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ORIGINAL RESEARCH

The Potential Impact of the FreeStyle Libre Flash Glucose Monitoring System on Mental Well-Being and Treatment Satisfaction in Patients with Type 1 Diabetes: A Prospective Study

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ABSTRACT

Introduction: This study assessed the treatment satisfaction and sense of well-being attained when patients with type 1 diabetes use the FreeStyle Libre flash glucose monitoring system (FSL; Abbott Diabetes Care, Inc., Alameda, CA, USA).

Methods: A 12-week prospective study was conducted from January 2018 to May 2018 at the Diabetes Treatment Center, Prince Sultan Military Medical City, Riyadh, Saudi Arabia. Study participants (aged 14–21 years) were treated for type 1 diabetes with an insulin pump (IP) (n = 10) or multiple dose injections (MDI) (n = 23), and used the conventional finger-pricking method for glucose self-testing. At the baseline visit, FSL sensors were placed on each participant by a trained diabetes educator. At baseline and 12 weeks, a trained interviewer administered the Arabic version of the Diabetes Treatment Satisfaction Questionnaire (DTSQ) and the WHO-5 Well-Being Index (WHO-5) (1998 version) questionnaire.

Results: As compared with the baseline, positive differences were found after 12 weeks of FSL use for all of the items in the DTSQ ($p < 0.001$) and the WHO-5 questionnaire ($p < 0.001$). The overall score for the DTSQ improved from a mean (SD) of 14.4 ± 6.5 at baseline to 32.1 ± 1.8 at 12 weeks. For the WHO-5 questionnaire, the overall well-being percentage score improved from 45.1% at baseline to 93.6% at 12 weeks ($p < 0.001$).

Conclusion: Use of the FSL along with IP or MDI led to higher treatment satisfaction and a greater sense of mental well-being compared with the baseline conventional finger-pricking method.

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Keywords: DTSQ; Flash glucose monitoring; FreeStyle Libre; Glycemic control; Perceived hyperglycemia; Perceived hypoglycemia; Treatment satisfaction; Type 1 diabetes; Well-being; WHO-5

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INTRODUCTION

Treatment of diabetes in the pediatric population can be challenging for a myriad of reasons. Some obstacles include unpredictable food intake, physical activities, fear of needles [1–2], increased sensitivity to short-acting insulin, and being asymptomatic or unable to convey a

hypoglycemic or hyperglycemic status [3–6]. An inability to control glycemic levels in the pediatric age group can lead to future health and treatment issues [3, 7, 8]. Fear of hypoglycemia has implications for treatment adherence, while prolonged hyperglycemia can lead to long-term multi-organ complications such as neuropathy, nephropathy, vascular and cardiac complications, and retinopathy [8].

Mental well-being and quality of life can also be affected by type 1 diabetes. Studies have shown that children to young adults can experience diabetes distress or anxiety, which in turn can lead to missed boluses, increased HbA1c, less glycemic control, and self-management issues [9–12]. In fact, a review of 14 studies found that about one-third of youths and adolescents with type 1 diabetes reported anxiety symptoms that could contribute to poor glycemic control [13]. Concerns about managing diabetes in public and the visibility of treatment devices can also impede treatment adherence [14–15].

Recent advances in diabetic technology may help to address some of these concerns. A novel option for glucose monitoring is the FreeStyle Libre flash glucose monitoring system (FSL; Abbott Diabetes Care Inc., Alameda, CA, USA), which measures interstitial glucose. The use of this system has been shown to lead to improvements in behavior and quality of life and to reduce worry in the pediatric and young adult population [16]. Other studies of the FSL have reported good precision, decreased glucose variability, increased time in range, and ease of wear [17–20]. Although this system has shown good glycemic-related outcomes and ease of use, less is known about the well-being and treatment satisfaction of pediatric and young adult users of this system [21–25]. An advantage of the current study is that it evaluates the sense of mental well-being and treatment satisfaction in the younger population using a novel modality that has only rarely been reported in the literature. Because adolescents and young adults have been shown to struggle with diabetes stigma and using diabetes treatments in public, understanding their treatment satisfaction and mental well-being associated with the use of the FSL system would be beneficial to clinicians [14–15].

