

Advantages of the Usage of Flash Glucose Monitoring System in Children and Adolescent with Type 1 Diabetes: A Survey Analysis

Al-Agha AE*, Kafi S, Alqurashi M and Zeinaldeen A

King Abdulaziz University, Saudi Arabia

Abstract

Objective: To assess the advantages and disadvantages of using freestyle libre flash glucose monitoring system (FGMS) in children and adolescent with type 1 Diabetes (T1DM).

Methods: A prospective pilot study included 70 children and adolescents with T1DM visiting the pediatric diabetes clinic at King Abdulaziz University hospital (KAUH), Jeddah, Saudi Arabia from June to August, 2016. 26 (37.1%) were males and 44 (62.9%) females, aged from 6-20 years, mean age 12.83 ± 3.2 years. A survey questions were addressing, the advantages, disadvantages and benefits of FGMS with sleeping, daily activities, exercise, accuracy and participants' satisfaction from FGMS.

Results: Parents of participants reported 95.7% of easily ability to measured glucose during sleep. 77.1% have given a negative answer about sensors disturbance during exercise. 85.7% did not have any difficulties in wearing or taking off clothes with the sensor. 72.8% denied any pain or itching from the sensor. 75.8% reported that the sensor is well fixed to the skin. 92.2% agreed that FGMS has advantages of facilitating more observation, regulating their glucose variability and adjustments of insulin doses.

Conclusion: Majority of children and adolescents with their parents preferred using FGMS to have a painless, easier detection and adjustment of hypoglycemic/hyperglycemic episodes in comparison to the widely traditional used finger sticking glucometers.

Keywords: Advantage; Disadvantage; Flash glucose monitoring system; Type 1 diabetes mellitus; Children; Adolescent

Introduction

Glucose monitoring has an important role in diabetes care, to meet ideal glycemic control for children and adolescent with type 1 diabetes. Monitoring their blood glucose regularly is very important [1]. Self-monitoring of blood glucose (SMBG) is an invasive method of glucose monitoring. Patients need an effort to perform and usually endure some pain, but it is still accurate [2]. Flash glucose monitoring system (FGMS) is a non-invasive uprising medical technology, which measures glucose from the interstitial fluid, sparing the pain that usually associated with SMBG. FGMS have a fairly acceptable accuracy [2]. There are various types of non-invasive glucose monitoring systems [3]. FGMS provides glucose readings at the moment and for the last eight hours, which help children, parents and treating physician with ambulatory glucose profile (AGP) data that would give an idea of the glucose variability and stability [4,5]. FGMS will help in a better compliance with glucose monitoring and easier insulin adjustments, with eventual better glycemic control. In this study, we aimed to assess the advantages and disadvantages of using freestyle libre FGMS in children and adolescent with type 1 diabetes (T1DM).

Methodology

Participants

A prospective, pilot, single center study; conducted on 85 participants over three months duration, from June to August 2016. Seventy participants have completed the survey, 26(37.1%) males and 44(62.9%) females, aged from 6-20 years, with a mean age of 12.83 ± 3.2 years. All were with type 1 diabetes, using FGMS and on intensive insulin therapies including multiple daily injection (MDI) and insulin pump therapy. Participants in this study were selected from pediatric diabetes outpatient clinic at King Abdulaziz University Hospital (KAUH). All data were obtained via a child/parental interviews and

or online survey. The survey was completed by both child and their parents for children aged younger than 12, while children older than 12 years of age answer edit alone.

FGMS

Freestyle[®] Libre™ sensor measures the interstitial fluid glucose values. The sensor is small, water-resistant and designed to be fixed on the lateral aspects of the upper arm for duration of 14 days. Sensor's users could perform their usual daily activities such as showering, swimming, and exercising. Frequent scanning of the sensor by a reader could help the participants to get their glucose data for the last 8 h (Table 1).

Sensor's accuracy (Mean Absolute Relative Difference "MARD")

The reported accuracy of FreeStyle[®] Libre™ sensor's numerical readings and clinical accuracy was 11.4% compared with glucometers [6].

