ORJİNAL MAKALE

Flash Glucose Monitoring Experiences of the Families of the Patient with Type 1 Diabetes Mellitus

Tip 1 Diyabetli Ailelerin "Flash Glucose Monitoring" Deneyimleri

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SUMMARY

Aim: Patients with type 1 diabetes and their families are increasingly interested in technological development in glucose monitoring. The comfort of frequently monitoring with flash glucose monitoring (Freestyle Libre/Abbott) is appealing although it is not commercially available yet in Turkey. In this study, we aimed to investigate the data obtained by this method as well as the experience, satisfaction, and the problems encountered by the families.

Materials-Methods: A questionnaire was given to the families of diabetic patients by a web based program. The questions involved information about age, gender, last HbA1c, and duration of diabetes as well as information about the device. Repetitious answers, incomplete data, and patients above 18 years of age were not included.

Results: Mean age of the 72 patients was 8.29 years and 42% was male. Mean duration of diabetes was 2.6 years and mean HbA1c was 7.27%. Freestyle Libre was used for 5.6 months (15 days-19 months). The families had heard about the device from internet (62%), friend (23.9%), doctor (9.9%), or relatives (4.2%). In response to confirmation of the results by finger stick measurement, 70.8% said sometimes, 27.8 frequently, 1.4% no. HbA1c was claimed to improve in 73.6%, and it did not change in 23.6%. 96% reported that the device made their life easier and 97% was willing to recommend it to other families.

Conclusions: The families are in search to make glucose monitoring easier for their children. Although, they have some concerns about the reliability of the measurements at extremely high and low blood glucose levels, they are happy because it is easy and practical to use.

Key words: Type 1 diabetes, children, continuous glucose monitoring, flash glucose monitoring.

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ÖZ

Amaç Tip 1 diyabetli birey ve ailelerin teknolojik cihazlara ilgisi giderek artmaktadır. Devamlı kan şeker takibinin ailelerde oluşturduğu güven ve rahatlıktan dolayı ülkemizde piyasaya sürülmese de "Freestyle Libre (Abbott)" isimli cihazın kullanımında artış dikkati çekmektedir. Burada cihazını kullanan diyabetik bireylerin verileri, ailelerin cihaz ile ilgili tecrübe, memnuniyet ve sorunları araştırılmıştır.

Gereç ve Yöntemler: Diyabetli ailelerin oluşturduğu sosyal platformdaki toplulukta, web tabanlı bir anket ile değerlendirme yapıldı. Anket, diyabetiklerin yaş, cinsiyet, ortalama Hba1c, diyabetin süresi gibi soruların yanında cihaz ile ilgili farklı soruları içeriyordu. Anket anne ve/veya babalar tarafınca dolduruldu. Tekrar yanıtlar, eksik veriler, 18 yaş üstü bireyler çalışmadan çıkarıldı.

Bulgular: Çalışmaya dahil edilen 72 olgunun ortalama yaşı 8,29 yıl olup, %42'si erkekti. Diyabet süresi 2,6 yıl, son HbA1c ortalaması %7,27 saptandı. Cihazın ortalama 5,6 ay (15 gün-19 ay) süreyle kullanıldığı dikkati çekti. Aileler cihazı, internet (%62), arkadaş (%23,9), doktor (%9,9) ve akrabalarından (%4,2) öğrenmişlerdi. "Cihazı parmak ucu kan şeker ölçümü ile teyit ediyor musunuz?" sorusuna %70,8 evet bazen, %27,8 "evet sıklıkla", %1,4 "hayır" yanıtı verildi. "Cihaz kullanımından sonra Hba1c veya kan şeker izleminde düzelme oldu mu?" sorusuna %73,6 "evet oldu", %23,6 "hayır aynı seyretti" yanıtı alındı. Ailelerin %96'si cihazın hayatlarını kolaylaştırdığını, yaklaşık %97'si diğer ailelere bu cihazı tavsiye ettiklerini bildirdi.

