

The FreeStyle Libre flash glucose monitoring system: How it has improved glycaemic control for people with type 1 diabetes in Eastern Cheshire, UK

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Many people with type 1 diabetes continue to run high HbA_{1c} levels. In this article, the authors describe how use of the FreeStyle Libre flash glucose monitoring system has influenced type 1 diabetes management in their area. In 92 users, HbA_{1c} decreased by an average of 10.7 mmol/mol (0.98%) after 3 months, and by 16.1 mmol/mol (1.47%) after 6 months. There was also a narrowing of the distribution of HbA_{1c}, with fewer people running an HbA_{1c} \geq 80 mmol/mol (9.5%). The Libre system is being used by increasing numbers of people with type 1 diabetes and is highly popular.

The achievement of better glycaemic control remains a challenge for people with type 1 diabetes and their healthcare professionals. Continuous glucose monitoring (CGM) devices display an estimate of blood glucose levels, along with trends in direction, in real time, and in the eyes of many they are proving to be a step change in diabetes management. Use of CGM is associated with a reduction in HbA_{1c} (Pickup et al, 2011).

Flash glucose monitoring, in contrast to CGM, does not provide real-time data with alerts and alarms (Kalra and Gupta, 2015), but allows users retrospectively to review the preceding 8 hours of continuous glucose data, along with a contemporary estimated blood glucose value and trend line. The glucose data are made available when the user chooses to swipe the reader over the sensor which, in the case of the FreeStyle Libre monitor, remains in place for up to 14 days.

Despite major advances in the pharmacological management of type 1 diabetes in recent years (Iqbal et al, 2018) and increasing access to expert patient programmes, many people with type 1

diabetes have continued to run high HbA_{1c} levels (Anderson et al, 2012; Heald et al, 2018).

In the area of Eastern Cheshire, UK, the diabetes specialist nurse (DSN) team has been an early adopter of flash glucose monitoring. In this article, we describe how use of the FreeStyle Libre flash monitor has improved the glycaemic control of many people with type 1 diabetes where the new technology has been intensively deployed.

Background

The DSN team in Eastern Cheshire work across a mixed urban and rural catchment area south of the conurbation of Greater Manchester. They provide an outreach service to GP practices across the area, as well as clinics at a central location. There are at least 1000 people known to have type 1 diabetes in Eastern Cheshire, of whom the majority are managed in primary care. The specialist service sees people with type 1 diabetes in an episodic care model in which, once glycaemia has been stabilised, the person with diabetes is again looked after in primary care.

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Article points

1. This study presents the outcomes of 92 consecutive adults with type 1 diabetes who have used the FreeStyle Libre flash glucose monitoring system for 6 months.
2. Mean HbA_{1c} fell from 83.0 mmol/mol at baseline to 72.3 mmol/mol at 3 months and 66.9 mmol/mol at 6 months.
3. In addition, at 6 months there was a narrowing of the distribution of HbA_{1c} and a reduction in the number of people with HbA_{1c} levels of \geq 80 mmol/mol.

Key words

- Devices and technology
- Flash glucose monitoring
- FreeStyle Libre
- HbA_{1c}
- Type 1 diabetes

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Since Spring 2018, the DSN team has been offering the FreeStyle Libre flash glucose monitor for type 1 diabetes management. The device is offered according to NICE NG17 guidance (NICE, 2015). Three individuals have declined to use the device when it was offered to them. We report here the outcome of deploying this technology.

Study methods

We report the outcomes of 92 consecutive adults (18 years of age or more) with type 1 diabetes who have begun using the FreeStyle Libre monitor. Initiation took place with education and support from one of the DSNs. An HbA_{1c} of 60 mmol/mol (7.6%) was taken as the threshold for suboptimal glycaemic control.

HbA_{1c} was measured using the Menarini autoanalyser (Menarini Diagnostics UK, Wokingham, Berkshire). HbA_{1c} was recorded at baseline and 3 months after the start of monitoring in all users, and after 6 months in the majority of users. BMI was recorded at the time of initiation of monitoring.

Most changes made were in the dose rather than the type of insulin. None of the participants attended an expert patient programme during the follow-up period or had attended such a programme in the previous 12 months.

