Differences of FreeStyle Libre Flash Glucose Monitoring System and Finger Pricks on Clinical Characteristics and Glucose Monitoring Satisfactions in Type 1 Diabetes Using Insulin Pump

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ABSTRACT

BACKGROUND: To evaluate the different experience of freestyle libre and finger pricks on clinical characteristics and glucose monitoring satisfaction (GMS) in patients with type 1 diabetes (T1D) using insulin pump (IP).

METHODS: A prospective study was carried out on 47 (aged 17-21 years) T1D, who used conventional finger-pricking method for self-testing the glucose. The experiments were conducted between March 2018 and September 2018. For carrying out the study, the flash glucose monitoring (FGM) sensors were placed on each participant, at the baseline visit, by a trained diabetes educator. Furthermore, to determine the total number of scans conducted during the study period, the respective ambulatory glucose profiles were generated by computing the data collected from the sensors. In addition, a trained interviewer handed over the GMS questionnaire to each patient, at the baseline and at 12 weeks of the study.

RESULTS: In comparison to the baseline (finger pricks), various parameters such as: HbA1c (P = .042), hypoglycemia (P = .001), mean capillary glucose (P = .004), total daily insulin dose (P = .0001), percentage of bolus insulin (P = .0001), daily bolus frequency (P = .0001), and daily carbohydrates intake (P = .0001) showed a significant improvement at 12 weeks. Similarly, substantial augmentation was noticed, in the sub domains of GMS, that is, openness (P = .0001), emotional burden (P = .0001), behavioral burden (P = .0001), and trust (P = .0001) at 12 weeks as compared to baseline. Overall, total GMS score at baseline was 1.72 ± 0.37, which increased up to 3.41 ± 0.49 (P = .0001) in the time period of 12 weeks. The HbA1c (r^2 = 0.45), hypoglycemia (r^2 = 0.58), and the mean number of FGM scans, exhibited a negative correlation, while GMS (r^2 = 0.52) and the mean number of FGM scans, exhibited a positive correlation.

CONCLUSION: The frequency of hypoglycemia, HbA1c level, capillary glucose, daily carbohydrates intake decreased, while the total daily insulin dose, daily bolus insulin and total GMS score increased with the use of FGM scanning for 12 weeks.

KEYWORDS: Type 1 diabetes, finger pricks, freestyle libre, satisfaction, glycemic control, hypoglycemia, self-testing

Introduction

With the advent of various modern therapies for diabetes mellitus, maintaining blood glucose has become trouble-free.[1] But for keeping the blood glucose under control, its measurement from time to time is important.[2] In this context, the self-monitoring of blood glucose (SMBG) which basically includes the finger pricking step has shown quite promising results under the condition of following the recommendations or instructions strictly. Thus, it should become an integral part of the blood glucose management plan for patients with diabetes.[3,4] Predominantly, SMBG gives information regarding an individual's blood glucose level, which in turn aids in proper scheduling of its diet, exercise, activity, medication, and stress management.[3,5] But, for both the newly diagnosed patient and the long-term ones, the process of measuring blood glucose via SMBG method is disappointing (pain of constant finger-pricking) in comparison to any other chronic disease among the young population, patients with type 1 diabetes (T1D)

have to accept needles as a part of their daily lives. Apart from this, it does not lead to consistent results, as well as pricking several times a day is extremely frustrating for the patients.[6] As a result, the children or adolescents with T1D, who are required to maintain their glycemic control, do not opt for self-monitoring because of the finger pricking. In this regard, many researchers have also reported that the fear of blood, pain, and discomfort associated with the finger prick method, in addition to, accumulated trauma to the fingers gets directly linked to the less frequent self-testing and poor glycemic control.[7]

In view of overcoming the limitations associated with the SMBG method, several continuous glucose monitoring (CGM) technologies were developed for better management of diabetes. However, the widespread used CGM devices has been restricted due to the association of few shortcomings which overcome by the flash glucose monitoring (FGM) features mainly factory calibration, obtaining glucose readings by scanning the sensor, small size patch glucose sensors, longer

wear time (14 days) and shorter warm-up period.[8,9] In addition, numerous real-life studies, carried out in young populations, have also reported declined usage of these CGMs over time.[10,11] Thus, to overcome the fear of finger-pricking and CGM discomforts, an approach was required, which makes the blood glucose measurement easy and handy. From this perspective, a new technology known as the FGM system (FreeStyleLibre™; Abbott Diabetes Care, Witney, UK) has evolved, which acts as an efficient and painless alternative method for monitoring interstitial fluid glucose in children as well as in adults.[12,13]

