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Original Article

Freestyle libre flash glucose monitoring improves patient quality of life measures in children with Type 1 diabetes mellitus (T1DM) with appropriate provision of education and support by healthcare professionals

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ABSTRACT

Background: In 2017 the UK's Association of Children's Diabetes Clinicians (ACDC) launched a national educational package to provide training in the use of Freestyle Flash glucose monitoring (GM) to healthcare professionals.
Objective: To evaluate metabolic outcomes and quality of life (QoL) of children with T1DM trained in the use of the Freestyle Flash GM system adopting the ACDC guidelines.
Methods: Prospective study conducted at a single UK children's diabetes unit from 2017 to 2018.52 children with T1DM (age 5–18 yrs) were commenced on the Freestyle Flash GM system, received education and were followed up for 12 months. The Peds QL 3.2 diabetes questionnaire was used to assess QoL before and after the use of the system. HbA1c was measured at 3, 6 and 12 months pre and post use of Freestyle.
Results: 52 children (33 M,19 F) with a mean age of 11.6 yrs (range 4 m–17.2 yrs) were evaluated. Mean HbA1c 3 months post Freestyle Flash GM showed a significant improvement when compared with HbA1c values at 12, 6 and 3 months pre Freestyle (p-value 0.040, 0.040, 0.012 respectively). This improvement was not sustained at 6 and 12 months (p-value 0.15, 0.50). The PedsQL3.2 diabetes scores demonstrated significant improvement in patient QoL, reduction of diabetes symptoms and treatment barriers following the use of the new technology (p-values 0.014; 0.018; 0.035 respectively).
Conclusions: Freestyle Flash GM technology associated with appropriate education and regular support by healthcare professionals improves patient quality of life measures in children with T1DM.

1. Introduction

Type 1 Diabetes Mellitus has a major impact on the life of a child or young person, as well as their family or carers [1]. Tight control of glucose levels reduces the risk of developing short and long term complications. Self-monitoring of glucose (SMBG) for children and young people involves a finger-prick, five or more times per day [2,3]. This causes pain, inconvenience, disturbance for night time tests and embarrassment [4,5]. The Freestyle Flash GM System represents an alternative to SMBG. It provides 'flash glucose monitoring' with glucose readings provided by scanning a sensor rather than pricking your finger. Recent studies showed that this new technology is accurate, safe and easy to use in children and young people with T1DM [6,7]. There is, however, a paucity of data looking at the use of the Freestyle Libre Flash GM system on glycaemic control and quality of life outcomes in the paediatric population. Our study aimed to evaluate whether the use of this new technology, along with structured education using the national guidelines launched by the UK's Association of Children's Diabetes Clinicians (ACDC) in January 2017(8), improved glycaemic control and quality of life measures in children and adolescents with T1DM.

2. Methods

This was a prospective observational study conducted in the

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paediatric diabetes unit at Ormskirk Hospital, a district general hospital in the North West of England. We included a total of 52 patients (33 Males and 19 Females) between 5 and 18 years of age in 2017. Exclusion criteria were children aged less than 5 years, patients on continuous glucose monitoring system (CGM) and patients with other unstable medical conditions. All participants or their parents/caregivers signed a written consent for inclusion in the study. The patients' demographic data, mean age at diagnosis, mean age at the start of the Freestyle Flash GM System, duration of diabetes, insulin treatment regimen, were recorded at the first clinic visit by a trained healthcare professional of the diabetes team.

As part of clinical care, all patients and parents were provided with key education on the use of the Flash GM system by trained Diabetes Healthcare Professionals following the ACDC guidelines [8]. A structured education was provided in 4 steps as described in Table 1. The first session of the structured education consisted of a 45 min workshop delivered before starting the patients on the new technology (step 1 and 2 education). Patients were given general information on how the Freestyle Glucose system works. They were shown how to insert the sensor on the upper outer area of their arm, how to use the reader, to set up a target glucose range and interpret glucose trends and patterns. Participants were instructed to confirm the blood glucose level with a capillary measurement in case of low (<4.0 mmol/l) or high (>14 mmol/L) glucose readings, rapidly changing glucose levels as indicated by upward or downward arrows next to the readings, or when readings did not match their clinical symptoms. A blood glucose value should have been obtained before making any treatment decision. Furthermore, they were instructed to scan the sensor at least every 8 h to avoid losing data.