Daily activities and exercise

Daily activities were defined in the study, as any activities that

***Corresponding author:** Abdulmoein Eid Al-Agha, FRCPC Associate Professor of Pediatric Endocrinology King Abdulaziz University Hospital Pediatric Department, P.O. Box 80215 Jeddah 21589, Saudi Arabia Tel: +966505590459; Fax: + 966 2 640 3841; E-mail: aagha@kau.edu.sa

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N	Questions	0	1	2	3	4	5
1-	Did the sensor disturb your sleep?	61.4%	14.3%	15.7%	2.9%	2.9%	2.9%
2-	Did the parents relieved in measuring their child glucose during sleep?	4.3%	0%	0%	2.9%	5.7%	87.1%
3-	How much did the sensor affect your daily activity?	42.9%	4.3%	10%	8.6%	8.6%	25.7%
4-	How much did the sensor affect your exercise habit?	61.4%	11.4%	4.3%	8.6%	4.3%	10%
5-	Do you have any difficulties during changing clothes with the sensor?	45.7%	27.1%	12.9%	8.6%	2.9%	2.9%
6-	Does the sensor cause any pain or itching?	37.1%	17.1%	18.6%	12.9%	4.3%	10%
7-	How fixed is the sensor to the skin?	2.9%	8.6%	12.9%	22.9%	28.6%	24.3%
8-	How easy the sensor can be removed?	15.7%	14.3%	5.7%	11.4%	15.7%	37.1%
9-	Does the sensor cause any embracement to your child?	52.9%	17.1%	11.4%	5.7%	7.1%	5.7%
10-	Do you face any technical difficulty during using the FGMS?	78.6%	7.1%	5.7%	2.9%	0%	5.7%
11-	How far is the difference between the FGMS and finger stick glucometer results?	9.6%	32.7%	19.2%	15.4%	19.2%	3.8%
12-	Do you prefer finger stick glucometer over FGMS?	34.3%	18.6%	24.3%	7.1%	8.6%	7.1%
13-	To what extent do you trust the FGMS result?	1.4%	4.3%	0%	24.3%	38.6%	31.4%
14-	How much the arrows did helped you in preventing high blood glucose?	2.9%	0%	2.9%	12.9%	11.4%	70%
15-	How much the arrows did helped you in preventing low blood glucose?	2.9%	0%	0%	15.7%	12.9%	68.6%
16-	How much did the FGMS helped in regulating your child glucose?	1.4%	4.3%	1.4%	17.1%	27.1%	48.6%
17-	To what extent you are satisfied with using of the FGMS?	1.4%	1.4%	0%	1.4%	22.9%	72.9%
18-	How extent do you advice other children with type1 diabetes to use this device?	2.9%	1.4%	2.9%	1.4%	18.6%	72.9%

0: Strongly disagree (0%), 1: Disagree to some extent (20%), 2: Limitedly disagree (40%), 3: Limitedly agree (60%), 4: Agree to some extent (80%), 5: Strongly agree (100%)

Table 1: shows questions and participant's answers.

participants do throughout the day, which involved movement, i.e., walking, climbing stairs and play with other children, while exercise was defined as a specific form of daily activities which is planned, purposeful, performed with the intension of acquiring fitness and health benefits, i.e., swimming, cycling, running and sports.

Survey Questions

The survey was composed of eighteen questions. Questions 1 and 2 were on the relation between the FGMS sensor and sleeping comfort, whether or not the sensor has disturbed their sleep and whether the parents have relived by using FGMS in measuring their child glucose during sleep. Questions 3-5 were concerned on the relationship between the sensor and daily activities, in regards of how much the sensor has affects the usual daily activities, their exercise habit and whether any difficulties in changing clothes with the sensor.

Questions 6-10 were in regards to the disadvantages of using the FGMS ,has the sensor caused any pain or itching, was the sensor adhesive to the skin, how easy the sensor could be detached, has the sensor caused any embarrassments to the child and any technical difficulties of using the FGMS .Questions 11-13 were to determine the accuracy of glucose readings, and how much the difference between the FGMS and finger stick glucometer results, to what extent they have trusted the FGMS result, and whether they have preferred using finger stick glucometers over FGMS. Questions 14-16 were to report the benefits of FGMS, how much the arrows helped in preventing high or low blood glucose and how much the FGMS helped in controlling their child's glucose. Questions 17 and 18 were about the participants' satisfaction with FGMS, to what extent, they were satisfied with using of the FGMS, and how extent do you advise other children with type1 diabetes to use this device? The scoring system for survey questions were ranged by percentages and numbers from zero to five; 0: strongly disagree (0%), 1: Disagree to some extent (20%), 2: Limitedly disagree (40%), 3: Limitedly agree (60%), 4: Agree to some extent (80%), 5: Strongly agree (100%).