The FGM is a novel monitoring tool, which offers an innovative approach for monitoring interstitial fluid glucose, with ease, in patients having diabetes. In other words, patients can monitor their glucose levels at any time throughout the day, without any discomfort including finger pricks. Apart from this, one can obtain both individual blood glucose readings (like glucometers), as well as the trend of glucose levels (like CGM). Thus, FGM seems to be a hybrid between glucometers and continuous glucose monitoring systems (CGMS). In addition, the elimination of the fingerstick calibration, the basic requirement in the CGM method, is one of the major advantages of using FGM. Also, it is very cost-effective, in comparison to the CGM devices. Thus, FGM which is quite accessible and user-friendly becomes an expedient tool for determining daily glucose profile.[12,14–16]

Recently, few researchers have drawn attention toward different goals concerning FGM, which mainly includes the influence of FGM on HbA1c levels and hypoglycemia.[17–19] Hence, the present investigation, the patients using an insulin pump (IP) were chosen. To be more precise, the patients already using the IP in its advanced form, but still, need to use the fingerpick blood sugar measurement to adjust the basal and bolus insulin, were selected. To the best of our knowledge, till date, limited exists research that addresses the effects of FGM and its influence on glucose monitoring satisfaction (GMS) among young patients with T1D using IP, which in turn motivated us to investigate the impact of FGM system on different clinical parameters and GMS among the using IP users.

Methods

Study design and sampling

A prospective study was carried out on 47 (aged 17-21 years) registered T1D patients using IP (Paradigm® Veo™ system; Medtronic MiniMed, Northridge, CA, USA), who used conventional finger-pricking method for self-testing the glucose and the HbA1c level > 7, with experiments being conducted between March 2018 and September 2018 at the Diabetes Treatment Center, Prince Sultan Military Medical City, Riyadh, Saudi Arabia.

For carrying out the study, the respondents were selected consciously and carefully, followed by the appellations of the selected suitable patients with specific identification numbers.

Patients diagnosed in the preceding 6.0 months with any dermatological disorders or changes at the site of sensor application, severe or unstable medical conditions, severe hypoglycemia (such that it requires third-party assistance), diabetic ketoacidosis, or a hyperosmolar–hyperglycemic state and previous use of CGM within the last 6 months were excluded. All participants reserved unconditional or absolute "right" of withdrawing themselves at any point of time, from being participating in the study, without giving any reason or prior notice. Prior to the commencement of the study, the participants or their parents/caregivers were instructed, regarding their roles in this study, as well as the signed informed consent was obtained from them.

At baseline, patients' demographic data, clinical characteristics, and treatment history (IP) were collected using a standardized case record form. The past 4 weeks clinical data, that is, conventional SMBG frequency by finger-prick, hypoglycemia frequency, and average capillary glucose were collected from Abbott FreeStyle Optium Neo® blood glucose meter using the freestyle auto-assist neo ®software prior to the commencement study. At baseline and 12 weeks, HbA1c were collected using the COBAS INTEGRA 400 plus/800 analyzers at the central laboratory of PSMMC. At baseline and 12 weeks mean IP data, that is, total daily insulin dose, basal and bolus insulin percentages, number of boluses, and daily carbohydrates intake were obtained by Medtronic CareLink® Therapy Management Software. At the end of the study, the flash data were collected from the FGM sensors and computed to generate the respective ambulatory glucose profiles (AGPs) so as to determine the total number of scans conducted during the study period. Study participants were instructed to take capillary measurements if they experienced impending or possible hypoglycemic events, glycemic variability, or inconsistent symptoms. The study protocol was approved (approval number 1196) by the Research Ethics Committee of the PSMMC in accordance with the Helsinki Declaration of 1964 (as revised in 2013).

Education about FGM

With the aim of avoiding errors during the study, the participants were made aware of the FGM system. For this purpose, comprehensive learning and written instruction about the FGM system, which basically comprises of directing the patients to maintain a distance of 1–4 cm between the reader and the sensor for 1.0 second while recording the blood glucose levels, acquainting that the sensor can be scanned through clothing, as well as demonstrating the process of replacing the sensor once every 14 days, was provided to each participant and their parents/guardians before the commencement of the study. Furthermore, the participants enrolled for the study were instructed to verify their blood glucose level using a capillary measurement in case of imminent and/or suspected hypoglycemia, abruptly changing glucose levels, or when the symptoms did not match the system's reading, with the help of blood glucose meter having an in-built reader. In addition, all

study participants were allowed to meet or contact the educator at any point of time during the entire period of study.