The objective of this study was therefore to evaluate mental well-being and treatment satisfaction in a pediatric and young adult population with type 1 diabetes who were treated with either an insulin pump (IP) or multiple dose injections (MDI) and used the FSL system for 12 weeks.

METHODS

Study Design

This 12-week prospective study included 33 consecutively enrolled patients (aged 14–21 years) with type 1 diabetes who used the conventional finger-pricking method for self-testing glucose. The study was conducted from January 2018 to May 2018 at the Diabetes Treatment Center, Prince Sultan Military Medical City, Riyadh, Saudi Arabia. Study participants had no prior experience with the FSL, and had received insulin treatment via IP therapy or MDI for at least the 6 months before inclusion in the study.

Exclusion criteria included the use of another interstitial glucose monitoring system concurrently or 6 months prior to study; a dermatological disorder or change at the site of sensor application within 6 months after starting the study; severe or unstable medical conditions; severe hypoglycemia requiring third-party assistance; diabetic ketoacidosis; or a hyperosmolar hyperglycemic state.

The Research and Ethics Committee of Prince Sultan Military Medical City, Riyadh, Saudi Arabia approved the study protocol. The study was conducted in accordance with the tenets outlined in the Declaration of Helsinki and with Good Clinical Practice. The participants or their parents/caregivers were advised of their roles in this study, and a signed informed consent was obtained from them prior to the recruitment of the subjects.

Comprehensive training and written instructions were provided to the study participants and their parents/guardians on the use of the FSL system, including sensor duration and replacement (every 14 days), as well as proper scanning technique. Educators were accessible to the participants at any time during the study.

Study participants were instructed to take capillary measurements if they experienced impending or possible hypoglycemic events, glycemic variability, or inconsistent symptoms.

At the baseline visit, the FSL sensors were placed on the back of the upper arm of each participant by a trained diabetes educator. Each study participant received 6 sensors and 2 extra sensors in case of sensor detachment. At baseline and at 12 weeks, a trained interviewer administered the Diabetes Treatment Satisfaction Questionnaire (DTSQ, status version) and the WHO-5 Well-Being Index (1998 version) questionnaire in the patients' native language (Arabic). The DTSQ is an accurate tool for evaluating treatment satisfaction in patients with type 1 diabetes, and consists of a six-item scale (0–5) assessing treatment satisfaction and two items assessing perceived frequency of hyperglycemia and hypoglycemia [26]. The WHO-5 Well-Being Index (1998 version) questionnaire includes 5 statements rated on a scale of 0 (at no time) to 5 (all of the time). Higher numbers indicate greater well-being. The percentage score is used to determine changes in well-being, with a 10% difference indicating a significant change.

Statistical Analysis

Data analysis was performed using Microsoft Excel 2013 (Microsoft Corporation, Seattle, WA, USA) and SAS Statistical Analysis Software (SAS) version 9.4. The paired *t* test was used to measure changes from baseline to 12 weeks. Differences greater than 0.05 were considered significant. In addition, a significant change in the WHO-5 was defined as a 10% change from baseline.

RESULTS

Demographics

There were a total of 33 study respondents, of whom 10 received treatment via IP and 23 received MDI ($n = 23$). Of the 33 study respondents, 54.5% were female, the average HbA1c was 8.8 ± 1.4, the average duration of diabetes was 7.7 ± 3.1 years, and the average age was 15.9 ± 1.7 years. The mean daily frequency of SMBG readings at baseline was 2.21 ± 0.81 times daily. In comparison, the mean daily frequency of FSL scans over 12 weeks was 7.79 ± 2.21 times daily. Demographics for this study population are further described in Table 1.