Multiple linear regression was employed to explore the predictors of HbA_{1c}. Kernel density estimation was used to compare HbA_{1c} levels achieved at baseline, 3 months and 6 months. Kernel density estimation is a fundamental data-smoothing solution in which inferences about the population are made based on a finite data sample.

Ethics statement

This was a quality improvement project. Ethics approval was not obtained for this study as the intervention was part of standard care according to NICE (2015) guidance. All individual patient data were anonymised prior to statistical analysis.

Results

The mean cohort age was 43 years for men and 39 years for women (overall range, 17–83 years); 42 (45.7%) of the participants were female. Baseline demographics are detailed in *Table 1*. One of the 92 individuals was on a mixed insulin regimen and

Table 1. Baseline characteristics by gender.

	Men (n=43)	Women (n=39)
Age (years; SD)	45.6 (16.2)	46.2 (14.2)
BMI (kg/m ² ; SD)	26.7 (5.6)	25.6 (5.7)
Duration of diabetes (years; SD)	18.3 (13.5)	22 (13.1)
Baseline HbA _{1c} (mmol/mol; SD)	83.7 (18.2)	82.5 (21.4)

SD=standard deviation.

three were on an insulin pump. The rest were on a basal–bolus regimen.

The mean pre-intervention HbA_{1c} was 83.0 mmol/mol (95% confidence interval [CI], 79.2–86.7). At 3 months after the intervention, mean HbA_{1c} fell significantly to 72.3 mmol/mol (95% CI, 68.6–76.1), a reduction of 10.7 mmol/mol (95% CI, 5.7–15.7; *P*<0.0001).

At 6 months, mean HbA_{1c} had fallen further to 66.9 mmol/mol (95% CI, 63.4–70.4; *P*<0.0001 compared with baseline). The greatest HbA_{1c} reduction at 6 months was by 87 mmol/mol.

Over the follow-up period there was not only a fall in mean HbA_{1c} but also a narrowing of the distribution of HbA_{1c} (*Figure 1*), with a lower proportion of high outliers: there were significantly fewer people with HbA_{1c} levels of ≥80 mmol/mol (seven people at 6 months compared with 24 at baseline).

Gender had no significant effect on the changes in HbA_{1c}, nor did duration of diabetes. In multiple regression modelling, increasing age was associated with a lesser fall in HbA_{1c} at 6 months (beta= −0.289; *P*=0.04) independent of BMI and gender; however, this association disappeared when HbA_{1c} at baseline was included in the model (for relation of change in HbA_{1c} vs baseline, beta=0.587; *P*<0.001).

None of the users discontinued the Libre over the 6-month follow-up period. Four users reported some mild skin irritation at the site of the monitor, but this was not sufficient to result in discontinuation. After the 6-month follow-up, two users did not wish to continue with the device as they were happy to return to their previous blood glucose monitor.

Discussion

Flash glucose monitoring is an effective tool with great potential for the management of type 1 diabetes in the adult population, and can help people to improve metabolic control and their quality of life. The technology provides significantly more data than the intermittent results obtained by traditional subcutaneous blood glucose monitoring, which may not capture intervals of extreme variability or nocturnal events and does not permit visualisation of trends.

With the help of a record of insulin dosing, meal intake, physical activity and stress factors, people with type 1 diabetes can achieve the full benefits of flash glucose monitoring and work together with healthcare professionals to act upon the information provided by the sensor. The graphs and trends available with flash monitoring allow an understanding of how different factors (e.g. physical activity and diet) impact glycaemic control, consequently motivating users to take charge of their health (Mancini et al, 2018). This approach to blood glucose monitoring has the advantage of preventing hypo- and hyperglycaemic events through the blood glucose trend system (Kalra and Gupta, 2015). However, flash monitoring is different from CGM in that it only provides

data on demand and, as such, is unable to provide alerts; the Libre has no alarm feature and so is it not suitable for individuals who have a lack of hypoglycaemia awareness.

This study has provided persuasive evidence for the effectiveness of flash glucose monitoring in improving glycaemia in people with type 1 diabetes who have a history of high blood glucose levels; in some cases, hyperglycaemia had persisted over a number of years. The mean reduction in HbA_{1c} was 16.1 mmol/mol over the 6-month follow-up. There was no significant influence of age, gender or duration of diabetes (covariates known to be associated with glycaemic outcomes) on the outcome when adjustment was made for starting HbA_{1c}.