The educational session was followed, by the insertion of the FL sensors on the back-side of the upper arm of each participant by a trained diabetes educator, who was considered proficient in performing the application and the training procedure. In each participant, 6.0 sensors were inserted excluding the two extra sensors in case of sensor detachment. Furthermore, the total number of scans performed during the period of study (12 weeks) was ascertained by computing the entire data from the sensors at the completion of the study, which in turn produced the corresponding AGPs. In addition, for data interpretation, the mean number of scans/day was considered. Moreover, the CareLink® Pro Therapy Management Software was utilized, for downloading the IP device for the previous 4 weeks to their visit, while FreeStyleLibre v1.0® (Abbott DiabetesCare Inc., Alameda, California, USA) was employed for FL, and FreeStyle Optium Neo software.[19]

Hypoglycemia and Glycated Hemoglobin

According to standardized concepts, the hypoglycemia events are defined as an event of measured glucose concentration $\leqslant 70$ mg/dL ($\leqslant 3.9$ mmol/L).[20] The hypoglycemia frequency episodes were collected at baseline by glucose meter and 12 weeks by blood glucose meter built-in the FGM reader. The HbA1c was analyzed by using the COBAS INTEGRA 400 plus/800 analyzers at the central laboratory of PSMMC, with the analyzation being carried out twice, that is, one at the baseline and other at 12 weeks of the initiation of FGM testing. The HbA1c level of <7% indicated a good control of the blood glucose level.

Survey of GMS

In view of estimating the level of openness, emotional burden, behavioral burden, and trust, type 1 diabetes version of the glucose monitoring satisfaction survey (GMSS) was employed. The GMSS survey comprises a 15-item questionnaire, in which 4 items (questions 1, 8, 10, and 14) belong to openness, another 4 items (questions 2, 5, 9, and 13) belong to emotional burden subscale, 4 items (questions 3, 6, 11, and 15) relates to the behavioral burden, and 3 items (questions 4, 7, and 14) falls in the category of trust. For rating the response to each item, a 5-point Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree) was utilized where higher scores indicated higher GMS.[21]

Statistical Analysis

The statistical analysis of the data was carried out using Microsoft Excel 2013 (Microsoft Corporation; Seattle, Washington, USA) and the Statistical Package for Social Sciences (version 22, SPSS Inc., Chicago, Illinois, USA). The differences among the clinical parameters (hemoglobin A1c, hypoglycemia, average capillary glucose, total daily insulin dose, % basal insulin, % bolus insulin, daily bolus frequency, daily carbohydrates intake) with respect to the different time points (baseline versus 12 weeks) and GMSS score were determined by

Table 1. Baseline characteristics of the study population (n = 47).

VARIABLE(S)	FREQUENCY	%
Age		
17-19 year	30	63.8
20-21 years	17	36.2
Gender		
Female	25	53.5
Male	22	46.5
Body mass index		
<25 kg/m²	21	44.7
≥25 kg/m²	26	55.3
Duration of diabetes		
≤5 years	13	27.7
>5 years	34	72.3
Duration of insulin pump therapy		
≥3 years	29	61.7
<3 years	18	38.3

carrying out a two-tailed paired t-test. On the other hand, the correlation between the total number of scans performed in a day (mean value) and the HbA1c levels, hypoglycemia, GMSS were performed using the Pearson's correlation coefficient. The $P < .05$ was considered to be statistically significant.

Results

The Table 1 illustrates the important characteristics of the population under study. Majority of the study population under investigation falls in the 17–19 years age group (63.8%), with the population comprising patients with diabetes for >5 years (72.3%), and have undergone insulin pump therapy (IPT) for duration ≥3 years (61.6%).

Table 2 presents the differences in the HbA1c, hypoglycemia, mean capillary glucose, total daily insulin dose, basal insulin, bolus insulin, daily bolus frequency, and daily carbohydrates intake, measured at baseline and 12 weeks. In comparison to the baseline, a significant improvement was noticed in the HbA1c ($P = .042$), hypoglycemia ($P = .001$), mean capillary glucose ($P = .004$), total daily insulin dose ($P = .0001$), percentage of bolus insulin ($P = .0001$), daily bolus frequency ($P = .0001$), and daily carbohydrates intake ($P = .0001$) at 12 weeks.

