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Flash glucose monitoring: Impact on markers of glycaemic control and patient-reported outcomes in individuals with type 1 diabetes mellitus in the real-world setting

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ABSTRACT

Aims: We aimed to evaluate both glycaemic parameters and patient-reported outcomes in patients prescribed FGM based on the local criteria at our institution.
Methods: This retrospective observational study included patients aged > 18 years with a diagnosis of type 1 diabetes mellitus (T1DM) who were prescribed FreeStyle Libre FGM (n = 90). Quantitative data on glycaemic parameters was collected pre- and post-initiation of FGM in addition to patient-reported outcome measures (PROMs). The primary outcome was change in pre- and post-FGM levels of glycosylated haemoglobin (HbA1C).
Results: There was a mean reduction in HbA_{1c} of −7.29 ± 10.76 mmol/mol ($p < 0.001$, $CI_{95\%}$ 4.94–9.64) sustained to the latest reading. There was also a mean reduction in the number of hypoglycaemic episodes per week of 3.20 (percentage reduction 51.86%, $p < 0.001$, $CI_{95\%}$ 1.64–4.77). A significant improvement in quality of life scores was noted in all five domains of the abbreviated DDS between before and after starting FGM ($p < 0.001$). Key themes highlighted in inductive content analysis include 'life-changing', 'positive experience', and 'convenient'.
Conclusion: Flash glucose monitoring is associated with significant improvement in HbA_{1c} to a mean follow-up of 4.6 months. Additionally, patients reported positive experiences of FGM with significant improvement in all aspects of a focussed Diabetes Distress Scale.

1. Introduction

Good glycaemic control is of paramount importance in those with type 1 diabetes mellitus (T1DM) in order to reduce the risk of both microvascular and macrovascular complications [1,2]. The endeavour to gain such control, however, can be challenging when balanced with the avoidance of hypoglycaemia [3]. Frequent glucose monitoring allows one to adjust insulin doses appropriately, increasing the likelihood of achieving normoglycaemia while reducing the risk of hypoglycaemic episodes [4].

The traditional method of monitoring glycaemic control in T1DM has been self-monitoring of blood glucose (SMBG). Current National Institute for Health and Clinical Excellence

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(NICE) guidelines for adults with T1DM recommends routine SMBG at least four times per day [5]. However, even with frequent monitoring, SMBG has its limitations as it only provides a series of 'snapshot' capillary blood glucose levels which are not truly reflective of day-to-day variability in glucose concentrations. In addition, patients may find SMBG stressful, painful and inconvenient and consequently it has been associated with poor quality of life and non-adherence [6–8].

In recent years, the development of continuous glucose monitoring systems (CGM) has provided a promising alternative to SMBG in terms of gaining a comprehensive understanding of a patient's glucose concentration profile. CGM were initially commercially introduced in 2000, however, the uptake of these devices has been limited due to significant cost implications and the requirement for daily capillary blood calibrations in the majority of devices [9–11].

The introduction of the FreeStyle Libre flash glucose monitoring systems (FGM - Abbott Diabetes Care, Witney, UK) provided an economical alternative that measures interstitial fluid glucose levels in real time. FGM devices use factory-calibrated patch glucose sensors which abate the need for calibration. Unlike real-time CGM, however, they lack the advantage of alarm alerts for both ends of glycaemic spectrum. These devices became commercially available in September 2014 in seven European countries including the United Kingdom and have been demonstrated to reduce the burden of glucose monitoring, impact positively on glycaemic control and reduce the risk of hypoglycaemia particularly in adults with T1DM [3].

With FGM devices, interstitial fluid glucose values are measured every minute, saved every 15 min and stored for up to 90 days which in turn can be downloaded to a computer or can be uploaded to a cloud-based system (e.g., LibreViewTM) or personal mobile (LibreLink app). This enables users to generate various parameters/summary reports including ambulatory glucose profiles (AGP), day-to-day trends, frequency/depth and duration of hypoglycaemic events, time in range, which in turn aid patients and health care professionals to make informed decisions. There is a 5–10-minute delay in interstitial fluid glucose response to changes in blood glucose and its mean absolute relative difference (MARD) has been reported to be approximately 10% when compared to capillary blood glucose levels [12,13]. Given the overwhelming amount of data provided by the FGM, patients require appropriate training and support to assertively analyse and interpret results.