Patients and parents/caregivers were provided with written information on the new technology [8]. At the end of the first educational session, the Freestyle Flash GM sensor was applied by a trained healthcare professional of the diabetes team. Two weeks later, a second session was organised for the Freestyle Flash GM glucose data to be downloaded. Participants had a new sensor inserted and continued to receive further education (steps 3–4 of the structured education) that focused on the understanding of trend arrows (Table 2) and treatment management. The trend arrow next to the glucose level indicated if the glucose was stable, rising or falling and how fast. Understanding the different arrow symbols was a guide as to whether any intervention was needed and how soon. Participants were encouraged to download the Freestyle GM system every 2 weeks using either Diasend or the Flash GM software, to identify glucose trends and make changes to the doses on insulin aiming to keep glucose levels within the target range. The sensor was replaced by the participant every 2 weeks.

Ongoing educational support was offered to each family via Skype, clinics, telephone consultation or arrangement of clinic visits if required at any point of time during the study. At the end of the study, the complete data stored in the Freestyle reader were downloaded onto the Diasend system to produce the corresponding average glucose profiles (AGPs). All participants had their HbA1c levels measured at 3, 6, and 12 months before the use of the Freestyle GM system. These levels were compared with the ones recorded at 3, 6 and 12 months after the use of this system as showed in Table 5. HbA1c levels were measured by monoclonal antibody agglutination method (Siemens DCA Vantage analyser).

The Paediatric Quality of Life Inventory (Peds QL) 3.2 diabetes [9] questionnaire was used to assess the quality of life scores of patients with T1DM and their parents (PedsQL Parent Report) before and 3 months after the use of the Freestyle Flash-GM. The PedsQL is a validated modular tool designed to measure health-related quality of life (HRQOL) in children and adolescents with Type 1 diabetes aged 2–18 years [9]. The PedsQL 3.2 Diabetes Module is composed of 33 items comprising 5 dimensions for ages 13–18 and 32 items comprising 5 dimensions for ages 2–12 years (one less item for the Worry scale). The 5 dimensions included: 15 questions on diabetes symptoms, 5 questions on treatment barriers, 6 questions on treatment adherence, 4 questions on

Table 1
Structured education.

Structured Education	
Step 1	• Getting started with flash glucose monitoring system (FGS) • Understanding the basic knowledge of your Freestyle Libre • Learn to identify trends and patterns
Step 2	• Learn to actively use target glucose range • Further understanding of trend arrows
Step 3	• Recap the target glucose range • Optimise the effect of FGS using trend arrows • How to use the total dose percentage adjustment tool • How to use the insulin sensitivity factor tool (ISF)
Step 4	• Recap the target glucose range • How to use the Ambulatory Glucose Pro le (AGP) • Diasend and Freestyle software

Table 2
Glucose trend arrows.

Arrow Trend	Description	10–15mins timing
↑	Glucose is rising quickly (more than 0.1 mmol/L per minute)	1–1.5 mmol/L in 10–15 min
↗	Glucose is rising (between 0.06 and 0.1 mmol/L per minute)	0.6–0.9 mmol/l in 10–15 min
→	Glucose is changing slowly (less than 0.06/L per minute)	Stable
↘	Glucose is falling (between 0.06 and 0.1 mmol/L per minute)	0.6–0.9 mmol/l in 10–15 min
↓	Glucose is falling quickly (more than 0.1 mmol/L per minute)	1–1.5 mmol/L in 10–15 min

communication problems, 2 or 3 questions on worry. The scoring method used a 5-point scale for ages 8–18 years as follow: 0 (Never a problem), 1 (Almost never a problem), 2 (Sometimes a problem), 3 (Often a problem), 4 (Almost always a problem), whilst a 3-point scale was used for ages 5–7 years as follow: 0 (Not at all), 2 (Sometimes), 4 (A lot). Items were reversed scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0). Scores were calculated both as dimension scores (the sum of all the items in a dimensional scale over the total number of items on that scale) and total scores (the sum of all the items over the number of items answered on all the scales). Higher scores indicated better quality of life or fewer problems.

