

Diabetes and Real-World Investigation of Glucose Instability, Variability and Exposure in Haemodialysis Patients (DRIVE-HD) – A Technology Validation.

Dr Katey Flowers¹, Dr Adam Kirk¹, Dr Louise Turner², Mark Lyons-Amos², Dr Iain Cranston³

¹Wessex Kidney Centre, Portsmouth, United Kingdom, ²University of Portsmouth, Portsmouth, United Kingdom,

³Academic Centre for Diabetes and Endocrinology, Queen Alexandra Hospital, Portsmouth, United Kingdom

The assessment of glucose levels in patients with diabetes and who are receiving renal replacement therapy is challenging. Risks relating to both high and low blood sugars are greater in this group than in other patients with diabetes. Traditional long-term control measures such as HbA1c are commonly invalidated by the rheological circumstances of individuals in this group, and traditional finger-stick monitoring is often problematic.

Interstitial fluid (ISF) continuous glucose monitoring devices have become commonplace in the management of patients with type 1 diabetes, but their utility and accuracy in individuals on renal replacement therapy remains to be formally validated, as theoretically the relationship between ISF glucose and blood glucose levels may be impacted by the dialysis. In order to undertake “real world” validation of this technology in this population group, as part of a wider program at Portsmouth Hospitals NHS Trust, we performed blinded interstitial glucose monitoring (FreeStyle Libre Pro – Abbott Diabetes Care) over 14 days in 69 individuals using insulin (11 type 1 diabetes and 58 type 2 / other diabetes) to treat their diabetes who were receiving in-centre haemodialysis. Results of ISF data were compared to those of time-linked fingerstick results undertaken by the individual over the same period, and blood glucose records from dialysis units. ISF sensors were applied to the upper (non-fistula) arm at an attendance for dialysis, and the usual BG meter of the individual checked for date / time consistency. After 14 days the sensors were removed and the SMBG meter of the individual was downloaded (Glooko-Diasend) where possible in order that capillary Glucose (CBG) values could be compared with their interstitially reported counterpart.

After validating CBG data for technique (2 individuals excluded), we compared CBG with its closest-timed ISF equivalent (within 7mins), excluding pairs in hypoglycaemia range (<4mmol/L) with a time difference of >2 mins or where an action to treat hypoglycaemia based on the CBG result was recorded. Results from 706 paired samples were compared using the Clarke Error Grid (figure 1), with 97.9% of results falling in the clinically acceptable A&B ranges.

To further investigate the impact of dialysis on the ISF validity, we compared the pairs from dialysis days (97.3% falling in A&B) with non-dialysis days (99.1% in A+B) confirming that whilst ISF values are slightly less concordant with CBG values on dialysis, they remain a clinically appropriate monitoring technique.

Conclusion

From this observational cross-sectional population study of individuals on haemodialysis treated with insulin for their diabetes we conclude that the accuracy of the ISF monitoring device FreeStyle Libre does not appear to be altered by the circumstances around haemodialysis and that such devices can be applied at any point during the dialysis period without significantly affecting the accuracy.