Sonuç: Tip 1 diyabetin tedavisinin kesin çözüme ulaşmaması nedeniyle insülin tedavi ve kan şekeri ölçümünde, aileler çocuklarının daha rahat edebileceği teknolojik cihazlara yönlenmektedir. Cihazın yüksek ve düşük kan glukoz değerlerinde güvenilirliği ile ilgili çeşitli endişeleri olsa da kullanım kolaylığı ve pratikliğinden dolayı memnuniyet artmaktadır.

Anahtar Kelimeler: Tip 1 diyabet, çocuk, devamlı kan şeker izlemi, flash glukoz izlemi

Introduction

There are various methods to use to evaluate glycemic control such as serum glucose, HbA1c, self-monitoring of blood glucose (SMBG), and continuous blood monitoring (CGM). CGMs are sophisticated devices which have been used by diabetic patients for over 10 years. The clinical benefits of CGMs have been demonstrated by meta-analysis (1). It is an especially helpful method in patients who use insulin pump. Flash glucose monitoring (FGM, Freestyle Libre, Abbott®) is also designed to measure glucose in interstitial fluid similar to CGM. The use and reliability of FGM in type 1 and 2 diabetes has been approved recently in Europe (2). FGM is preferred because it has a factory calibrated sensor which can be used for 14 days with minimal need for professional assistance. The device was designed by upgrading the Freestyle Navigator which is manufactured by the same company and named FGM. Although it is not approved by FDA yet, it is in the marketing 7 European countries. The sensor is the size of a coin which is precalibrated, and placed on the upper arm. A 24-hour profile can be obtained by reading every 15 minutes and at least one measurement every 8 hours. Android telephones with Near Field Communication (NFC) can be linked to sensor and the data can be read by a program called Librelink. The data can be downloaded in pdf format as well.

Recently, patients with type 1 diabetes and their families are increasingly interested in technological advances in our country. In addition, use of "Freestyle Libre" is also increasing because of confidence and practicality expressed by the families although it is not commercially available in Turkey. Because of the same reason, the physicians and nurses are not very familiar with it. Moreover, there are not many studies in children about its use. In this investigation, we studied the data about the use of FGM, and the experience, satisfaction, and concerns of the families.

Material and Methods

A questionnaire was given to the families of diabetic patients by a web based program. The questions involved information about age, gender, last HbA1c, and duration of diabetes as well as information about device (Table 1). Repetitious answers, incomplete data, and patients above 18 years of age were not included. The study protocol was accepted by the Ethics Committee of our hospital.

Table 1: Questionnaire

1. Name of the patient	
2. Age and gender	
3. Duration of diabetes	(months, years)
4. Last HbA1c?	
5. How long have you used Freestyle Libre?	(months)
6. How did you hear about the device?	Friend/Internet/Doctor/others
7. How did you obtain the device?	Germany/Austria/France/Internet/other
8. Are you confirming the results of the device by finger stick measurements?	Yes frequently/Yes sometimes/no
9. Is your life easier with this device?	Strongly agree/Agree/Neutral/ Disagree/Strongly disagree
10. Did your glucose or HbA1c improve after using this device?	Yes/Same/No
11. Do you recommend this device to other patients or families?	Strongly agree/Agree/Neutral/ Disagree/Strongly disagree
12. What are the positive or negative aspects of the device?	

