

Impact of Freestyle Libre 2 on diabetes distress and glycaemic control in people on twice-daily pre-mixed insulin

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In the UK, people with type 1 diabetes and those with type 2 diabetes managed with multiple daily insulin injections (MDI) meet the eligibility criteria for continuous glucose monitoring (CGM) use. Previous studies have shown that CGM results in improvements in diabetes distress and HbA_{1c} in people with type 2 diabetes on MDI; however, studies in people with type 2 diabetes on pre-mixed insulin regimens have not been published to date. This service evaluation of ten people with type 2 diabetes on twice-daily pre-mixed insulin regimens using the FreeStyle Libre 2 CGM system demonstrates improvements in both diabetes distress scores and HbA_{1c}. Although only a small study, the findings suggest that expanding CGM eligibility criteria to include this patient group may be beneficial.

Diabetes distress is an emotional response to living with diabetes and the burden of self-management, in which people experience feelings such as stress, guilt or denial (Kreider, 2017). It has been linked to worse health outcomes. Diabetes distress can fluctuate over time, and if left untreated, mild diabetes distress may develop into severe diabetes distress and/or depression. It is estimated that severe diabetes distress affects one in four people with type 1 diabetes and one in five of those with insulin-treated type 2 diabetes (Hendrieckx et al, 2019).

In 2014, the FreeStyle Libre (FSL) intermittently scanned continuous glucose monitoring system became available as a potential alternative to fingerprick self-monitoring of blood glucose. The sensor utilises wired enzyme technology to continuously measure interstitial glucose levels (see [How to initiate and support continuous glucose monitoring](#)). A reader or smartphone app can be used to scan the sensor and provides information on current and previous glucose levels and trends. The FSL has been updated by a new version, FreeStyle Libre 2 (FSL2) which, in addition to the above, has optional alarms to alert users when glucose levels fall outside their target range. More recently,

following an update to the FSL app, the FSL2 sensor can send a glucose reading to the user's phone every minute, effectively making it a real-time continuous glucose monitor.

In the UK, the use of FSL is not limited to people with type 1 diabetes; certain cohorts of people with type 2 diabetes also qualify for prescription of the FSL2 system. However, the eligibility criteria are open to interpretation. In Scotland, FSL2 is recommended in individuals with diabetes who are actively engaged in the management of their diabetes and who intensively manage their condition with multiple daily insulin injections or insulin pump therapy (Scottish Health Technologies Group, 2018).

Several studies have shown a statistically significant reduction in diabetes distress when using FSL compared with conventional fingerprick self-monitoring of blood glucose in people with type 2 diabetes who are on a basal-bolus insulin regimen (Haak et al, 2017; Ogawa et al, 2021). Furthermore, HbA_{1c} has also been shown to significantly reduce within the first 6 months of using FSL in people with type 2 diabetes who were previously on multiple daily injections of insulin, with consequent improvements in treatment satisfaction and reductions in diabetes-related complications

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Article points

1. There are limited studies on the use of continuous glucose monitoring (CGM) in people with type 2 diabetes on twice-daily pre-mixed insulin regimens.
2. In this small service evaluation, CGM use was associated with reductions in PAID (Problem Areas In Diabetes) scores of diabetes distress and in HbA_{1c}.
3. Local and national guidelines may need to be amended to include twice-daily pre-mixed insulin in the eligibility criteria for CGM use in people with type 2 diabetes.

Key words

- Continuous glucose monitoring
- Insulin
- Pre-mixed insulin
- Type 2 diabetes

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(Yaron et al, 2019; Eeg-Olofsson et al, 2023). Reducing diabetes distress can lead to an improvement in overall glycaemic control (Elotla et al, 2023).

Twice-daily pre-mixed insulin is an alternative insulin regimen used to treat type 2 diabetes for those who prefer a simpler regimen to basal–bolus insulin. The present service evaluation looks at the impact of using FSL2 on diabetes distress and HbA_{1c} in people with type 2 diabetes who were on a twice-daily pre-mixed insulin regimen attending a pharmacist-led diabetes clinic in Scotland.

Methods

Ethical approval

As this was a service evaluation and not a research programme, ethical approval was not needed.

Data collection

People with type 2 diabetes on a twice-daily pre-mixed insulin regimen who had recently (within 3–6 months) started using FSL2 were included in this audit. The participants were identified from two GP practices by running a search on the EMIS electronic patient record system. Altogether, ten participants were identified.

Diabetes distress was calculated using the Problem Areas In Diabetes (PAID) scale, a widely used and validated tool to measure diabetes distress (de Wit et al, 2022). The tool comprises 20 questions pertaining to problem areas, such as not having clear goals for the management of diabetes and worrying about the complications of diabetes.

Before sending out the PAID questionnaire to participants, consent was obtained via a telephone call. Following consent, the PAID questionnaires were posted along with clear instructions on how to complete; the participants completed the same questionnaire twice: once to detail how they felt about their diabetes before they started using FSL2, and the second to detail how they felt about their diabetes since they started using FSL2. A stamped addressed envelope was also included to allow ease in returning the completed questionnaire.

Participants indicated which of the 20 PAID items was currently a problem for them, with scores ranging from 0 (not a problem) to 4 (a serious problem). The score of each item

Table 1. Participant characteristics (N=10).