Figure 1 compares the baseline and 12 weeks of GMS sub domains scores among the studied population. The comparison indicates a significant improvement in the sub domains of GMS, which mainly includes openness ($P = .0001$), emotional burden ($P = .0001$), behavioral burden ($P = .0001$), and trust ($P = .0001$), at 12 weeks than at the baseline, with total GMS score at

Table 2. Baseline and 12 weeks comparison of clinical variables (n = 47).

CLINICAL VARIABLES	BASELINE	12 WEEKS	CHANGES	PAIRED "T" TEST	SIG (2 TAILED)
Hemoglobin A1c	8.42 ± 0.65	8.09 ± 1.14	0.33	1.29	0.042
Hypoglycemia/month	7.12 ± 3.1	4.42 ± 1.8	2.7	5.01	0.001
Average capillary glucose, mg/dL	189 ± 47	172 ± 31	17	3.4	0.004
Total daily insulin dose, UI/kg/24 h	0.71 ± 0.13	0.81 ± 0.14	−0.09	−4.7	0.0001
% Basal insulin	47.7 ± 5.7	47.6 ± 6.1	0.10	0.062	0.95
% Bolus insulin	47 ± 6.2	53 ± 5.5	−6.51	−4.81	0.0001
Daily bolus frequency, n	4.4 ± 0.9	5.4 ± 1.5	−1.0	−3.44	0.0001
Daily carbohydrates intake, g	214 ± 40.2	182 ± 41.2	32	3.86	0.0001
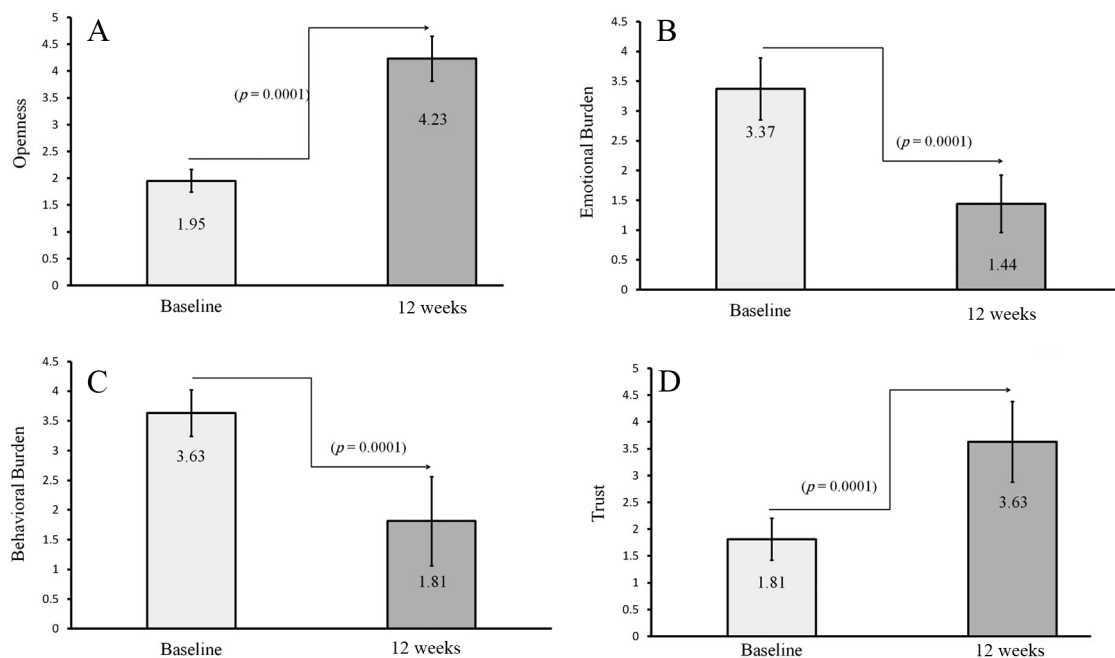
Figure 1. Baseline, 12 weeks comparisons of glucose monitoring satisfaction subdomains scores: (A) Openess, (B) Emotional burden, (C) Behavioral burden, and (D) Trust.
Total glucose monitoring satisfaction score baseline 1.72 ± 0.37 and 12 weeks 3.41 ± 0.49 ($r^2 = 0.52$).

baseline and at 12 weeks being 1.72 ± 0.37 and 3.41 ± 0.49 ($P = .0001$), respectively. No episodes of severe hypoglycemia or serious device-related events occurred during the follow-up.