Statistical Analysis

Data entry and analysis was by using Google drive and the study was

a descriptive statistics by describing qualitative variables as frequencies and percentages.

Results

Eighty five participants were asked to fill up a survey form. Out of all participants, 70 (85.4%) has completed the answers of all the questions, 26 (37.1%) were male and 44 (62.9%) female, aged from 6-20 years old, diagnosed with type 1 diabetes who were using FGMS.

Discussion

In this study, 70 participants were completed the survey to assess the advantages and disadvantages of using freestyle libre FGMS in children and adolescent with T1DM. One of the parental concerns was sleep comfort by using FGMS in comparison with SMBG, 91.3% answered that it has not affected their child's sleepiness and 8.7% has affected, according to that 95.7% of the parents reported they relived from this concern by using FGMS because they did not need to wake the child up from sleep with easy ability to measured it while sleeping and 4.3% have not. In comparison with British study, which involved an online survey of 100 participants of both children and adults with T1DM, 81% of them were able to sleep more easily with less disturbance and safety feeling, while 10% of participant were not [6].

Regarding daily activities and exercise, 57.1% answered that FGMS have not affected their daily activities, while 42.9% response positively, 77.1% answered that exercise have not been affected, while 22.9% answered yes. Whether or not, sensors causing any difficulties in wearing on or taking off clothes, 85.7% have not faced any difficulties, while 14.3% have. Regarding whether the sensor caused any pain or itchiness, 72.8% have denied and 27.2% got pain or itchiness as a result to the adhesive patch. Was a sensor fixating to the skin, 75.8% reported that the sensor was well fixed while 24.2% reported was not, however, as the sensors need to be replaced every 2 weeks 64.3% of participants reported that was easily to detach the sensor and 35.7% reported not. In a study in Michigan, 43 participants aged from 3-25 year, 43%reported skin irritation or pain at insertion site [7]. Another USA study included 58 participants with T1DM, for which 43% of participants reported

discontinuation of the sensor due to irritation of the skin, pain and discomfort while using the sensor [8]. As the FGMS have an arrow system which helped in preventing any complication, about the study, 70% of the participants reported that this device helped them in preventing high glycemic readings and 2.9% see no difference, 68.6% answered that it also helped them in preventing low glycemic readings while 2.9% did not. According to that, we asked the participants if FGMS facilitated in the regulation of their glucose, 92.2% agreed while 7.1% answered not. 77.2% preferred FGMS over finger stick glucometer which was preferred by 22.8% as for better accuracy of glucose reading given by glucometer, 92.9% trusted the FGMS results and 7.1% did not, therefore 97.2% reported their satisfaction from using FGMS versus 2.8% therefore, 94.3% of the participants would recommend other patients about FGMS versus 5.7%.

In this study FGMS were compared with finger stick glucometer results, 73% of the participants reported no difference versus 27% noticed a difference in glucose readings. Those who were asked what if the differences were significant 38.5% answered yes while 61.5% not. Finally, 91.4% of the participants had no difficulties in using FGMS as it easy to use while 8.6% of them had. However, 73% of participants preferred using FGMS which gave them noninvasive measurement of interstitial glucose instead of regular finger stick glucometers while 23% did not and 4% preferred using both techniques. 100 participants with T1DM in study in London, 10% of all participants relived from finger stick by reducing the frequency of SMBG, while 1% reported increased frequency [9].

Conclusion

FGMS has advantages of allowing participants to have a better sleep, helped in preventing hypoglycemic/hyperglycemic events through arrows system and few side effects of itchiness and skin irritation.

Study Limitations

The study design has no control group to compare with. Literature related to the current study with data for comparison is limited.

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