

Use of FreeStyle Libre Pro™ for the management of type 2 diabetes in primary care settings

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Background/Objective

- The FreeStyle Libre Pro Flash Glucose Monitoring System is a professional continuous glucose monitoring (CGM) device intended to be used by health care professionals (HCPs) to perform retrospective glucose data analysis on patients with diabetes.
- Consensus agreements^{1,2} recommend the use of Ambulatory Glucose Profile (AGP) and time in ranges, however, there is a shortage of studies on the utilisation of professional CGM in primary care.
- **This study aimed to determine whether understanding glycaemic status and management is better with the use of HbA1c with FreeStyle Libre Pro (used with LibreView software) than with HbA1c alone.**

¹Danne T, Nimri R, Battelino T, Bergenstal RM, Close KL, DeVries JH, et al. International consensus on use of continuous glucose monitoring. Diabetes Care. Dec 2017; 40(12): 1631-1640

²Battelino T, Danne T, Bergenstal RM, Amiel SA, Beck R, Biester T et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. Aug 2019;42(8):1593-1603

Methods and Materials

- This prospective 2-week single arm study was conducted across 7 primary and 2 secondary care sites in the United Kingdom (study flow was carried out as seen in **Figure 1**).

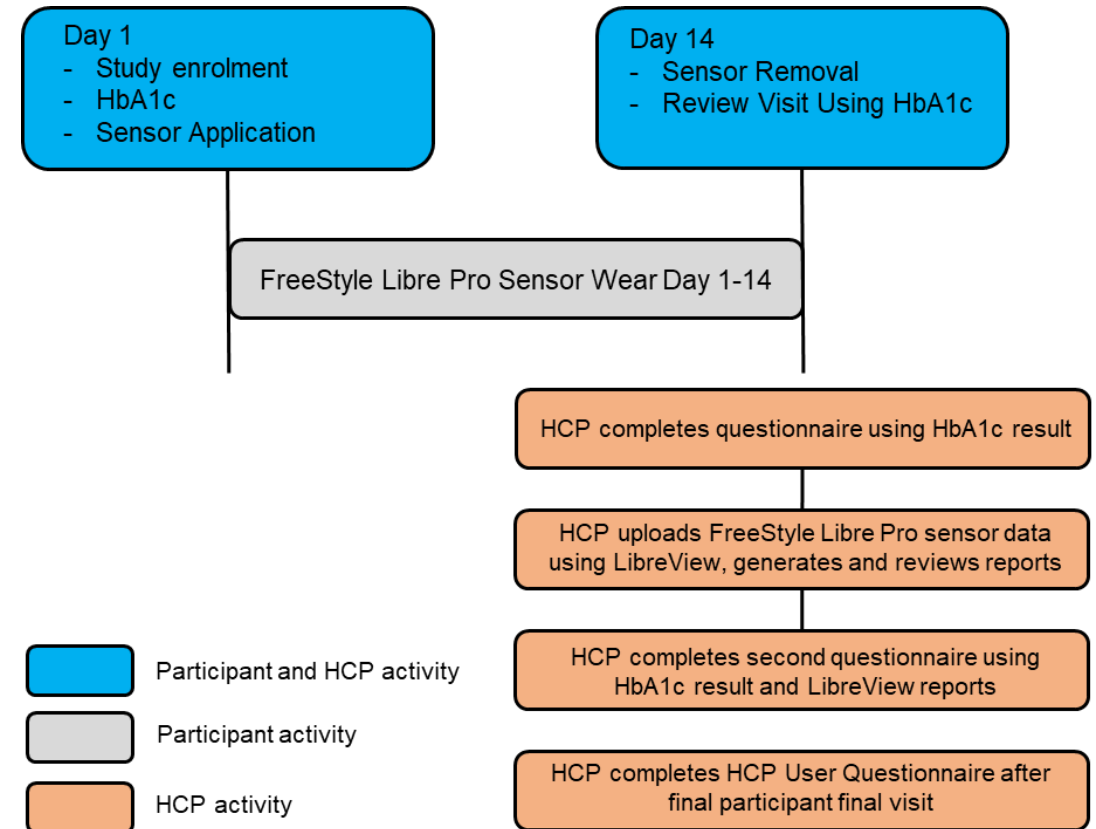
- **Key inclusion criteria**

- Aged 18 years or over
- Has type 2 diabetes, on oral glucose lowering medication or oral glucose lowering medication and premixed insulin

- **Key exclusion criteria**

- Currently prescribed basal or bolus insulin
- Currently prescribed glucagon-like peptide (GLP-1) without premixed insulin
- Concomitant disease or condition that would compromise patient safety
- Undergoing dialysis
- Pregnancy

Figure 1: Study Visit Flow Diagram



Demographics

- A total of 44 participants with type 2 diabetes consented and enrolled, no participants withdrew during the study. All participants were taking oral glycaemic agents (OGA) either alone or with premixed insulin. Only 38.6% performed routine BG testing. Participant demographics are seen in **Table 1**.
- HCPs included general practitioners (GPs) (n=9), endocrinologists (n=1) and diabetes nurses (n=1). Professional experience ranged from 4 to 26 years. All but 3 HCPs had previous CGM experience. Each HCP assessed 4 patients.