2.1. Statistical analysis

Data analysis was performed using Excel Microsoft and the Statistical Package for Social Sciences 21.0 (version 23; SPSS Inc., Chicago, IL, USA). Two-tailed paired *t*-test was used to determine the difference between HbA1c among the sets at different time points (3, 6 and 12 months before versus 3, 6, and 12 months after). P-value < 0.05 was considered statistically significant.

3. Results

52 children (33 males and 19 females) with a mean age of 8.1 years (SD3.8, range 0.9–15.7) at diagnosis and mean duration of diabetes of 4.2 years (SD3.8, range 0.2–16.7); were evaluated. The patients' baseline characteristics are reported in Table 3. Our study showed that the mean HbA1c 3 months after starting the Freestyle Flash GM significantly improved when compared with HbA1c values at 12, 6 and 3 months before starting the new technology (Table 4). However, due to the limited ability of some patients to continue to self-fund the Flash GM system, only 36 children (69%) were still using the Freestyle Flash GM system at 6 months and 30 (58%) at 12 months. HbA1c levels at 6 and 12 months after starting the Freestyle Flash GM system, compared with HbA1c levels before starting this new technology, showed improvement but did not reach significance and plateaued despite the initial improvement at 3 months, as shown in Table 4.

The PedsQL3.2 diabetes scores showed improvement in the quality of life; reduction of diabetes symptoms and treatment barriers as reported by parents (Table 5).

4. Discussion

Appropriate monitoring of glucose levels is essential in preventing complications of diabetes [1,2]. Maintaining a good glycaemic control can, however, be particularly challenging in children due to an unpredictable frequency of food intake, variable levels of physical activity, illnesses, psychological and hormonal challenges [10,11]. The National Institute for Health and Care Excellence (NICE) recommends performing at least 5 capillary blood glucose tests per day in children with T1DM [1]. Capillary blood glucose monitoring is a painful, inconvenient, and often an embarrassing procedure for children with diabetes [4,5]. The Freestyle was introduced across Europe in 2014, and is now available in more than 30 countries and used by more than 300,000 people with diabetes around the world. It is a well-recognised alternative method to monitor blood glucose in children with T1DM, and its accuracy, safety and user acceptability for the paediatric population have been demonstrated [6,7,11].

Our study showed that the use of this new technology associated with structured education improves HbA1c and quality of life of children with T1DM and their families. This is in accordance with two European clinical studies, the IMPACT and the SELFY [12,13]. The former showed that younger adults with T1DM using the Freestyle GM system had a significantly improved time in range (TIR) of glucose levels and a reduced time spent in hyperglycaemia.

Table 3
Patients Characteristics ([a]Age expressed as Mean age±SD; min-max).

Gender	N = 52(%)	Ethnicity	N = 52(%)	Age at diagnosis	[a]Age at the start of the Flash GM system	[a]Duration of diabetes	Insulin Treatment N = 52(%)
Male	33 (63.5)	White Caucasian	51 (98)	8.1 ± 3.8; (range 0.9 –15.7)	11.6 ± 3.6 (4.10–17.2)	4.2 ± 3.8 (range 0.2 –16.7)	MDI 16(31)
Female	19 (33.5)	Latvian	1(2)				CSII 36(69.2)

[a] Mean ± Standard deviation; MDI, multiple daily insulin regimen; CSII, continuous subcutaneous insulin infusion.

