Effect of intermittently scanned continuous glucose monitoring (isCGM) in people with diabetes with a psychosocial indication for initiation

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Abstract

Aim

The aim of this study was to understand the effect of intermittently scanned continuous glucose monitoring (isCGM) in people with diabetes with a 'psychosocial' indication for access.

Methods

The study utilized baseline and follow-up data from the Association of British Clinical Diabetologists nationwide audit of people with diabetes in the United Kingdom. Diabetes-related distress (DRD) was assessed using the two-item diabetes-related distress scale (DDS). Participants were categorized into two groups: high DRD (DDS score ≥3) and lower DRD (DDS score <3). T-test was used to assess the difference in the pre- and post-isCGM continuous variables.

Results

The study consisted of 17,036 people with diabetes, with 1314 (7%) using isCGM due to 'psychosocial' reasons. Follow-up data were available for 327 participants. 322 (99%) of them had Type 1 diabetes with a median diabetes duration of 15 years. 75% (n=241) had high levels of DRD. With the initiation of isCGM, after a mean follow-up period of 6.9 months, there was a significant reduction in DDS score; 4 at baseline vs. 2.5 at follow up (P<0.001). The prevalence of high DRD reduced from 76% to 38% at follow-up (50% reduction in DRD, P<0.001). There was also a significant reduction in HbA1c (HbA1c 78.5mmol/mol (9.3%)at baseline vs 66.5 mmol/mol (8.2%)at follow-up (P<0.001). This group

also experienced an 87% reduction in hospital admissions due to hyperglycaemia/Diabetic Ketoacidosis (P<0.001).

Conclusion

People with diabetes who had isCGM initiated for a psychosocial indication had high levels of DRD and HbA1c, which improved, with the use of isCGM.

Introduction

The nationwide audit for Free Style Libre (FSL), a form of intermittently scanned continuous glucose monitoring (isCGM), conducted by the Association of British Clinical Diabetologists (ABCD) in the United Kingdom has provided real-world insights into the use of isCGM and its effect on several key aspects of diabetes care[1-3]. The use of isCGM has been shown to significantly improve glycaemic control, hypoglycaemia awareness and to reduce diabetes related distress[1-9]

Type 1 diabetes (T1DM) is a chronic condition that requires continuous management to achieve glycaemic control and prevent long-term complications. Managing T1DM can be challenging, and individuals with T1DM often face a significant burden of disease management[10]. This can include monitoring blood glucose levels, administering insulin, managing diet and exercise, and dealing with potential complications. Despite the best efforts of individuals with T1DM to manage their condition, it can be difficult to achieve glycaemic targets, which can lead to long-term complications such as retinopathy, neuropathy, and nephropathy[11]. According to the International Diabetes Federation, the

global prevalence of T1DM is estimated to be around 1 in 300 people, with an estimated 1.1 million children and adolescents living with T1DM worldwide[12]. In addition to the physical challenges of managing T1DM, individuals with the condition may also experience diabetes-related distress, which can have a significant impact on their quality of life[13, 14]. Diabetes-related distress can be caused by factors such as the constant need for self-management, fear of hypoglycaemia, and anxiety about long-term complications[14]. The prevalence of diabetes-related distress among adults with T1DM ranges from 10% to 45%, depending on the measurement tool used[3, 15]. Recognizing the significant psychological burden that people with T1DM face, the National Health Service England (NHSE) in 2019 published national guidance to support glucose monitoring in this population. The guidance recommends using continuous glucose monitoring (CGM) systems, which can provide individuals with glucose data and help them to make informed decisions about their diabetes management[16]. The guidance also recommends that healthcare professionals provide education and support to help individuals with T1DM manage their condition more effectively and reduce the burden of disease management[16-18]. One of the criteria set out in this guidance for initiation of isCGM in type 1 diabetes at that time, was for psychosocial reasons[16]. In clinical practice, the decision to initiate isCGM for psychosocial reasons was determined by the Diabetes multi-disciplinary team (MDT). Examples of diagnoses in this category included (but not limited to); depression, anxiety, sleep disorders and risk of suicide. Other indications for initiation of isCGM were also outlined in this guideline[16]