In view of accumulating evidence to support the use of the FreeStyle Libre, NICE published a medtech innovation briefing, summarising its intended place in clinical practice [14]. Accordingly, Diabetes UK then published a consensus guideline for FGM in August 2017 [15]. Two months later, Health Technology Wales (HTW) published an interim statement on the prescribing of FreeStyle Libre FGM for those with diabetes under a National Health Service (NHS) tariff [8]. In March 2018 based on the above guidance, the multi-disciplinary diabetes team in our institution designed a criterion to select suitable T1DM patients for consideration of Libre device with NHS funding (Appendix 1). Once selected, patients were provided with group education and ongoing open-access support via diabetic specialist nurses (DSN). Patients are reviewed at three months by the DSN to assess whether they meet eligibility criteria to continue NHS funding based on a continuation criterion (Appendix 2) at which point the prescription responsibility is transferred to primary care.

We aimed to evaluate the clinical effectiveness of FGM in the real-world setting through comparing a number of relevant parameters before and after starting the FGM device in those with T1DM in our centre. In addition, we aimed to qualitatively and quantitatively assess patients' experiences of using FGM in the context of a nationally funded healthcare system.

2. Methods

2.1. Data collection

Following local institutional approval (registration no. 19/067), all patients aged >18 years with a diagnosis of T1DM who were prescribed FreeStyle Libre FGM through our institution from May 2018 to February 2019 were retrospectively identified (n = 90). Electronic patient records were accessed with both clinic letters and investigation results reviewed. Data was collated onto a secure electronic database containing twenty-two unique categories encompassing patient demographics, diabetes history and investigation results pre- and post- FGM initiation.

Additionally, patients were requested to complete a short questionnaire assessing their experience of using FGM within our service. Usage data including mean number of scans per day and percentage scans within target range (usually 3.9–10), in the hyperglycaemic range (>10), and hypoglycaemic range (<3.9) were collected alongside subjective measures such as improved hypoglycaemia awareness and the patient's overall rating of their experience with FGM. Patients' responses to a focussed Diabetes Distress Score (DDS) were also recorded; questions were representative of each section of the validated DDS. Patients were asked to answer retrospectively for their distress prior to their use of FGM, and then to answer reflecting on their life whilst using FGM. Free text comments were also recorded.

The primary outcome measure was change in HbA1C pre- and post-FGM. Key secondary outcomes included pre- and post-FGM changes in number of SMBGs per day, clinically relevant reduction in hypoglycaemia (defined as 30% reduction), individual modified Diabetes Distress Score items between the pre-FGM and post-FGM timepoints, correlation between patient education and time-in-target with markers of glycaemic control, and the effects of FGM on outcomes in patients with a continuous subcutaneous insulin infusion (CSII) device.

2.2. Data analysis

Statistical analysis was undertaken in SPSS version 25.0 for Windows (IBM corporation). The Shapiro-Wilk test (if $n < 50$) or Kolmogorov-Smirnov test (if $n > 50$) was performed to assess for normality of distribution, defined as $p > 0.05$. Parametric data were analysed using paired-samples *t*-test for pre- and post-FGM values, independent samples *t*-test for

non-paired data, and Pearson's correlation. Non-parametric data were analysed using Mann-Whitney *U* test and Chi-square test as appropriate. Parametric data is presented as mean ± standard deviation unless otherwise stated. Non-parametric data is presented as median ± range/interquartile range. Statistical significance was defined as per the standard value of $p < 0.05$.

Qualitative analysis was undertaken using an inductive content approach. Two members of the study team independently reviewed free text responses and listed key themes, which were then agreed on under supervision of a third team member. Responses were then coded by the original two team members according to the agreed themes, with discrepancies resolved by the third team member. The results were collated as frequencies.