Results

The questionnaire was given in July 2016, and a total of 72 patients entered the study. Their mean age was 8.29 years (2.5-16) with 42% male, and 58% female. The mean duration of diabetes was 2.6 years and mean HbA1c was 7.27%. The device was used for a mean period of 5.6 months (15 days-19 months). The families had heard about the device from the internet (62%), friend (23.9%), doctor (9.9%), and relatives (4.2%).The device was obtained from Germany (70%), Austria (15%), France (5%), and other European countries. Regarding the confirmation of the results of the device by finger stick measurements, 70.8% responded as sometimes, 27.8% as frequently, and 1.4% as never. The change in HbA1c was reported better in 73.6%, same in 23.6%, and worse in 2.8. 88.9% strongly agreed, and 8.3% agreed to recommend the device to other families, while 2.8% was uncertain. Whether the device made life easier was answered as strongly agree by 90.3%, agree by 5.5%, and uncertain by 4.2% (Figure 1).
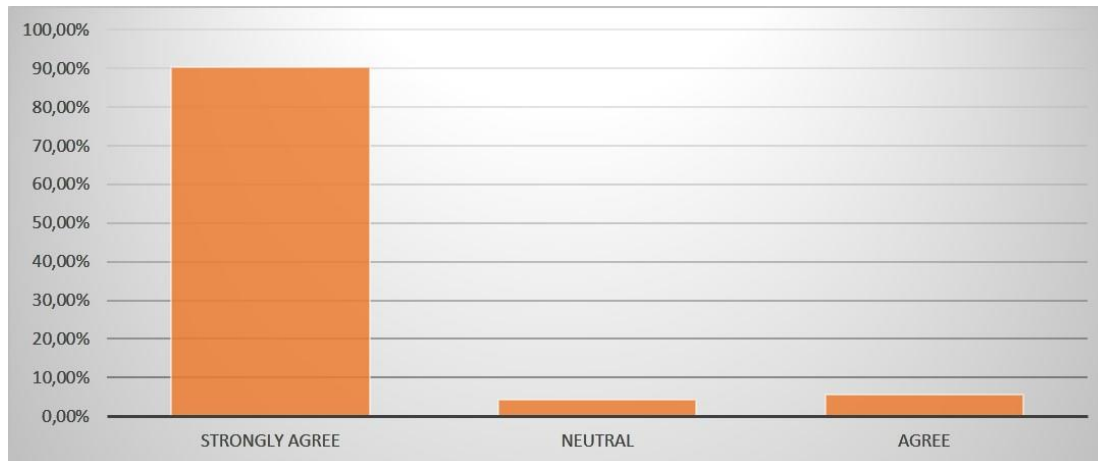
Figure 1. Is your life easier with this device?

The way it made life easier was expressed as less concern about pain due to finger sticks, easy measurement at night during sleep, and psychological well-being. In addition, detection and treatment of hypoglycemia and observing the trend of glycaemia was found easier by the families. Points that need improvements were reported to be discordance with finger stick measurements at high (>250 mg/dl) and low (<70 mg/dl) glycemic levels, lack of hypoglycemia and hyperglycemia alarm, and upper arm application only which may make it easier for accidental detachment. The advantages of the device and the points that need improvement according to the families are listed in Table 2.

Table 2: The positive and negative aspects of the device according to the families.

Positive	Negative or needs improvements
Comfort of frequent measurement	Increased difference from capillary measurements at high and low blood glucose
Psychological comfort	
Seeing the progression with up and down marks	Not compatible with insulin pump
Comfort to detect hypoglycemia	No hypo- or hyperglycemia alarm
Practical use	
Easy interpretation on the screen and computer	
Compatible with some smart phones	
No need for calibration	
Having the sensor in place for 14 days	

Discussion

These results showed that Freestyle Libre or FGM was used by many families who are in touch by social media on the internet and it was favorably accepted. It is difficult to detect nocturnal hypoglycemia and show the postprandial hyperglycemia profile by SMBG. This is one advantage of FGM. A controlled randomized study showed that time spent with hypoglycemia was reduced by 38% with the use of FGM. However, HbA1c did not improve in this study which was attributed to selection bias, because all of the patients had already HbA1c below 7 at the beginning of the study (3). In contrast, Dover et al (4) reported that 25 adult patients with type 1 diabetes improved their HbA1c by 0.5 at the end of 16 weeks after using FGM and the number of patients in good range doubled. The families reported that detailed data about the time and duration of hypoglycemia provide by the device enabled them to intervene early. They also reported that mean glucose and HbA1c also decreased. Factory calibrated sensors have been shown to be feasible (5). Feasibility and acceptability in children has been investigated in only one study, which showed that diabetes distress scale, emotional burden, and regime related distress decreased after using this device. This study concluded that FGM is a feasible option with a high rate of acceptance (6). In our study, most of the families expressed that stress and anxiety of their children and themselves decreased after using this device.

