± 6.95		

TABLE 3 Mean Glucose and Hypoglycemia Data Throughout 14 Days (n = 22)

	Overall Value (Mean ± SD)	Overall Change (Mean ± SD)	*P*
TIR, %			
Visit 2	29.82 ± 18.11	7.18 ± 15.21	0.03
Visit 3	37.00 ± 21.77		
Hypoglycemic events, *n*			
Visit 1 (glucose logs)	2.45 ± 2.01	–	–
Visit 2	9.05 ± 6.57	–	–
Visit 3	8.27 ± 5.48	–	–
Visit 1 to visit 2	–	6.59 ± 6.83	0.001
Visit 2 to visit 3	–	0.77 ± 5.79	1.00
Visit 1 to visit 3	–	5.81 ± 5.39	<0.001
Glucose levels (mmol/L)			
Visit 1 (glucose logs)	12.06 ± 2.31	–	–
Visit 2	11.98 ± 3.55	–	–
Visit 3	11.39 ± 3.05	–	–
Visit 1 to visit 2	–	0.81 ± 3.22	1.00
Visit 2 to visit 3	–	0.59 ± 2.38	0.76
Visit 1 to visit 3	–	0.67 ± 3.07	0.94

Discussion

In this 4-week pilot program, FGM use in adolescents with suboptimal glycemic control improved TIR and identified hypoglycemic events more frequently compared with SMBG. Self-efficacy improvements achieved significance ($P = 0.05$), and efficacy scores associated with insulin management behaviors improved significantly. There was no reduction in the occurrence of hypoglycemic events. Adolescents were guided by the diabetes APN every 14 days to use glycemic trends to determine insulin doses for food and exercise. (See data on CIDS questions 1–10 in Figure 2.) Other participant self-reported gains include the perceived advantage of a "fingerstick-free" glucose monitoring device and better awareness of glycemic control on a day-to-day basis.

Hypoglycemic events were identified more frequently at visit 2 than at visit 1 because of the increase in available data from FGM compared with capillary blood glucose testing with traditional SMBG. There was no reduction in hypoglycemic events at visit 3 as compared with visit 2 (Figure 3). Recurrent hypoglycemia can result in impaired hypoglycemia awareness that is often unrecognized with capillary blood glucose testing. Given the short duration of this pilot program, it is difficult to determine whether continued use of FGM would have translated into reduced hypoglycemia. Data downloads occurred frequently. There was inconsistent uptake of recommendations by the APN (e.g., recommendations for making insulin dose adjustments and dietary changes) after visit 2, which could explain the lack of reduction in hypoglycemic events.

Adherence to therapy is a challenge in adolescence, with only one-third of adolescents with type 1 diabetes meeting glycemic goals (18). Although these adolescents seemed to have improved self-efficacy with regard to diabetes self-care, this improvement did not equate to greater frequency of engagement in self-care tasks to reduce hypoglycemic events. Two commonly reported explanations for poor adherence were busy school schedules and a lack of motivation or commitment to using FGM. Additionally, managing type 1 diabetes requires other skills of higher executive function such as calculating and administering of correct doses, timing of insulin use, and monitoring of food intake, all of which can be difficult in adolescence. Clinicians should adopt a

TABLE 4 Daily FGM Scans Performed Over 14 Days (n = 22)

Daily Scans, *n*	Overall Value (Mean ± SD)	Overall Change (Mean ± SD)	*P*
Visit 2	7.14 ± 6.01	0.13 ± 2.33	0.78
Visit 3	7.27 ± 5.71		

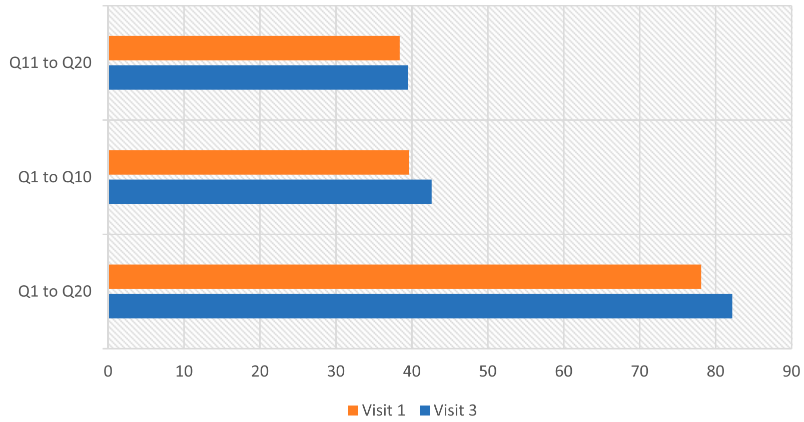

FIGURE 2 Mean overall CIDS scores measuring the self-efficacy of adolescents who completed the 4-week pilot program (n = 22). Q, question.