3. Results

3.1. *Baseline characteristics*

90 patients were prescribed the FreeStyle Libre FGM between May 2018 and February 2019 at our institution. There were 43 male patients and 47 female patients (M:F 1:1.09). The mean age of patients at starting FGM was 45.3 years (range 18–75 years). There was no significant correlation between patient age and number of scans per day, number of hypoglycaemic episodes, or HbA1c after commencing FGM.

77/90 (85.6%) patients opted to respond to the questionnaire regarding patient experience of FGM. The mean duration of diabetes diagnosis for these patients was 25.99 years (±15.22 years). A longer duration of diabetes diagnosis was significantly associated with better HbA_{1c} at both the pre-FGM ($r = -0.0476$, $p < 0.001$) and latest FGM timepoints ($r = -0.489$, $p < 0.001$), and was also significantly associated with more hypoglycaemic episodes per day pre-FGM ($r = 0.420$, $p = 0.001$), however diabetes duration was not significantly associated with number of hypoglycaemic episodes per day post-FGM or with any difference in number of SMBGs per day.

The most frequently cited indications for commencing FGM were high-frequency of SMBG (>8 times/day, 43/77 (55.8%) patients), >2 episodes of asymptomatic hypoglycaemia (detected on SMBG) per week (10/77 (13.0%) patients), and fear of extreme hypoglycaemia (6/77 (7.8%) patients). At the time of questioning, 9/77 (11.7%) had stopped using FGM; six patients had not attended the required follow-up appointments to allow the prescription to repeat or had not engaged with the service, one patient reported a lack of benefit, one patient reported concerns regarding trusting the device's accuracy, and one patient reported topical reaction to the adhesives.

21/77 (27.3%) patients had used FGM via self-funding prior to commencing on our institution's NHS funded programme. For all patients, their pre-FGM quantitative values have been taken from before their use of FGM to reduce risk of confounding.

3.2. *Impact on blood glucose monitoring and glycaemic control*

HbA_{1c} readings were obtained for pre-FGM, at three months post-FGM, at six months post-FGM where possible, and latest HbA_{1c} (where mean time from starting FGM to latest HbA_{1c} = 4.6 months (range 3–12 months)). There was a mean reduction in HbA_{1c} of −7.94 ± 10.67 mmol/mol between pre-FGM (mean HbA_{1c} 72.82 ± 15.71 mmol/mol (8.8%)) and three months post-FGM (mean HbA_{1c} 64.88 ± 12.91 mmol/mol (8.1%)) ($p < 0.001$, $CI_{95\%}$ 5.44–10.45). This was sustained in the smaller cohort at six months post-FGM (mean paired HbA_{1c} 71.48 ± 15.65 mmol/mol (8.7%) pre-FGM and 62.78 mmol/mol (7.9%) at six months) with a mean reduction of −8.70 ± 15.00 mmol/mol ($p = 0.006$, $CI_{95\%}$ 2.77–14.64), and also seen when comparing pre-FGM HbA_{1c} with the latest HbA_{1c} reading (mean paired HbA_{1c} 71.45 ± 15.55 mmol/mol (8.7%) pre-FGM and 64.26 ± 12.88 mmol/mol (8.0%) at the latest timepoint) (mean reduction −7.29 ± 10.76 mmol/mol, $p < 0.001$, $CI_{95\%}$ 4.94–9.64). These results are summarised in Table 1.

Patients were stratified into two sets of pairs according to HbA_{1c} readings; those with poor control (HbA_{1c} > 75 mmol/-mol) versus not, and those with optimal control (HbA_{1c} < 58 -mmol/mol) versus not. When comparing HbA_{1c} in those >75 mmol/mol and not, there was a significant decrease in HbA_{1c} between baseline and latest reading ($p < 0.001$), with no significant reduction in episodes of hypoglycaemia ($p = 0.06$). When comparing HbA_{1c} in those <58 mmol/mol and those not, there was no significant decrease in HbA_{1c} between baseline and latest reading ($p = 0.806$), however there was a significant reduction in episodes of hypoglycaemia in this cohort ($p = 0.014$).

Patients were asked to report the number of hypoglycaemic episodes (defined as blood glucose <4 mmol/L) per week prior to FGM and at the time of the questionnaire. The overall mean number of hypoglycaemic episodes per week pre-FGM was 6.17 ± 6.32. The mean number of hypoglycaemic

Table 1 – Changes in HbA_{1c} before and after starting FGM.