There are no data looking at the effect of isCGM on glycaemic control, diabetes related distress and resource consumption in people living with diabetes who were started on isCGM for “psychosocial” reasons. It is unclear, to what extent the benefits of isCGM

identified from previous studies would be seen this cohort of patients. The objective of this study therefore was to use data from the ABCD FSL national audit to understand the effect of intermittently scanned continuous glucose monitoring in people living with diabetes with a psychosocial indication for access to isCGM.

Materials and methods

The study was performed using baseline and follow-up data from the Association of British Clinical Diabetologists (ABCD) nationwide audit of people with diabetes who initiated the isCGM (Free Style Libre 1) in the United Kingdom. The baseline and follow-up data were collected as part of routine clinical care. Baseline data, reason for initiation of isCGM, previous diabetes structured education, hypoglycaemia awareness using the GOLD score[19], Diabetes related distress and demographics were collected. Diabetes-related distress (DRD) was assessed using the two-item diabetes-related distress scale (DDS)[20] defined as the average of the two-item score of greater or equal to three (≥3). The DDS asks respondents to indicate the degree to which each item may be bothering in their life. If the item is not a bother or a problem for them, they indicate “1” and they would indicate “6” if the item is very bothersome. The two items are; 1) Feeling overwhelmed by the demands of living with diabetes, 2) Feeling that I am often failing with my diabetes routine. People living with diabetes were categorized into two groups: those with high diabetes related distress, defined as an average DDS score of ≥3 and those with low DRD, expressed as a DDS score of < 3. Baseline and follow up data were also collected on hypoglycaemia, severe hypoglycaemia, admission with hyperglycaemia/Diabetic ketoacidosis (DKA) and Haemoglobin A1c (HbA1c).

Ethical approval

The ABCD nationwide audit program has Caldicott Guardian approval. The program is an audit, not research. The NHS encourages audit of clinical practice. There are guidelines, which were followed, in particular, that contributing centres only collect data from routine clinical practice, and all data collected were anonymized at the point of submission to the central secure online database.

Research Methods

The study was conducted using the national ABCD-FSL audit data. The audit consisted of baseline and follow-up forms, where clinicians were able to input the demographics, clinical characteristics and the indications for starting isCGM. Data was also collected at baseline and follow-up for resource utilisation, such as paramedic call-outs, hospital admissions for hyper and hypoglycaemia and DKA, one year prior to starting isCGM and during the follow-up period after starting isCGM.

Statistical methods

We compared the baseline characteristics of participants by indication of isCGM initiation. We then restricted the analysis to participants initiated on isCGM for psychosocial reasons who had at least one follow-up visit following the initiation of isCGM. We used Chi-square test to assess the difference between categorical variables, while the t test assessed the difference in pre and post isCGM continuous variables.

To identify factors associated with a reduction in DDS, the change in diabetes distress following use of isCGM was modelled as a dependent variable in a linear logistic regression model with age, gender, baseline body mass index (BMI), duration of diabetes, time in range, baseline diabetes related distress and number of scans per day as independent

predictors. All statistical analyses were done using R statistical software (v4.1.2; R Core Team 2021).

Results

The study consisted of 17,036 people with diabetes, of which 1314 (7%) were initiated on isCGM because of a 'psychosocial' indication. Table 1 compares the demographic characteristics of two groups: those using isCGM for psychosocial indication (n=1314) and those using isCGM for other indications (n=15722).