Figure 2 depicts the correlation between the mean number of FGM scans, HbA1c, and hypoglycemia, where a negative correlation can be seen in the HbA1c level ($r^2 = 0.45$ $P < 0.001$), hypoglycemia ($r^2 = 0.58$; $P < .001$), and the mean number of FGM scans, while GMSS ($r^2 = 0.52$) and the mean number of FGM scans, exhibited a positive correlation.

Discussion

The present study, investigated whether FGM usage over a period of time can influence the clinical characteristics and GMSs in T1D patients treated with IPT. The findings of the

present study revealed that the participants enrolled for the study used FGM for self-testing more frequently, which in turn implies that the participants chose FGM system over the finger-pricking method. Remarkably, the frequency of self-testing among the studied population by the finger-pricking method was 1.91 times/day at the baseline, while it was found to be 8.32 by FGM scanning (difference of 6.41 times per day), which is significantly greater than the self-testing method which involves the finger-pricking step. Previous study reported that the SMBG frequency of <3.5 times/per day appeared to be a risk factor for poor glycemic control in T1D.[22] However, favorably among the FGM users researchers have reported the SMBG frequency (scanning) was higher and a similar pattern of results has been observed in this present study.[19]
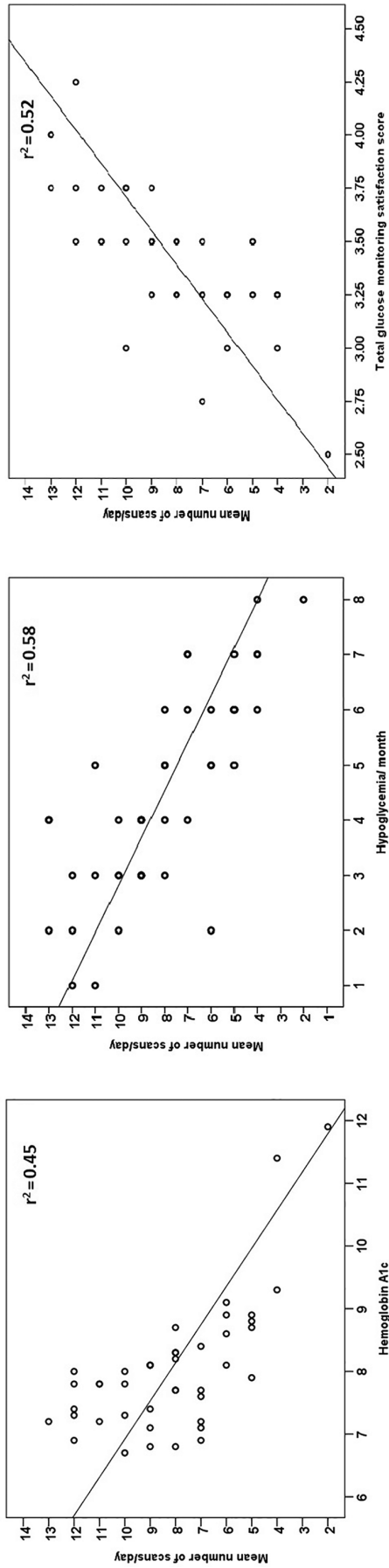
Figure 2. Relationship between mean number of scans/day and hemoglobin A1c, hypoglycemia, and mean total glucose monitoring satisfaction at 12 weeks.