	N	HbA_{1c} value (mmol/mol) + (%)	Mean Reduction in HbA1c (mmol/mol)	SD (+/−)	p	$CI_{95\%}$
Pre-Libre HbA_{1c}	72	72.82 (8.8%)	−7.94	10.67	p < 0.001	5.44–10.45
HbA_{1c} at 3 months	72	64.88 (8.1%)				
Pre-Libre HbA_{1c}	27	71.48 (8.7%)	−8.70	15.00	p = 0.006	2.77–14.64
HbA_{1c} at 6 months	27	62.78 (7.9%)				
Pre-Libre HbA_{1c}	83	71.45 (8.7%)	−7.29	10.76	p < 0.001	4.94–9.64
Latest HbA_{1c}	83	64.26 (8.0%)				

episodes post-FGM was 2.97 ± 2.32, giving a mean reduction in the number of hypoglycaemic episodes per week of 3.20 (percentage reduction 51.86%, $p < 0.001$, $CI_{95\%}$ 1.64–4.77).

Patient reported mean number of SMBGs per day pre-FGM was 7.46 ± 4.86 while the mean number of SMBGs per day post-FGM was 1.31 ± 2.12, giving a mean reduction in SMBGs per day of 6.15 ($p < 0.001$, $CI_{95\%}$ 4.97–7.32).

Data reporting the mean number of FGM scans in target range (50.4 ± 23.2%), above target range (40.2 ± 24.0%) and below target range (9.4 ± 8.4%) was available for 34 patients. A Pearson bivariate correlation was undertaken to determine the relationship between percentage scans in target range and latest HbA_{1c}. This demonstrated a significant negative correlation, indicating that as the number of scans in target range increases, HbA1c decreases ($r = -0.523$, $p = 0.001$). A Pearson bivariate correlation was also undertaken to determine the relationship between the mean number of scans per day and latest HbA_{1c}. This demonstrated a significant negative correlation, indicating that as the total number of scans per day increases, HbA_{1c} decreases ($r = -0.408$, $p = 0.001$).

14/77 (18.2%) patients were using continuous subcutaneous insulin infusion (CSII) devices at the time of starting FGM. There was no significant difference in number of hypoglycaemic episodes per week between patients using a CSII and not using a CSII prior to starting FGM ($p = 0.569$) which remained the case after starting FGM ($p = 0.637$). There was a significant difference between HbA_{1c} in the CSII and non-CSII groups at baseline which persisted at the mean latest timepoint of 4.6 months ($p = 0.030$) although it is worth noting that the gap has narrowed post FGM initiation.

Table 2 compares changes within CSII and non-CSII groups pre- and post-FGM. While there was a significant decrease in HbA_{1c} in the non-CSII cohort ($p = 0.034$), this was not mirrored in the CSII cohort. However, there was a significant decrease in the number of self-reported hypoglycaemic episodes between pre- and post-FGM in both CSII (56.47% reduction, $p = 0.009$) and non-CSII groups (47.52% reduction, $p = 0.002$).

Information on whether a patient underwent structured education prior to FGM was available for 74 patients. 51.2% (38/74) patients had received structured education either through the Dose Adjustment For Normal Eating (DAFNE) course or the Wrexham Insulin Dose Adjustment Course (WIDAC - a locally adapted version of DAFNE). Prior to starting FGM there was no significant difference in HbA_{1c} between those who had undergone a structured education programme and those who hadn't ($p = 0.188$). This persisted at three months post-FGM and at the latest HbA_{1c} reading post-FGM ($p = 0.340$ and $p = 0.158$, respectively). No significant difference was observed in mean number of hypoglycaemic episodes at any timepoint between those who had undergone structured education and those who had not.

3.3. *Patient-reported outcome measures (PROMs)*

48/68 (70.6%) patients who continue to use FGM self-reported an improved awareness of hypoglycaemia since commencing FGM.

A significant improvement in quality of life scores was noted in all five domains of the abbreviated DDS between before and after starting ($p < 0.001$). Mean score and mean differences are displayed in Table 3.