There was no significant difference in the percentage of females between the two groups (47% vs 50%, P=0.28). The mean duration of diabetes was significantly shorter in the isCGM for psychosocial indication group (15.7 ± 13) compared to the isCGM for other indication group (20.8 ± 4.9) (P<0.001). Participants with isCGM for psychosocial indication had a higher mean baseline HbA1c (80.4±18.6 mmol/mol) compared to the other group (70.2±18.6mmol/mol) The mean baseline DDS score was higher in the psychosocial indication group (3.5±1.5) compared to the other indications (2.8±1.3) (P<0.001). The isCGM for psychosocial indication group had a lower mean baseline Gold score (2.1±2.8) compared to the isCGM for other indication group (2.35±1.3) (p=0.002). The percentage of individuals using insulin pump therapy was significantly lower in psychosocial indication group (9%) compared to the other indication group (19%) (P<0.001). The median number of times the psychosocial indication group tested blood glucose levels (SMBG) was 4.5 (IQR 4-6) per day. This was lower than the group initiated on isCGM for other indications (Median is 7 (IQR- 4-8). Unfortunately, this variable (SMBG) was missing in more than 50% of the sub-population initiated on isCGM for psychosocial indication.

Of the 1314 participants initiated on isCGM for psychosocial reasons, follow up data was available for 327 participants. The prevalence of Diabetes-related distress (DRD) was high in this study population. 76% had high DRD. With the initiation of isCGM, after a mean follow-up period of 6.9 months, there was a significant reduction in diabetes-related distress. The median DRD score fell from 4 (IQR=2.8-5) at baseline to 2.5 (1.5-3.0) at follow-up (P<0.001) as shown in figure 1. In addition, the prevalence of high DRD reduced from 76% at baseline to 38% at follow up. This represents a 50% reduction in DRD (P<0.001).

There was also a significant reduction in the HbA1c with the use of isCGM (figure 2). The mean HbA1c decreased from 78.5 mmol/mol (9.3%) at baseline to 66.5 mmol/mol (8.2%) at follow up (P<0.001). The use of isCGM was not associated with a change in Gold score; median (IQR) Gold scores pre and post isCGM were similar, 2 (1-3) (P=0.44). This group experienced a reduction in some diabetes-related acute events but not others. The number of hospital admissions due to hyperglycaemia/Diabetic ketoacidosis reduced from 40 in 12 months at baseline, to 3 in 7 months at follow up, representing an 87% reduction(P<0.0001). Hypoglycaemia-related admissions reduced from 7 admissions in 12 months at baseline to 1 admission in 7 months, although this reduction was not statistically significant (P=0.154). Similarly, paramedic call outs for hypoglycaemia reduced by 74% (from 13 call outs in 12 months at baseline to 2 call outs in 7 months at follow up, but this was not statistically significant, P=0.059).

The factors associated with reduction in diabetes-related distress at follow-up (Table 2) were time in range (β = 0.015 [±0.004]) (*P*<0.001), baseline DDS score (β = 0.611 [±0.056]) (*P* <0.001) and number of isCGM scans per day (β =0.023 [±0.010]) (*P* =0.02). BMI, age, duration of diabetes and gender were not associated with reduction in diabetes-related

distress following use of isCGM. The model however only explained 47.8% of the variation in Diabetes-related distress following isCGM use (adjusted R^2 = 0.478).

Discussion

In this nationwide study, we show that the prevalence of diabetes-related distress (DRD) is very high in those with psychosocial indication for use of isCGM. Three in every four participants had high DRD. Our study shows that the use of isCGM in individuals initiated for psychosocial reasons improved glycaemic control, reduced DRD and resource utilisation.

In the national audit data, we have previously shown a reduction in HbA1c of 5.5 mmol/mol with the use of isCGM in the people living with diabetes. A similar reduction in HbA1c was seen in the Flash UK randomized control trial [21] . However, in this subgroup of people living with diabetes with a psychosocial indication for isCGM initiation, we show a larger improvement in the mean HbA1c of 12mmol/mol. This is possibly because these participants had a higher baseline HbA1c. Furthermore, those with a psychosocial indication for isCGM had high DRD which is known to negatively impact glycaemic control.