Age (mean)	73.2 years
Gender (n; %)	
Male	8 (80%)
Female	2 (20%)
Ethnicity (n; %)	
Caucasian	7 (70%)
South Asian	3 (30%)
Duration of diabetes (median)	19.3 years
Diabetes-related comorbidities (n; %)	
Cardiovascular disease	5 (50%)
Chronic kidney disease	7 (70%)
Microalbuminuria	7 (70%)
Background diabetic retinopathy	5 (50%)
Glucose-lowering drugs (n; %)	
Metformin	5 (50%)
Gliclazide	1 (10%)
GLP-1 RA	4 (40%)
DPP-4 inhibitor	1 (10%)
SGLT2 inhibitor	4 (40%)
Pre-mixed insulin	10 (100%)
Bolus insulin	1 (10%)

was summed and then multiplied by 1.25, to generate a total score out of 100. Any total score of 40 or above was deemed to be severe diabetes distress, while any score of 3 or 4 on individual items were deemed to be moderate to severe diabetes distress.

Results

Table 1 shows the clinical characteristics of the study population, which consisted of ten participants with type 2 diabetes. The median age of the study population was 73.2 years and 80% were male. The median duration of diabetes was 19.3 years.

Table 2 (overleaf) compares PAID scores and HbA_{1c} before and after commencing the FSL2. The mean PAID score decreased from 44.4 to 24.0 (a 46.4% reduction) after initiating FSL2. The prevalence of severe diabetes distress reduced from 50% to 20%, while the rate of moderate to severe diabetes distress reduced by a relative 55%. Average HbA_{1c} also reduced by 18 mmol/mol (1.7%).

Visually, no relationship between HbA_{1c} and level of diabetes distress was apparent (Figure 1).

Discussion

This service evaluation looked at the impact of using FSL2 on diabetes distress and HbA_{1c} in people with type 2 diabetes who were on a twice-daily pre-mixed insulin regimen and attending a pharmacist-led diabetes clinic.

The results show that, after 3–6 months of using FSL2, reductions were seen in both diabetes distress and HbA_{1c}. The mean diabetes distress score reduced by 46.4%, and a reduction in moderate to severe diabetes distress was seen. Average HbA_{1c} also fell.

There was no apparent relationship between HbA_{1c} and levels of diabetes distress, suggesting that optimal HbA_{1c} is not necessarily an indicator of low diabetes distress. This finding is comparable with other published studies (Gonzalez et al, 2016; Fayed et al, 2022).

To the author's knowledge, this is the first research to explore the effect of using FSL2 on diabetes distress and HbA_{1c} in people with type 2 diabetes who are on twice-daily pre-mixed insulin. However, due to the small cohort of ten participants, the study lacked power for statistical analysis. Furthermore, as PAID scores before using the FSL2 were based on the participants' recall, this may have introduced biases such as recall and confirmation bias. Finally, as the dataset was small and limited to two GP practices, the results may not be generalisable to the wider UK population.

Although other studies have not compared the effect of diabetes distress and HbA_{1c} in people with type 2 diabetes who are on twice-daily pre-mixed insulin who are using FSL2, the findings of this service evaluation are comparable with studies conducted in people with type 2 diabetes using multiple daily injections of insulin.

The results suggest that people with type 2 diabetes on twice-daily pre-mixed insulin regimens will benefit greatly from using FSL2, as a result of improved quality of life and, given the observed reductions in HbA_{1c}, diabetes outcomes.

Further research needs to be performed in this group of people, as currently the criteria for use of FSL2 are limited to those with type 1 diabetes and those with type 2 diabetes who are

Table 2. PAID questionnaire scores and HbA_{1c} observed before and after commencing FSL2.

Measurement	Pre-FSL2	Post-FSL2
Mean PAID score	44.4	24.0
Number (%) of participants with total PAID score ≥40	5 (50%)	2 (20%)
Mean number of PAID items with a score of 3–4	5.8	2.6
Mean HbA _{1c} (mmol/mol)	91.5	73.2

FSL2=FreeStyle Libre 2; PAID=Problem Areas In Diabetes scale.

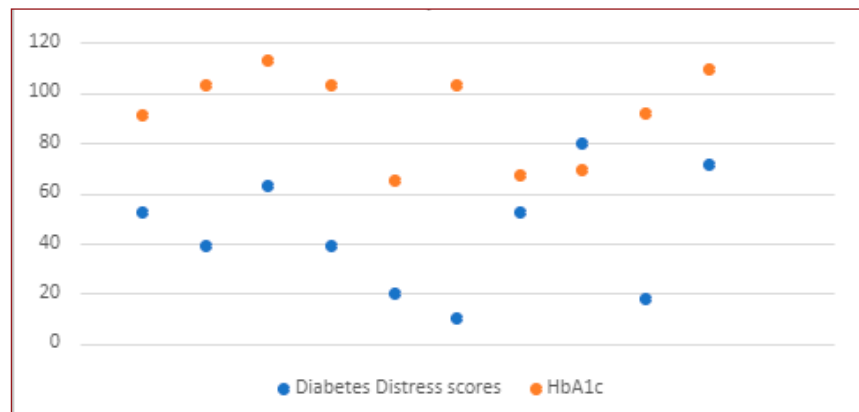


Figure 1. HbA_{1c} and diabetes distress scores prior to starting FreeStyle Libre 2.

on multiple daily insulin injections. Local and national guidelines may need to be amended to include the use of FSL2 in people with type 2 diabetes on twice-daily pre-mixed insulin. ■

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