It has been reported that SMBG leads to statistically significant reduction in the HbA1c levels, regardless of whether the patients were made aware regarding the interpretation and utilization of the test results.[23] Apart from this, several studies have stated that the frequency of self-monitoring is associated with improved HbA1c levels while reducing other diabetes-related complications at the same time, due to the direct link between daily monitoring and control.[5,22,23] These outcomes were agreed by the results obtained in the present investigation, where patients with a higher number of daily FGM scans showed significantly improved levels of HbA1c. The present study findings were further confirmed by a Korean study that reported that a higher SMBG frequency was significantly associated with lower HbA1c.[24] Furthermore, a study from Germany also reported that the SMBG frequency was significantly associated with better metabolic control with a drop of HbA1c of 0.20% for one additional SMBG per day. The researchers further reported that increasing the SMBG frequency exceeding 5 times/day did not result in any additional improvement of metabolic control.[25] This improvement in the levels of HbA1c can be expounded on the basis of better insulin adjustment for the consumed food, and an improved ability to correct out-of-target glucose values in time.[26,27] In this study, the bolus insulin was observed to be 47 and 53, at baseline and at 12 weeks, respectively, thereby indicating a clear trend of correction of the insulin among the participants after the 12 weeks use of FGM. In comparison to the baseline, the frequency of hypoglycemia decreased significantly from 7.12 to 4.42 after 12 weeks use of FGM. All the results obtained, in the present study, were in concordance with the past reports, which states that early and frequent monitoring of lower glucose values, before the symptomatic hypoglycemia may allow for the correction of diabetes level, thereby decreasing the risk of overcorrection and the resultant hyperglycemia.[19,28–30] To further validate the observed results, the correction analysis was carried out, which also showed a negative correlation between the HbA1c ($r^2 = 0.45$), hypoglycemia ($r^2 = 0.58$), and the mean number of FGM scans. The analysis also revealed that upon increasing the number of self-testing (i.e. FGM), the level of HbA1c and hypoglycemia decreased. Thus, the study confirms the well-established fact that self-testing is highly effective in enhancing the degree of self-care in patients with diabetes. Since self-testing helps patients in estimating their blood glucose accurately, in response to the alterations made in their lifestyle and medications, one can evidently state that it strengthens the feeling of empowerment in patients with diabetes.[5]

The HbA1c levels should not be the only decisive factor for assessing the effectiveness of diabetes treatment. Instead, patient-reported outcomes, including patient satisfaction, well-being, and quality of life, should also be given paramount importance.[31,32] Indeed, enhancement in treatment

satisfaction may play a crucial role in raising patient self-efficacy and commitment to therapy, thereby assisting in achieving long-term stable glycemic control, in addition to, the minimization of the risk of diabetic complications.[33] Upon augmenting the frequency of scanning by FGM system, in the present study, significant improvement was observed in the tested factors of GMS subdomains of GMS, which mainly includes (1) openness ($P = .0001$), (2) emotional burden ($P = .0001$), (3) behavioral burden ($P = .0001$), and (4) trust ($P = .0001$) at 12 weeks as compared to baseline, with total GMS score being 1.72 ± 0.37 at baseline, which further increased up to 3.41 ± 0.49 ($P = .0001$) at 12 weeks of FGM use. Also GMSS ($r^2 = 0.52$) and the mean number of FGM scans, exhibited a positive correlation. The results obtained elucidate that increased frequency of FGM scan exhibits a positive correlation with the GMS of diabetes patients. However, these outcomes are not surprising because the application of advanced technology improves the frequency of self-testing among the individuals of the population under investigation.[30,34]

Although the limitations that exist in the present investigation such as (1) the small sample size; (2) no randomization, no control group; and (3) the inclusion of only one center for study, can be overcome by carrying out the study on a larger scale, the present study, with the above limitations, delivers valuable data about the FGM system as well as provides helpful insights regarding the significant positive improvement observed among adolescents with T1D, due to the replacement of finger prick method with the FGM system. Conclusively, the findings of this prospective study evidently illustrated that the frequency of hypoglycemia, HbA1c levels can be effectively reduced, while the GMS can increase by frequent FGM scanning. Also, the frequency of self-testing among patients got increased due to the use of FGM scanning for determining blood glucose level, in comparison to the self-testing by the conventional finger-pricking method. However, further studies are required, for ascertaining whether the prolonged and consistent use of the FGM system will result in improved outcomes.

Author Contributions
AAAH and MAAD conceived and designed the study and contributed to the writing of the manuscript. AAAH and AAR wrote the first draft of the manuscript and agreed with manuscript results and conclusions. MAAD and AAR made critical revisions and approved the final version of the manuscript. All authors reviewed and approved the final manuscript.

Data Sharing Statement
No data sharing as this manuscript and the data were not published elsewhere.

Ethical Approval
The study protocol was approved by the Research and Ethics committee of Prince Sultan Military Medical City, Riyadh, Saudi Arabia (approval number 1196).

Informed Consent
During the informed consent process, study participants were assured that data collected would be used only for stated purposes and would not be disclosed or released to others without the consent of the participants.

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