Key themes highlighted from qualitative analysis are summarised in Table 4. Key individual themes with the highest frequency of reporting include 'life-changing' (reported by 16 patients), 'positive experience' (reported by 15 patients) and 'convenient' (reported by 10 patients).

4. Discussion

This observational study assesses the clinical effectiveness of FGM in a demographically varied population in terms of impact on glycaemic control, blood glucose monitoring and reduction in hypoglycaemic episodes outside of trial settings. Of note, our study demonstrated a significant reduction in HbA_{1c} with sustained effect at both three and six months. The reduction in HbA_{1c} was significant despite a significant reduction in the average number of SMBGs and reduction in the number of hypoglycaemic episodes. To our knowledge, this study presents novel data in the form of inductive content qualitative analysis, which was used to gain a better understanding of patients' experiences.

In order to gain data representative of the real-world, inclusion criteria were broad; all adults (>18 years) with T1DM being managed in our service who had been prescribed the FreeStyle Libre were eligible. This is in contrast to a number of published randomised controlled trials evaluating changes following FGM use in HbA_{1c} and/or hypoglycaemia in type 1 diabetes which included participants with ages ranging 33–51 years and 37.5–63.5 years respectively [3,16]. Indeed, recent observational studies have mirrored this with ages ranging 30–64 years [17]. In our wider cohort, there was no significant correlation in any of the variables assessed based on the age of the patient thus supporting the use of FGM in individuals of all age groups.

The landmark randomised controlled study published by Bolinder et al. studied individuals who had established tight control (HbA1c < 58) and demonstrated that FGM reduced the number of episodes of hypoglycaemia without compromising

Table 2 – Changes in hypoglycaemic episodes and HbA_{1c} pre- and post-FGM in the CSII and non-CSII groups.

	Pre-FGM	Post-FGM	*p*
Mean hypoglycaemic episodes CSII	6.57	2.86	0.009
Mean HbA_{1c} at latest timepoint CSII	59.79	56.57	0.141
Mean hypoglycaemic episodes non-CSII	6.06	3.00	0.002
Mean HbA_{1c} at latest timepoint non-CSII	70.44	65.33	0.034

Table 3 – Mean responses to the modified DDS.

	Mean pre-FGM	Mean post-FGM	Difference in means	p value
Feeling overwhelmed	3.38	2.04	1.34	<0.001
Failing routine	3.46	2.09	1.37	<0.001
Energy-consuming	3.37	2.09	1.36	<0.001
Depressed	2.69	1.82	1.17	<0.001
Frequent testing	3.34	1.37	1.97	<0.001

Table 4 – Results of inductive content analysis.

Major theme	Sub-theme	Frequency
Quality of life	Life-changing	16
	Positive experience (e.g. great, fantastic)	15
	Convenient	10
	Convenient for use around children	2
	Overwhelmed by constant readings	3
Libre device	Easy to use	9
	Issues with adhesive	8
	Issues with perceived accuracy	8
	Limited sites for attachment of device	3
Technology and data transfer	Need for hypoglycaemia alarm	4
	Need for FGM to communicate with CSII	1
	Need for automatic data transfer to hospital	3
	Compatible with more technologies	1

the HbA1c [3]. This is supported by the findings in our study in which patients with a baseline HbA1c < 58 mmol/mol had a significant reduction in the number of hypoglycaemic episodes without a significant change in HbA1c. Conversely, there aren't any randomised controlled trials establishing whether an improvement in HbA_{1c} is achieved using FGM in those with less tight control, however our results support the assumption that this may be the case with a significant reduction in HbA_{1c} in patients with a starting HbA_{1c} > 75 mmol/mol; thus, we feel in our population that starting HbA_{1c} should not limit access to FGM [18]. Of note, in our subgroup of patients with HbA_{1c} > 75 mmol/mol there was no significant reduction in the number of hypoglycaemic episodes. This could be attributed to the assumption that those with poor glycaemic control are unlikely to have had frequent hypoglycaemic episodes prior to initiation of FGM therefore reducing the margin for improvement; in our cohort, the mean number of hypoglycaemic episodes per week pre-FGM was 4.04 compared to an overall cohort mean of 6.17.