Our study showed a significant reduction in DRD, with a nearly 50% reduction in the overall DDS. The use of isCGM has previously been associated with a reduction in diabetes related distress in the larger national UK audit[3]. Another observational study reported a reduction in DRD following the use of isCGM. The same study however noted unexplained likelihood of increase in anxiety and depression scores with use of isCGM[22]. Our study has also shown that the number of scans performed by an individual per day and time in range were associated with a reduction in diabetes-related distress. These data demonstrate an association rather than causation and further work to explore relationship between diabetes related distress and the interaction and subsequent benefit from diabetes

technology is much needed. Although our study showed a significant reduction in DDS in this subgroup of population it remains to be seen if there is a return to baseline levels of DDS or a worsening of DDS with long-term use of isCGM. Population based studies with large follow-up time will be needed to answer this question

Regarding hospital admissions, the findings of our study are in agreement with two observational studies[22, 23]of type 1 diabetes patients using isCGM that showed fewer admissions with diabetic ketoacidosis. One of these studies[22], like our findings, reported no changes in the GOLD scores. In our study, the use of isCGM did not reduce hypoglycaemia related admissions or paramedic call outs due to hypoglycaemia. The use of isCGM did not affect hypoglycaemia awareness in this group of participants, in contrast with the wider ABCD audit results, which showed significant improvement in hypoglycaemia awareness following use of isCGM. This likely reflects the fact that impaired awareness of hypoglycaemia was also an indication for isCGM funding and this group were the most likely to demonstrate benefit in terms of Gold score. This is further supported by the fact that the cohort with a psychosocial indication had good hypoglycaemia awareness at baseline (median GOLD score of 2), indicating normal hypoglycaemia awareness.

Our study has several limitations. This is an observational study with no comparator arm, and hence a randomized controlled trial will be needed to confirm these findings. In addition, although the prevalence of psychosocial issues in this population may be comparable to the general T1DM population, follow-up data was available for only 25% of them. This may not be representative of the whole population. Furthermore, the high DRD in this population are likely related to patient selection with the 'psychosocial indication' criteria; it is possible that the high DRD itself contributed to the initiation of people on

isCGM. Nonetheless, we show a significant reduction in DDS and improvement in glycaemic control and resource utilization in this subgroup of people with diabetes.

The NICE UK guidelines released in March 2022[24]now recommend isCGM or real time Continuous Glucose Monitoring (rtCGM) to all adults living with Type 1 diabetes. These recommendations will widen access and ensure more equitable access to this technology which has been shown in multiple studies to improve a range of clinical and psychological outcomes. Further work is now required to explore the wider impact of isCGM on psychological outcomes in those living with type 2 and rarer forms of diabetes.

Conclusion

This analysis of real-world data of people with Type 1 diabetes using isCGM initiated for psychosocial reasons shows a significant improvement in DRD, glycaemic control and hospital admissions due to hyperglycaemia/DKA.

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Author contributions:

HD, EGW and TS conceived the presented idea. ES, KAA and HD contributed to data analysis. ES wrote the first draft of the manuscript. All of the authors reviewed the manuscript and

made comments, criticism, and changes in the final draft of the paper. ES is the guarantor of this work and, as such, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of interest:

- The ABCD nationwide FSL audit is supported by a grant from Abbott Laboratories.
- The FSL audit was independently initiated and performed by ABCD, and the authors remain independent in the analysis and preparation of this report.
- REJR has received speaker fees, and/or consultancy fees and/or educational sponsorships from Besins, BioQuest, GI Dynamics, and Novo Nordisk.
- EGW has received personal fees from ABCD, Abbott, AstraZeneca, Dexcom, Eli Lilly, Embecta, Glooko, Insulet, Medtronic, Novo Nordisk, Roche, Sanofi, Ypsomed and research support from ABCD, Abbott, Diabetes UK, Embecta, Insulet, Novo Nordisk, Sanofi.
- No other potential conflicts of interest relevant to this article were reported.