Table 1: Participant demographics (*Mean±SD. [Min, Max], †total number of non missing values)

Sex n=44		Age n=44	BMI n=43 [†]	Baseline HbA1c n=44		Time Since Diagnosis n=44	Glycaemic Therapies n=44	
Male	Female	(years)	(kg/m ²)	(%)	(mmol/mol)	(years)	Premixed Insulin	OGA only
28 (63.6%)	16 (36.4%)	62.3 ± 9.8* [32, 83]	31.7 ± 5.8* [20.1, 48.7]	7.7 ± 1.6* [5.6, 13.2]	60.2 ± 17.8* [38, 121]	8.2 ± 6.3 [0, 28]	6 (13.6%)	38 (86.4%)

Primary Endpoint: Glycaemic status

- Using HbA1c alone, HCPs identified 23 (52%) individuals who had adequate diabetes control.
- This was modified to 19 (43%) when using LibreView glucose reports.
- Feedback from HCPs showed the benefits of LibreView glucose reports (**Table 2**).

Table 2: HCPs feedback after using HbA1c combined with LibreView glucose reports to review their patient’s glucose control

HCP assessment of the difference between using HbA1c + LibreView versus HbA1c alone	
LibreView enabled a more detailed review	36 (81.8%)
LibreView made it easier to identify glucose issues/patterns	35 (79.5%)
LibreView made more data available to review	42 (95.5%)

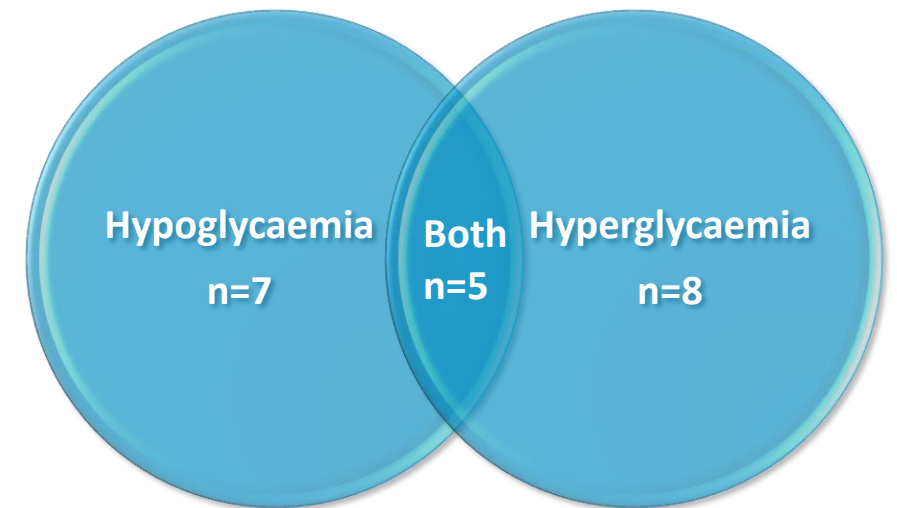
Secondary Endpoints: Glycaemic status

- Use of LibreView glucose reports allowed HCPs to identify those patients who had previously unknown hyperglycaemia (n=13, 30%) or hypoglycaemia (n=12, 27%). Five patients had previously unidentified hypo and hyperglycaemia (**Figure 2**).
- All HCPs saw value in using the LibreView glucose reports in combination with HbA1c data to support patient understanding.

Safety Endpoints

Five anticipated sensor insertion site symptoms were experienced by three participants (6.8%). All symptoms were mild and were resolved without intervention. There were no serious adverse events reported during the study.

Figure 2: Previously unknown hyper/hypoglycaemia identified through LibreView



Conclusion

- This study, conducted in primary and secondary care settings with patients with T2D who are mainly on non-insulin based therapies, showed that the use of FreeStyle Libre Pro (used with LibreView software) offered more data for HCPs to further assess whether the patient has adequate glucose control.
- The device and software also helped identify those with previously unknown glucose abnormalities, and therefore has the potential to support improving the patient's understanding of glycaemia and how their lifestyle may impact this.
- Future work is warranted to investigate the role of this glucose monitoring strategy in optimising glycaemic control in individuals with T2D including those managed on less intensive therapies such as oral glycaemic agents.

Acknowledgements

We would like to thank the staff at the study sites for their valuable contribution to the study.



Atherstone Surgery



TROWBRIDGE HEALTH CENTRE



ShIPLEY Medical Practice

Kiltearn Medical Centre