In addition to a fall in mean HbA_{1c}, the proportion of outliers with high HbA_{1c} fell. This is likely to have positive consequences over time owing to reduced complication rates, as demonstrated in the DCCT/EDIC (Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications) study (de Boer et al, 2011).

None of the users in this study attended a structured expert patient programme during the 6-month follow-up or in the previous 12 months.

“In addition to a fall in mean HbA_{1c}, the proportion of outliers with high HbA_{1c} fell. This is likely to have positive consequences over time owing to reduced complication rates.”

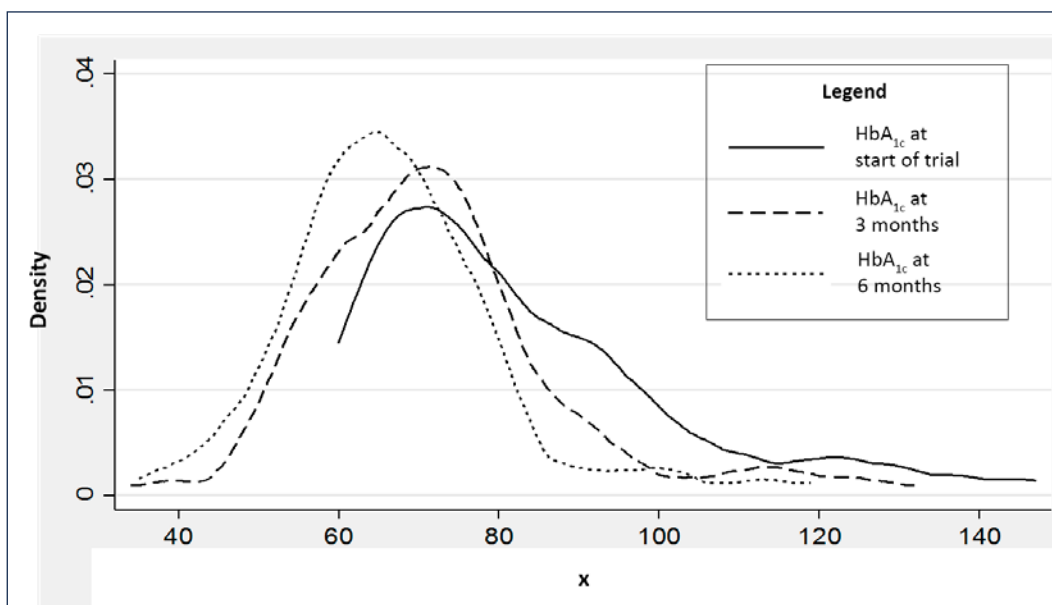


Figure 1. Kernel density plot of HbA_{1c} in FreeStyle Libre users with type 1 diabetes (n=92) at baseline and after 3 and 6 months' follow-up.

Note: The baseline data begin at 60 mmol/mol, as no one in this study had an HbA_{1c} below this as the threshold for Libre initiation.

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Therefore, the changes in glycaemia are likely to be a result of modifications in insulin dose and lifestyle made as a consequence of the information provided by the flash glucose monitor.

Side effects of itchiness and skin irritation were minimal, as reported elsewhere (Mancini et al, 2018). Although we have not reported it formally here, the feedback from users of the Libre was very positive, with little desire to move back to finger-prick monitoring as a way of measuring blood glucose through the day. Only two out of 92 people wished to discontinue the Libre after 6 months. For those individuals who drove, use of conventional capillary blood glucose monitoring continued when driving, as per DVLA guidance at the time.

Conclusion

We have shown that flash glucose monitoring is an effective tool in improving glycaemic control in people with type 1 diabetes. This has significant health-economic implications which, although not addressed here, will need to be worked through. ■

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Contribution statement

AHH, KL, LH and TS conceived the study. AHH, LH, AM and ZK collected the data. AH, GY, SGA and LK

conducted the data analysis. AHH, GY, LK, ZK, ZD, KL, AM, LH and TS all contributed to writing of the paper. TS provided an overview of the manuscript.

Data Availability

Any requests for data extracts will be considered by Dr Adrian Heald as corresponding author.

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