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Legends to figures:

Figure 1: Distribution of Diabetes Distress scores change pre- and post-isCGM use in the ABCD nationwide audit of isCGM for participants initiated on isCGM for psychosocial reasons

Figure 2: Distribution of HbA1c change pre- and post-isCGM use in the ABCD nationwide audit of isCGM for participants initiated on isCGM for psychosocial reasons

Table 1: Demographic characteristics of the study population

	isCGM for psychosocial indication (n=1314)	isCGM for other indication (n=15722)	P-value
Age	38.9 (±17.7)	40.7 (±18.5)	<0.001
Type 1 diabetes	1275(97%)	15140(96%)	0.17
%Female	47%	50%	0.28
BMI	25.7 (±7)	26(±23.8)	0.3
Duration of Diabetes	15.7(±13)	20.8(±4.9)	<0.001
Baseline HbA1c	80.4(±18.6) (9.5%)	70.2(±18.6) (8.6%)	<0.001
Baseline DDS	3.5(±1.5)	2.8(±1.3)	<0.001
Baseline Gold score	2.1 (±2.8)	2.35(±1.3)	0.002
% Insulin Pump	9%	19%	<0.001

Table 2: Linear regression model showing factors associated with reduction in Diabetes-related distress following use of isCGM

Characteristic	**Beta (β)**	**Standard error**	**P value**
Age	0.010	0.006	0.066
Gender (female)	-0.019	0.161	0.907
BMI	0.002	0.014	0.889
Duration of diabetes	0.001	0.006	0.915
Time in range	0.015	0.004	**<0.001**
Number of scans per day	0.023	0.010	**0.02**
Baseline DDS score	0.611	0.056	**<0.001**

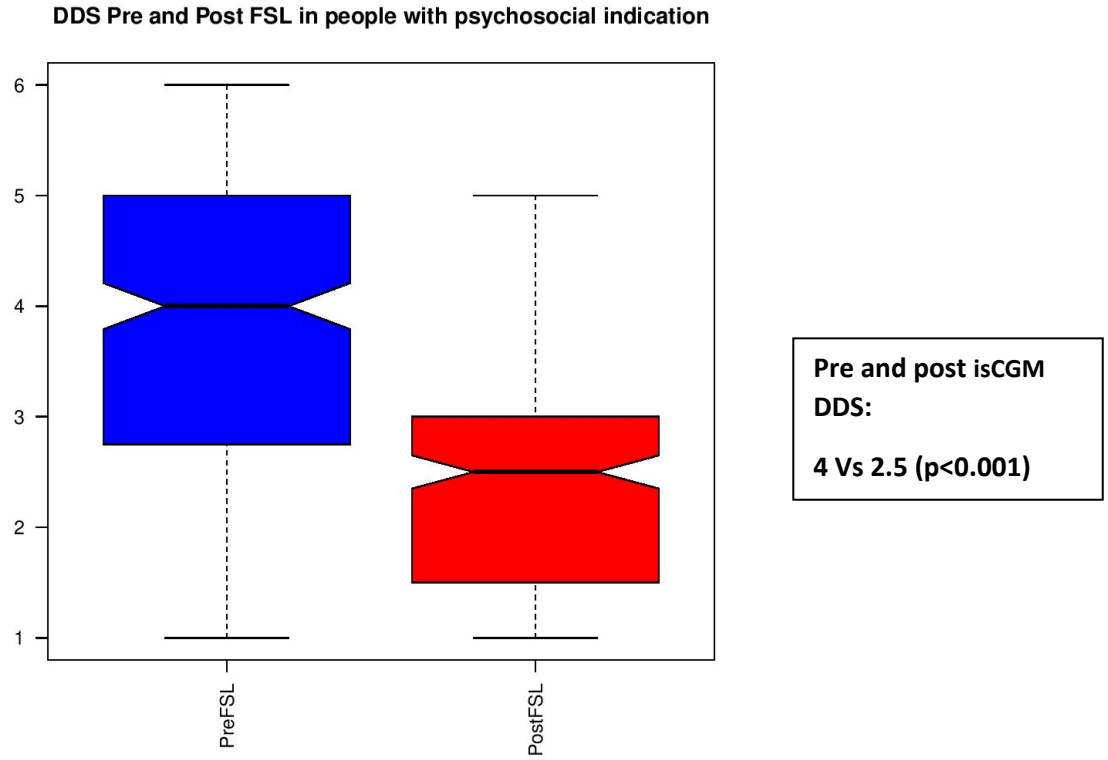

Figure 1: Distribution of Diabetes Distress scores change pre- and post-isCGM use in the ABCD nationwide audit of isCGM for participants initiated on isCGM for psychosocial reasons