DTSQ Outcomes

Mean individual values at baseline and after 12 weeks of FSL use are shown in Table 2. The overall mean summary score for DTSQ improved significantly from 14.4 ± 6.0 at baseline to 31.7 ± 1.9 at 12 weeks ($n = 33$, $p < 0.001$). The IP group and the MDI group both showed statistically significant improvements in overall DTSQ score from baseline to 12 weeks. Mean treatment satisfaction scores were comparable for the IP (31.8 ± 1.8) and MDI (31.6 ± 2.0) groups; however, the MDI group ($n = 23$) showed a greater mean change in treatment satisfaction than the IP group ($n = 10$): 20.0 ± 5.1 vs. 11.0 ± 5.9, respectively ($p < 0.001$).

For perceived frequency of hyperglycemia, mean values improved significantly from baseline (5.4 ± 0.6) to 12 weeks (2.6 ± 1.3) ($n = 33$, $p < 0.001$). There was no statistically significant difference between the IP and MDI groups. Likewise, mean values for the perceived frequency of hypoglycemia improved from baseline (5.2 ± 0.7) to 12 weeks (2.8 ± 1.4) ($n = 33$, $p < 0.001$), and there was no statistically significant difference between the IP and MDI groups.

WHO-5 Outcomes

Mean scores for the WHO-5 questionnaire are shown in Table 3. The well-being index raw score improved statistically significantly from baseline to 12 weeks, with mean scores of 11.3 ± 4.2 vs 23.4 ± 1.6 and thus a change of 12.1 ± 4.0 ($p < 0.001$). Differences were greater for the MDI group (13.1 ± 3.7) than the IP

Table 1 Background characteristics of the study population

	Overall (N = 33)	IP (N = 10)	MDI (N = 23)	p value
Age (in years)				
n	33	10	23	
Mean (SD)	15.9 (1.7)	16.4 (1.4)	15.7 (1.8)	0.316†
Median (Min, Max)	16.0 (14.0, 21.0)	16.5 (14.0, 18.0)	15.0 (14.0, 21.0)	
Gender *n* (%)				
Male	15 (45.5)	6 (60.0)	9 (39.1)	0.269*
Female	18 (54.5)	4 (40.0)	14 (60.9)	
Education, *n* (%)				
Primary	2 (6.1)	0	2 (8.7)	0.463*
Secondary	25 (75.8)	9 (90.0)	16 (69.6)	
Intermediate	3 (9.1)	0	3 (13.0)	
University	3 (9.1)	1 (10.0)	2 (8.7)	
BMI				
n	33	10	23	
Mean (SD)	22.3 (2.5)	23.1 (2.8)	21.9 (2.4)	0.2015†
Median (Min, Max)	22.7 (17.3, 26.2)	24.5 (17.3, 24.5)	21.5 (17.3, 26.2)	
HbA1c (%)				
n	33	10	23	
Mean (SD)	8.8 (1.4)	7.9 (0.5)	9.2 (1.5)	0.002†
Median (Min, Max)	8.3 (7.1, 13.0)	8.0 (7.1, 8.6)	8.5 (7.2, 13.0)	
Duration of diabetes (years)				
n	33	10	23	
Mean (SD)	7.7 (3.1)	8.7 (3.4)	7.3 (2.9)	0.233†
Median (Min, Max)	8.0 (3.0, 16.0)	8.5 (4.0, 16.0)	7.0 (3.0, 11.0)	

SD standard deviation, *IP* insulin pump therapy, *MDI* multiple dose injections
*Chi-square test
† Two-sample *t* test

group (9.8 ± 3.9). The overall well-being percentage score showed a significant improvement, with a change of 48.5% from baseline (45.1%) to 12 weeks (93.6%) ($p < 0.001$). The well-being percentage score showed a statistically significant difference in mental well-being for both the IP and MDI groups. At 12 weeks, a higher percentage of patients reported "more than half of the time" or "all of the time" for all of the WHO-5 questionnaire items when compared with baseline responses (Fig. 1).