Table 4
HbA1c levels at 12, 6 and 3 months pre Libre compared to HbA1c levels 3 months after Libre initiation.

Pre Libre	Mean HbA1c (mmol/mol)	Post Libre	Mean HbA1c (mmol/mol)	Difference (95% Confidence interval)	P-value
12 months	62	3 months	59.5	2.5 (0.1–4.8)	0.040
6 months	61.9	3 months	59.5	2.4 (0.1–4.4)	0.040
3 months	65.2	3 months	59.5	5.7 (1.4–11)	0.012
3 months	66.8	6 months	62.6	4.2 (−1.6 to 9.9)	0.15
3 months	65.9	12 months	63.7	2.2 (−4.3 to 8.6)	0.50

Table 5
Peds QL 3.2 pre and post Freestyle FG monitoring system scores (child/*proxy questionnaires).

	Peds QL 3.2	Difference (95% CI)	P-value
Pre Freestyle total score	75.6	−6.9 (−1.6 to −12.1)	0.014
Post Freestyle total score	82.5		
Pre Freestyle symptoms	57.8	−8.6 (1.7 to −15.6)	0.018
Post Freestyle symptoms	66.5		
Pre Freestyle treatment barriers*	63.3	−10.6 (−2.4 to −0.9)	0.035
Post Freestyle treatment barriers*	73.9		

The latter showed that teenagers using the Freestyle GM system, had a significantly improved TIR, reduced hyperglycaemia and improved HbA1c. Lee et al. demonstrated that in real-world conditions, the Freestyle Flash GM system allows frequent glucose check with higher rates of scanning linked to improved glycaemic outcomes, including TIR and reduced time in hyper and hypoglycaemia.

Patients using the Freestyle Flash GM system, scanned on average 16.3 times per day, compared to an average of 2.1 tests per day for patients not using the Freestyle Flash GM or a CG [14]. Estimated HbA1c was also reduced in groups with an increased number of scans as well as time in euglycaemia which increased by 40%, episodes of hyperglycaemia and severe hypoglycaemia instead, decreased by 44% and 49% respectively [15]. Campbell and al. also showed that the use of Freestyle Flash GM system as a replacement for self-monitoring of blood glucose (SMBG) by children and adolescents with T1DM improves glycaemic control, reduced HbA1c with no change in hypoglycaemia and enhanced treatment satisfaction [16]. In addition, Hayek et al. revealed that the frequent use of Flash-GM scanning reduces the frequency of hypoglycaemia, HbA1c levels, and improves quality of life in teenagers with T1DM. In accordance with the current evidence, our study provides supporting evidence that the use of the Freestyle Flash GM system improves glycaemic control and QoL of children with Diabetes and their families. Our study demonstrated that HbA1c levels significantly improved 3 months after the starting of the new technology, and then reached a plateau. We demonstrated that the use of this new technology is associated with improved patient experience, QoL scores, reduction in symptoms of diabetes and treatment barriers. The Freestyle Libre GM system can be used as an alternative to finger prick blood glucose testing and help children reduce the amount of daily finger prick measurements, their discomfort, and improve their glycaemic control and quality of life [17].

Limitations of our study were that we analysed a small sample population and observed glycaemic outcomes and quality of life scores for a limited period. This was not in the context of a randomised trial. High drop off rate was also a limitation of our study due to the inability of patients to fund the Flash GM. 31% and 42% of patients stopped using the Freestyle Flash GM system at 6 and 12 months respectively, mainly due to the high cost of the Freestyle sensors as this was during the period that Freestyle Flash GM was not on prescription. The authors also acknowledge that other factors could have influenced the glycaemic control such as frequency of follow up and support, insulin dosage, compliance, length of diagnosis of the subjects, but these could not be taken into account. We recommend that further research is needed looking at long term outcomes and larger sample populations in children.

5. Conclusions

Our study supports the use of Flash GM system in children with T1DM. The Flash GM technology associated with appropriate education at the initiation of the technology and regular support by healthcare professionals improves patient quality of life measures in children with T1DM. Further long term randomised control trials studies are necessary to look at the glycaemic control in the long term.