patient-centric care approach to assess the needs, challenges, and priorities of adolescent patients with type 1 diabetes.

Some reported barriers to FGM use included sensor dislodgement during daily activities and sports, difficulty finding time for telehealth and data management, a lack of interest in glycemic awareness and self-care, and refusal to wear a sensor because doing so was considered inconvenient or associated with social stigma. This feedback could reflect participants' diabetes burnout given their generally long duration of diabetes (mean 7.0 ± 3.5 years) in combination with preexisting stress related to interference with self-care tasks such as fingerstick glucose monitoring and dietary recommendations.

A recent international consensus conference on TIR (held on 8 June 2019) yielded recommendations including intervening by setting SMART goals and providing intensive diabetes education and support to facilitate improvement in TIR and prevention of hypoglycemia (19). Focusing on TIR can provide information that further informs glycemic control efforts beyond A1C data.

Limitations

The FGM system used in this project did not identify hypoglycemic events in real time or provide alarms in response to glycemic excursions. In late 2018, a new FGM system (FreeStyle Libre 2, Abbott Diabetes Care) was launched only in Europe, featuring customizable and notifiable real-time alarms for low and high glucose levels. A new application has also recently launched that allows a smartphone or FGM reader to monitor real-time glucose levels on the go. For adolescents with high motivation and self-efficacy, these two new options could result in better engagement. According to the manufacturer's safety information, the use of FGM in children aged 4–17 years requires supervision by a caregiver who is at least 18 years of age (20). Because glucose results are available only when the sensor is scanned with a reading device, adult supervision might enhance adherence rates in adolescent patients.

Implications and Conclusion

This 4-week pilot program illustrated the feasibility of FGM as a useful home-based system that does not require

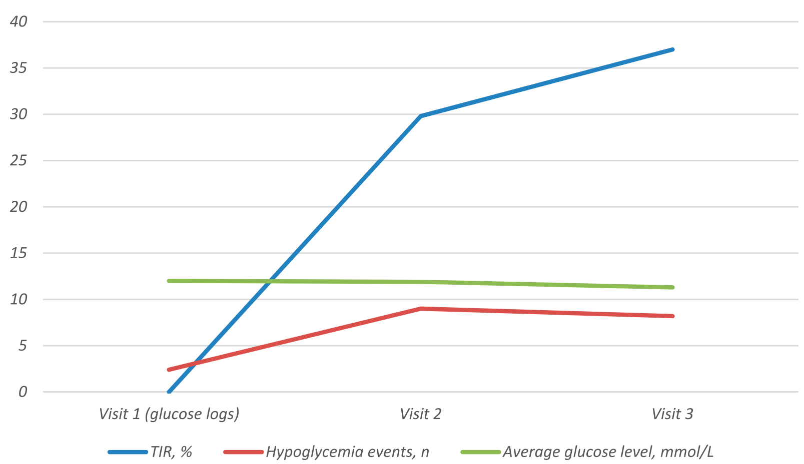

FIGURE 3 Mean overall glycemia measures recorded by FGM over 14 days, including percentage of TIR, number of hypoglycemic events, and average glucose levels (n = 22).

intensive training. Although participants' TIR improved, hypoglycemic events did not decrease. The cost-effectiveness of this system remains unclear for this population of patients.

Careful patient selection and further research could determine the best selection criteria for adolescents who might benefit from FGM use. Diabetes technology expenses are generally paid out of pocket by patients in Singapore. In this population of adolescents with poorly controlled diabetes, a more advanced closed-loop automated pump and sensor system might better facilitate improved TIR and reduced hypoglycemia.

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DUALITY OF INTEREST

No potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

S.T.J.L. and K.P. wrote and edited the manuscript. F.H. and N.L. reviewed the manuscript. N.L. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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