Table 2 Diabetes Treatment Satisfaction Questionnaire (DTSQ) comparison of mean (±SD) results for baseline vs. 12 weeks of FreeStyle Libre system use

DTSQ results	Baseline (mean ± SD)	After 12 weeks of FreeStyle Libre system use (mean ± SD)	Change from baseline (mean ± SD)	*p* value
Satisfied with current treatment	2.2 ± 1.2	5.1 ± 0.7	2.9 ± 1.3	< 0.001
Convenience of current treatment	2.4 ± 1.2	5.5 ± 0.7	3.1 ± 1.3	< 0.001
Flexibility of current treatment	2.5 ± 1.4	5.4 ± 0.5	2.8 ± 1.5	< 0.001
Understanding diabetes	2.8 ± 1.3	5.5 ± 0.6	2.7 ± 1.4	< 0.001
Recommend the current treatment	2.4 ± 1.1	5.2 ± 0.7	2.8 ± 1.4	< 0.001
Continue the present treatment	2.1 ± 1.7	5.1 ± 0.7	2.9 ± 1.9	< 0.001
Total satisfaction score (Q 1, 4, 5, 6, 7, 8)	14.4 ± 6.0	31.7 ± 1.9	17.3 ± 6.7	< 0.001

DISCUSSION

Comprehensive diabetes management should include not only clinical measures, such as HbA1c levels, but also the patient experience relative to well-being, satisfaction, and quality of life, as these measures have also been shown to influence diabetes care [27]. In the current study, we sought to understand more about the patient experience by evaluating outcomes for well-being and treatment satisfaction. Results at 12 weeks showed statistically significant improvements in treatment satisfaction and mental well-being scores in study participants who used the FSL system. In the WHO-5 questionnaire, both groups showed marked improvements in well-being scores, particularly the MDI group, who presented greater changes in well-being scores compared with the IP group. Other noteworthy findings of this study were the between-group differences in DTSQ treatment satisfaction. The MDI group had a higher mean score for the Treatment Satisfaction Scale than the IP group. Likewise, the WHO-5 questionnaire showed slightly higher well-being raw scores for the MDI group than for the IP group. Relative to perceived hypoglycemia or hyperglycemia, both groups reported statistically significant improvements from baseline.

Our results are consistent with a recent study of an adult Japanese patient population with type 1 diabetes and type 2 diabetes who used the FSL for 14 days, which found significant improvements in DTSQ and WHO-5 for the type 1 diabetes group [28]. In contrast, their study found no significant changes relative to perceived hyperglycemia or hypoglycemia in the DTSQ. Additionally, the mean scores for the WHO-5 and DTSQ at 12 weeks were higher in our study compared with their study scores at 14 days [28]. Further research would be necessary to understand the cause of these differences, such as the ages of the study populations, the duration of FSL use, or the type of insulin delivery. A possible explanation may be that our study period was 12 weeks, compared with 14 days for the other study. In addition, the study participants in the other study were adults rather than youths. Consensus results for IP versus MDI have shown mixed results for quality of life outcomes; however, adolescent

Table 3 WHO-5 Well-Being Index questionnaire comparison of mean (±SD) results for baseline vs. 12 weeks of FreeStyle Libre system use

	Over the last two weeks:	Baseline (mean ± SD)	After 12 weeks of FreeStyle Libre system use (mean ± SD)	Change from baseline	*p* value
1	I have felt cheerful and in good spirits	2.1 ± 0.8	4.8 ± 0.4	2.7 ± 1.0	< 0.001
2	I have felt calm and relaxed	2.3 ± 1.0	4.5 ± 0.6	2.2 ± 1.0	< 0.001
3	I have felt active and vigorous	2.2 ± 1.3	4.8 ± 0.4	2.5 ± 1.3	< 0.001
4	I woke up feeling fresh and rested	2.2 ± 1.1	4.7 ± 0.5	2.5 ± 1.1	< 0.001
5	My daily life has been filled with things that interest me	2.4 ± 1.2	4.6 ± 0.7	2.2 ± 1.3	< 0.001

patients using CSII have reported high levels of satisfaction due to a greater sense of control, independence, fewer physical complaints, and increased flexibility in diet and daily schedule [29]. More research is warranted to understand why patients in the MDI group of the current study had a greater change in well-being compared with the IP group.