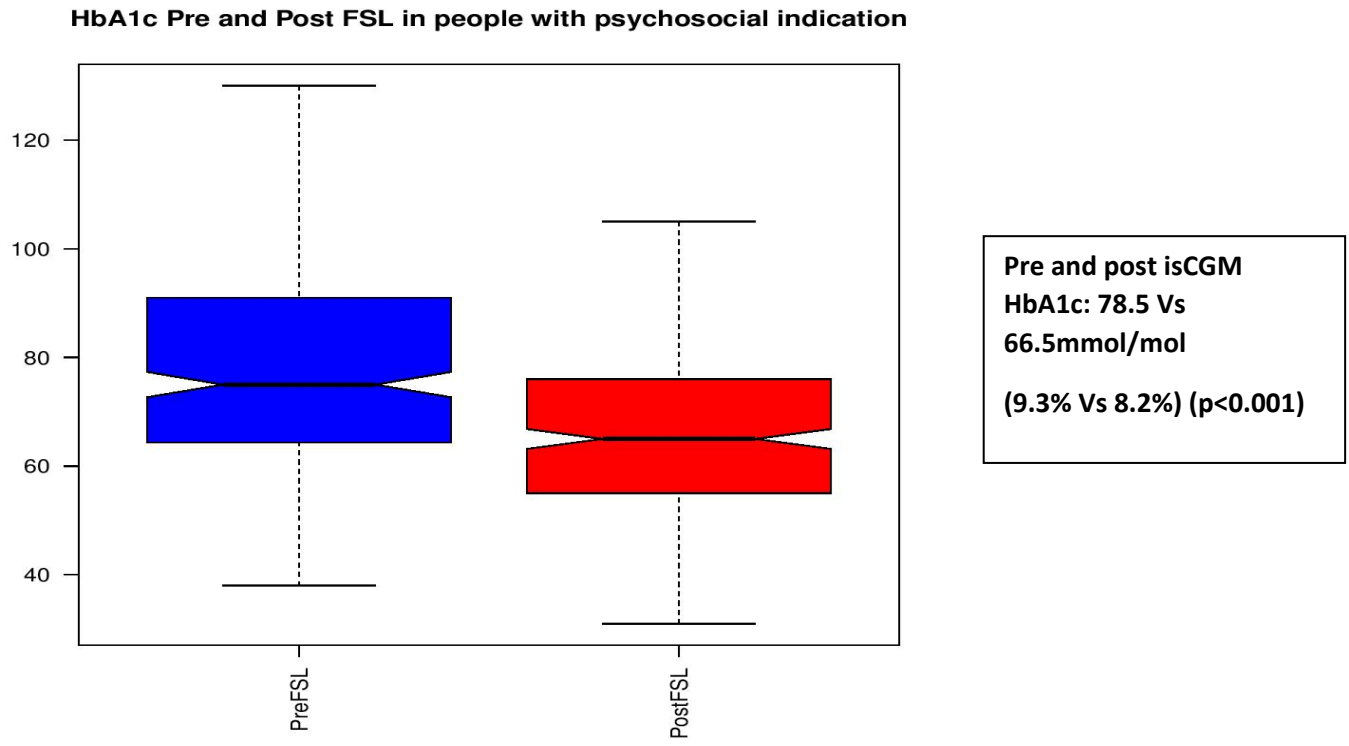

Figure 2: Distribution of HbA1c change pre- and post-isCGM use in the ABCD nationwide audit of isCGM for participants initiated on isCGM for psychosocial reasons