On the other hand, there are also disadvantages or aspects that need to be improved about the device. In a study on 46 patients (mean age 10), data loss was observed in 13% and spontaneous detachment on the sensor in 15%. Freestyle Libre Pro which is another version device designed for health professionals had 7% sensor failure, and 16% loss of the sensor by dropping and other causes (7). Despite general acceptance of the device, some families expressed concern about sensor failure.

One of the most important results of the study is the difference between the reading of he device and the finger stick measurements which was done by almost all families. A study on 72 type 1 and 2 diabetics reported mean absolute relative difference (MARD) as 11.4%, and mean lag time as 4.5 ± 4.8 minutes (8). In another study that compared FGM with Dexcom G4 Platinum which is considered to be the most reliable method for CGM, the results of the two sensors correlated well and they were not different in terms of mean glucose profile and MARD compared to SBGM. However, between the 11th and 14th days of FGM sensor, MARD was found 19% in hypoglycemia, 16% in normoglycemia, and 13% in hyperglycemia compared to the first 10 days (9). This is the most criticized aspect of the device which needs improvement.

The limitations of the study are heterogeneous age range, and subjective opinions of the families with little numerical data because of the questionnaire study. In conclusion, technological devices for easy glucose monitoring attract the families to make life easier for their children. FGM has been an acceptable option because of easy use. The awareness of physicians and health personnel about the

technological advances will help them support the patients, and their families. More studies on use of these devices in children are needed.

Ethics: Ethics Committee Approval: The study protocol was accepted by the Ethics Committee of our hospital. Informed Consent: Consent form was filled out by all participants. Peer-review: Internally peer-reviewed.

Authorship Contributions: Surgical and Medical Practices: Erdal Eren, Ömer Tarım. Concept: Erdal Eren, Design: Ömer Tarım, Data Collection or Processing: Erdal Eren, Analysis or Interpretation: Ömer Tarım, Literature Search: Erdal Eren, Writing: Ömer Tarım, Erdal Eren. Conflict of Interest: No conflict of interest was declared by the authors. Financial Disclosure: The authors declared that this study received no financial support

References

1. Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. BMJ. 2011;7:343:d3805.

2. Kalra S, Gupta Y. Ambulatory glucose profile: Flash glucose monitoring. J Pak Med Assoc. 2015;65:1360-2.

3. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. Lancet. 2016;388:2254-2263.

4. Dover AR, Stimson RH, Zammitt NN, Gibb FW. Flash Glucose Monitoring Improves Outcomes in a Type 1 Diabetes Clinic. J Diabetes Sci Technol. 2016 Jul 26. pii:1932296816661560.

5. Hoss U, Budiman ES, Liu H, Christiansen MP. Feasibility of Factory Calibration for Subcutaneous Glucose Sensors in Subjects with Diabetes. J Diabetes Sci Technol. 2014;8:89-94.

6. Rai S, Hulse A, Kumar P. Feasibility and acceptability of ambulatory glucose profile in children with Type 1 diabetes mellitus: A pilot study. Indian J Endocrinol Metab. 2016;20:790-794.

7. Distiller LA, Cranston I, Mazze R. First Clinical Experience with Retrospective Flash Glucose Monitoring (FGM) Analysis in South Africa: Characterizing Glycemic Control with Ambulatory Glucose Profile. J Diabetes Sci Technol. 2016;10:1294-1302.

8. Bailey T, Bode BW, Christiansen MP, Klaff LJ, Alva S. The Performance and Usability of a Factory-Calibrated Flash Glucose Monitoring System. Diabetes Technol Ther. 2015;17:787-94.

9. Bonora B, Maran A, Ciciliot S, Avogaro A, Fadini GP. Head-to-head comparison between flash and continuous glucose monitoring systems in outpatients with type 1 diabetes. J Endocrinol Invest. 2016;39:1391-1399.