In another study of 67 children (4–18 years old) with type 1 diabetes, the usability questionnaire results showed that high satisfaction was reported by adolescents and children after 14 days of use, as well as good correlation with SMBG [30]. Likewise, in a study of children and adolescents with type 1 diabetes who attended a summer camp, the usability questionnaire outcomes revealed high overall satisfaction for patients and practitioners and satisfactory clinical accuracy [31]. However, a shared concern for these studies was the need for further research relative to clinical decision-making based on sensor readings. In the current study, participants were instructed to take capillary measurements in the event of impending or possible hypoglycemic events, glycemic variability, or inconsistent symptoms. This remains an important factor, as some patients remain asymptomatic or unaware of hypoglycemia, which can be particularly problematic and even life-threatening [5]. After 12 weeks of FSL use in the current study, participants reported significant improvements from baseline relative to how often they felt blood sugars were either unacceptably high or low, as well as increased satisfaction with their understanding of diabetes. Improvements in patient perception of hypoglycemia may be beneficial for patients who experience fear of hypoglycemia, which has been shown to affect treatment adherence and increase anxiety [32].

Findings from the current study provide insight into the mental well-being and treatment satisfaction experienced by pediatric and young adult patients with type 1 diabetes. The outcomes evaluated in this study were from validated questionnaires which have been used to assess mental well-being and satisfaction. These results may be useful for health care practitioners who treat pediatric patients, particularly those who have frequent hypoglycemic or hyperglycemic excursions and have fears associated with those episodes. Results from this study indicate that patients experienced less fear associated with hypoglycemia, which is consistent with our previously reported reduced frequency of hypoglycemic episodes with the FSL compared with the conventional finger-pricking method [16]. The FSL system was used for 12 weeks in this study, which provided a longer duration of treatment for comparison with baseline. Other studies could assess whether these quality-of-life endpoints improve over time, as the mean scores in this study were numerically higher than the results reported for another adult population [28].

There are, nevertheless, some evident limitations inherent to this study. First, these data