There was a significant correlation between increased number of scans and lower HbA1c suggesting that FGM facilitates frequent close monitoring, which has been established to correlate with improved HbA1c outcomes [4]. There was also a significant correlation between increased percentage scans in target and HbA_{1c}, again, this may represent a surrogate marker for concordance but nonetheless supports an improvement in the key measures of glycaemic control.

Hypoglycaemia in patients with T1DM is associated with both increased morbidity and mortality as well as increased hospital admissions, particularly in those patients who have impaired hypoglycaemic awareness [19,20]. As such, fear of hypoglycaemia is recognised as one of the major barriers to achieving optimal glycaemic control. Increased incidence of hypoglycaemia is correlated positively with worsening hypoglycaemic awareness and thus presents another rationale for addressing the issue of hypoglycaemia. Frequency of asymptomatic hypoglycaemia and fear of hypoglycaemia represented the second and third most common indications for our patients to have been initiated on FGM respectively.

There was a significant reduction in number of hypoglycaemic episodes per week experienced by our patients despite an overall improvement in glycaemic control. With the level of clinical significance typically set at 30%, the reduction of 51.86% is certainly of clinical significance [3]. While these results contrast with a recent observational study by Tyndall et al, they are in keeping with the other published outcomes including those by Bolinder et al.

70.6% of the individuals using FGM in our study self-reported an improved awareness of hypoglycaemia since commencing FGM. Although improved awareness was self-reported, this nonetheless has significant implications on the management of their diabetes. Impaired awareness of hypoglycaemia increases the risk of severe hypoglycaemia six-fold and is said to affect 30% of adults with T1DM [21,22]. In a systematic review and meta-analysis which looked at the effectiveness of various interventions that are considered to restore awareness of hypoglycaemia in adults with T1DM, authors suggested a stepwise approach with structured education in combination with optimised multiple dose insulin injection (MDI) therapy along with the utilisation

of technology in selective individuals (including CSII therapy, CGM) [23].

The reduction in the number of SMBGs per day demonstrated in our study also show that users had the confidence to rely on the system to make adjustments to manage their glucose level and can avoid the need to perform the previous recommended number of tests which patients find both inconvenient and painful [5,7].

Approximately one fifth of patients in our cohort who were prescribed FGM use CSII. This cohort of patients had a significantly lower mean HbA1c than those who were not using CSII at baseline. Tighter control was, however, not associated with increased number of hypoglycaemic episodes in CSII users. There was a significant improvement in HbA1c at the latest timepoint for those who were not using CSII which was not achieved in those using CSII. The reduction in the number of hypoglycaemic episodes at the latest time points were significant in each group. These results demonstrate that patients who used CSII had tight control prior to FGM initiation and suffered on average 6.57 hypoglycaemic episodes per week, yet the number of hypoglycaemic episodes could be significantly improved using FGM without compromising HbA1c control. These findings are comparable to the results of the Bolinder study in T1DM patients who had tight control, where 32% of patients in the intervention arm used CSII [3]. Our results also demonstrate a clinically significant reduction in hypoglycaemia regardless of HbA1c prior to initiation of FGM.

Patient-reported outcomes were strongly in favour of FGM in our study. Results of responses to our modified Diabetes Distress Scale indicate significant improvement in all domains; this is in keeping with a number of studies, including the recently published observational study by Tyndall et al. Other studies, such as that by Olafsdottir et al, have highlighted positive ratings of 9/10 or greater in the majority of domains related to how FGM use has impacted day-to-day life [24]. In addition, our study reports (to the best of our knowledge) the first inductive content analysis of free text responses from patients using FGM. This has highlighted 'life-changing' as the single biggest response from patients when asked about their overall experience with FGM. The degree of psychological distress associated with type 1 diabetes is well documented [25], and as such interventions that can reduce this to the extent of being described as 'life-changing' should not be underestimated.