References

[1] National Institute for Health and Care Excellence (NICE). Diabetes type-1-and-type 2-in-children-and-young-people-diagnosis-and-management. NICE guidelines [NG18]. Available at: https://www.nice.org.uk/guidance/ng28; 2015.

[2] Diabetes Control Complications Research Group, Nathan DM, Genuth S, Lachin J, Cleary P, Crofford O, et al. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329(14):977–86.

[3] Diabetes Control Complications Trial Research Group, Nathan DM, Genuth S, Lachin J, Cleary P, Crofford O, et al. Effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with insulin-dependent diabetes mellitus: diabetes Control and Complications Trial. Diabetes Control and Complications Trial Research Group. J Pediatr 1994;125(2):177–88.

[4] Hall RF, Joseph DH, Schwartz-Barcott D. Overcoming obstacles to behaviour change in diabetes self-management. Diabetes Educat 2003;29(2):303–11.

[5] Whittemore R, Jaser S, Chao A, Jang M, Grey M. Psychological experience of parents of children with type 1 diabetes: a systematic mixed-studies review. Diabetes Educat 2012;38(4):562–79.

[6] Campbell FEJ, Acerini C, et al. Abstracts from ATTD 2016 9th international conference on advanced technologies & treatments for diabetes milan, Italy-february 3-6, 2016. Diabetes Technol Ther 2016;18(Suppl 1):A1–139.

[7] Laffel L. Improved accuracy of continuous glucose monitoring systems in pediatric patients with diabetes mellitus: results from two studies. Diabetes Technol Ther 2016;18(Suppl 2):S223–33.

[8] Association of Children's Diabetes Clinicians (ACDC). Real time flash glucose scanning training for healthcare professionals and patients. Available at: http://www.a-c-d-c.org/wp-content/uploads/2012/08/Libre-patient-leaflet-final-5.pdf; 2017.

[9] Varni JW, Burwinkle TM, Jacobs JR, Gottschalk M, Kaufman F, Jones KL. The PedsQLTM in type 1 and type 2 diabetes: reliability and validity of the pediatric quality of life InventoryTM generic core scales and type 1 diabetes module. Diabetes Care 2003;26(3):631–7.

[10] Gregory JW. What are the main research findings during the last 5 years that have changed my clinical practice in diabetes medicine? Arch Dis Child 2012;97(5):436–9.

[11] Edge J, Acerini C, Campbell F, Hamilton-Shield J, Moudiotis C, Rahman S, et al. An alternative sensor-based method for glucose monitoring in children and young people with diabetes. Arch Dis Child 2017;102(6):543–9.

[12] Campbell F, Bolinder JAN. FreeStyle Libre™Use for self-management of diabetes in teenagers and young adults. Diabetes 2018;67(Supplement 1).

[13] Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kroger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. Lancet 2016;388(10057):2254–63.

[14] Lee WC, Smith E, Chubb B, Wolden ML. Frequency of blood glucose testing among insulin-treated diabetes mellitus patients in the United Kingdom. J Med Econ 2014;17(3):167–75.

[15] Dunn TC, Xu Y, Hayter G, Ajjan RA. Real-world flash glucose monitoring patterns and associations between self-monitoring frequency and glycaemic measures: a European analysis of over 60 million glucose tests. Diabetes Res Clin Pract 2018;137:37–46.

[16] Campbell FKF, Murphy N. FreeStyle Libre use for self-management of diabetes in children and adolescents. Diabetologia 2017;60(Suppl 1). 1-608.

[17] Al Hayek AA, Robert AA, Al Dawish MA. Evaluation of FreeStyle Libre flash glucose monitoring system on glycemic control, health-related quality of life, and fear of hypoglycemia in patients with type 1 diabetes. Clin Med Insights Endocrinol Diabetes 2017;10. 1179551417746957.