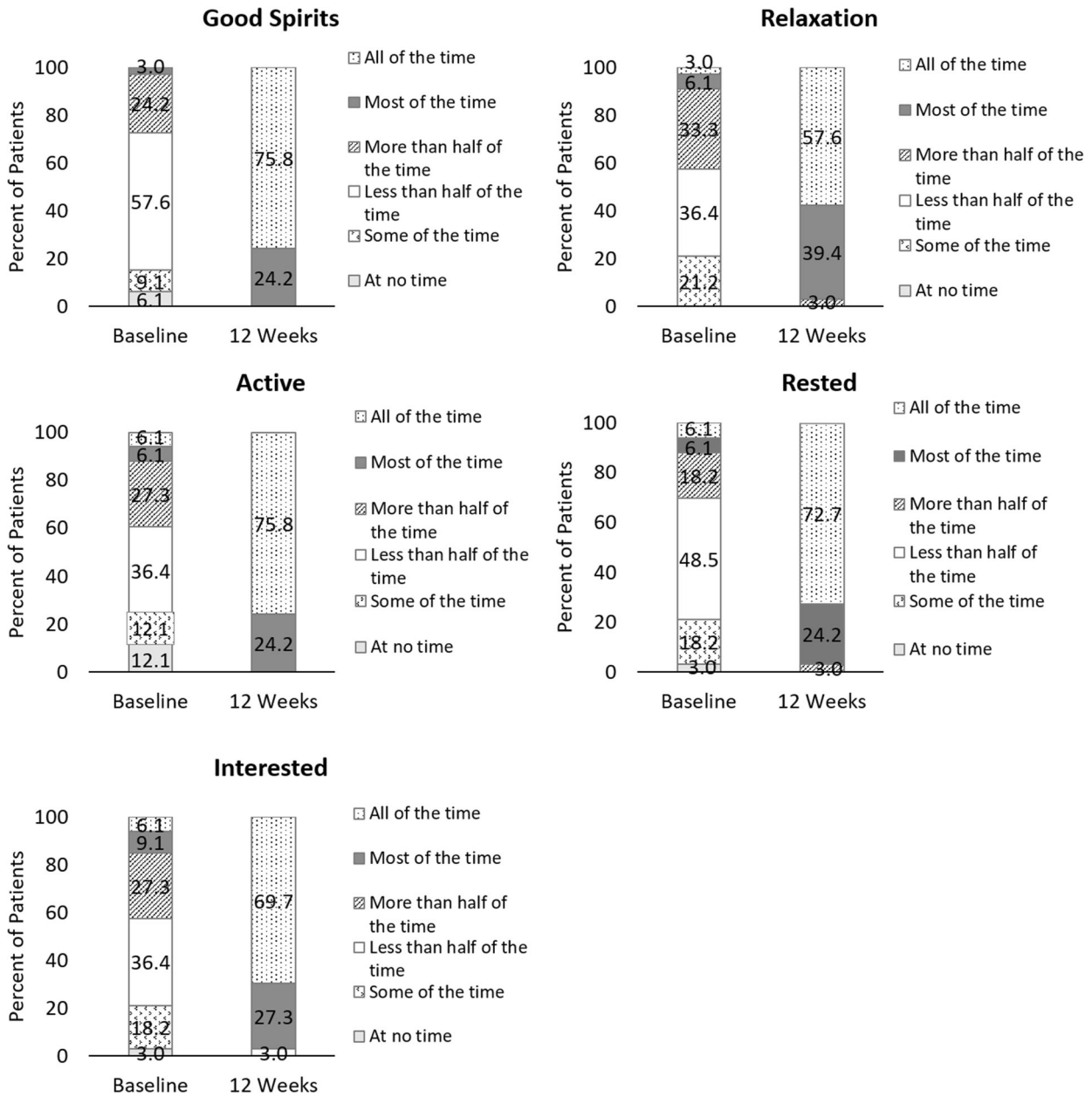

Fig. 1 Distribution of patient responses to the WHO-5 questionnaire items at baseline and after 12 weeks of FreeStyle Libre system use

correspond to a small-sized cohort study because of the low expected frequency of patients, especially those who are receiving combined therapy with FSL plus IP. Future studies could include a larger sample size and multiple centers for comparison, and other patient populations such as those with type 2 diabetes or gestational diabetes. It should also be noted that there was a significant difference between the baseline A1c levels of the MDI and IP groups, with higher A1c seen in the MDI group. However, both groups had A1c levels of nearly 8% or higher, and the overall outcomes of the combined groups provide meaningful information about youths with poorly controlled diabetes.

In addition, there are limited published outcomes for the DTSQ and WHO-5 in pediatric populations, so future studies with these validated questionnaires would add to this body of knowledge. The Diabetes Treatment Satisfaction Questionnaire (DTSQ) was first developed in the early 1980s, and has been widely used in clinical trials and for routine clinical monitoring [33]. In our study, we used the DTSQs, the original status version, in Arabic at baseline and 12 weeks after FSL use, as it has been shown to be useful for comparing the levels of satisfaction in diabetic youths and adolescents when using different treatment strategies [34]. Future studies could also use another version of the DTSQ, the change version (DTSQc), which has been developed to overcome potential ceiling effects [33]. This version has been suggested for use along with the DTSQs as an indicator of how satisfaction and perceived hyperglycemia and hypoglycemia has changed; however, it does not evaluate whether it was high or low to start with, or where it is at the endpoint.

CONCLUSION

In conclusion, the use of the FSL along with IP or MDI treatment in children and young adults with type 1 diabetes led to significantly greater satisfaction and a stronger sense of well-being compared with the baseline conventional finger-pricking method.

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Authorship Contributions. Ayman A. Al Hayek and Mohamed A. Al Dawish researched the data, reviewed/edited the manuscript, and contributed to the discussion.

Disclosures. Ayman A. Al Hayek and Mohamed A. Al Dawish have nothing to disclose.

Compliance with Ethics Guidelines. The Research and Ethics Committee of Prince Sultan Military Medical City, Riyadh, Saudi Arabia approved the study protocol. The study was conducted in accordance with the tenets outlined in the Declaration of Helsinki and with good clinical practice. The participants or their parents/caregivers were advised of their roles in this study, and a signed informed consent was obtained from them prior to the recruitment of the subjects.

Data Availability. The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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