We acknowledge that there are several limitations to our study. Firstly, our collection of quantitative data was largely retrospective and thus is open to greater degree of influence due to unmeasured confounders, and also to selection and misclassification bias although every effort was made to minimise these by having two data collectors corroborate entries whenever unclear. Some key outcome measures are self-reported, and thus are relying on patients to provide accurate data; this introduces a risk of reporting bias in measures such hypoglycaemic episodes. A validated scoring system was not used to assess improved awareness of hypoglycaemia and thus this outcome may also be open to reporting bias. Due to resource limitations we were unable to assess hospital admissions pre- and post-FGM, which may have provided further insight into potential morbidity benefits associated with FGM use in these patients. There was limited data on number of scans in target range (n = 34); this was limited by patients being able to access the required data at the time of being asked, and the reduced number of included patients for this sub-analysis may limit generalisability. Follow-up was only to three months (mean greatest length of follow-up was 4.6 months), and thus medium and long-term follow-up data is incomplete for our study. Nonetheless, this highlights that significant changes occur within a short time frame after starting FGM.

5. Conclusion

Flash glucose monitoring is associated with significant improvement in HbA_{1c} and, while limited by the self-reported nature of data collection, is also associated with clinically significant reduction in hypoglycaemic episodes to a mean follow-up of 4.6 months. Benefit was also demonstrated in subgroup analysis, including in patients using CSII and in those with good glycaemic control prior to commencing FGM. Additionally, patients reported positive experiences of FGM with significant improvement in all aspects of a focussed Diabetes Distress Scale. Although evaluation of long-term outcomes is needed, this study supports the role of FGM in facilitating improvement in glycaemic parameters and quality of life in a real-world T1DM population.

Declaration of Competing Interest

The authors do not have any conflicts of interest to declare.

Acknowledgements and disclosures

No competing financial interests exist for any other the authors.

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None.

Appendix 1. BCUHB FreeStyle Libre Flash glucose testing INITIATION request form for an ADULT

Name of applicant:
Job title and base:
Date:
Patient's name:
Date of birth: **Hospital number:**
Address:
NHS number:
GP name and Practice:
Diagnosis: Type 1 Diabetes LADA
Is the patient currently self-funding their FSL: **YES/NO** **How long have they been self-funding? (date):**
Name of blood glucose test strip currently used (previously used if FSL self funder): **Number of BG test strips used per day:**
Baseline HbA1c: **Date taken:**
Criteria for usage in adult, that despite optimised use of insulin therapy and conventional blood glucose monitoring: *please tick **all** relevant boxes*

- Patient is testing eight or more times a day on a regular basis.
- Has hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day.Continue only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.
- Has more than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Has frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with their daily activities.
- Has extreme fear of hypoglycaemia.
- Has complete loss of awareness of hypoglycaemia.
- As a management tool by healthcare professionals to obtain a more detailed picture of the glucose profile for an individual.
- Patient is aware that treatment will ONLY continue if a benefit can be demonstrated. There will be a continual assessment of benefit.
- Review to be carried out within ..... months (Maximum of 3 months)
- Date of patient's next review:

Appendix 2. BCUHB FreeStyle Libre Flash glucose testing CONTINUATION request form for an ADULT

Name of applicant:
Job title and Base:
Date:
Patient's name:
Date of birth: **Hospital number:**
Address:
NHS number:
GP name and Practice:
Diagnosis: Type 1 Diabetes LADA
Latest HbA1c **Date taken:**
Name of any blood glucose test strip currently used: **Number of BG test strips used per day:**
Criteria for continued usage of FreeStyle Libre continuous glucose monitoring: *please tick **all** relevant boxes*

- Patient is no longer testing eight or more times a day on a regular basis.
- HbA1c level has fallen from baseline. At annual review, continue only if HbA1c can be sustained at or <53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.
- Patient has not had an episode of severe hypoglycaemia (unless precipitated by an obviously preventable cause).
- Patient has had a reduction (<2 episodes a week) in their asymptomatic hypoglycaemia that was causing problems with their daily activities.
- Patient has a reduction in their fear of hypoglycaemia.
- Patient has a restored awareness of hypoglycaemia.
- Patient has uploaded their profile for healthcare professional to obtain a more detailed picture of the glucose profile for the individual.
- Review to be carried out within ..... months (Maximum of 6 months)
- Date of patient's next review:

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2019.107893.

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