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Free Style Libre Pro (FSLP) Flash Glucose Monitor (FGM) – A Novel Monitoring Tool for Children with Type 1 Diabetes Mellitus

Flash glucose monitoring using Free Style Libre Pro (FSLP) was undertaken among fifteen diabetic children. Data revealed high glycaemic variability, Time in Target Range (TIR) to be 27% and 12% of time in hypoglycaemia. Sensor insertion and retention were problematic in 33%. Though user friendly, sensors may need an additional adhesive plaster for retention.

Keywords: *Diagnosis, Glycosylated hemoglobin, Hypoglycemia*.

Flash glucose monitoring system (FGM), a method of glucose testing, is seen as hybrid between glucometers and continuous glucose monitoring systems (CGMS) [1]. Consensus recommendations for use of ambulatory glucose profile (AGP) in clinical practice have been proposed [2]. The utility of FGM in children with poor glycemic control and practical issues associated with FGM were analyzed in this study.

This observational study was done at the diabetic clinic of Institute of Child Health and Hospital for Children from October 2015 to June 2016. With ethical clearance and informed parental consent, fifteen children aged 10-15 years with type 1 diabetes mellitus of more than 2 years duration and with glycated hemoglobin (HbA1c) >10% were included. Free Style Libre Pro (FSLP) FGM equipment was used. The sensor was fitted in the posterior aspect of left arm and data was captured at the end of 2 weeks. Finger prick blood glucose was performed four times a day (thrice pre-meal and at 2 am). Sensor insertion, glycemic variability, time in target range (TIR) and hypoglycaemia and blood HbA1c were the study parameters.

Of the 15 sensors inserted, one got displaced on day 1 and one got stuck to the applicator. Insertion was successful in 13 (87%) children. Sensor was secured with additional plaster in all children, yet 3 (20%) got displaced. Complete data were available in 10 (67%) children at the end of 2 weeks.

Mean (SD) age of children was 11.8 (1.14) years. The median (IQR) of diabetes duration was 3 (2.75-5.75) years. The mean (SD) of HbA1c was 11.14 (1.54%) and insulin requirement was 1.4 (0.38) units/kg/day. The mean (SD) coefficient of variation as a measure of glycemic variability was 46.29 (10). The mean (SD) inter quartile range of glucose values was 161.3 (48.3) mg/dL. Average TIR was 27% while nearly 12% of time was spent in hypoglycemia. A good correlation between HbA1c measured in blood and that predicted by FGM was observed (correlation coefficient (r) = 0.81) as shown in ***Fig.* 1**.

The study group showed high glycemic variability as evidenced by high coefficient of variation and interquartile range [3]. Mean TIR was 27% which was similar to a previous study [4]. The goal of 70% of glucose values in target range which is termed as optimal glycemic control is difficult to achieve even in those with lower HbA1c as seen in that study. In addition, on an average 12% of time was spent in hypoglycemia which is much higher than the desirable level of 5% [5]. Most of the hypoglycemia were nocturnal and asymptomatic. FGM is useful in picking up asymptomatic nocturnal hypoglycemia.

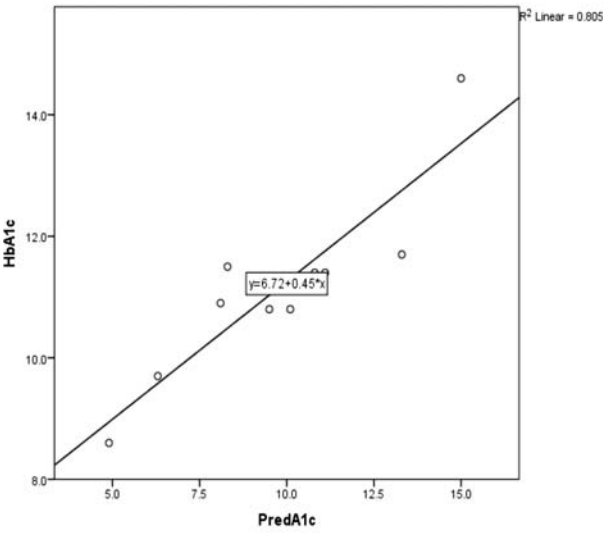

FIG. 1 *Correlation between HbA1c measured in blood (HbA1c) with predicted HbA1c (PredA1c) by flash glucose monitor.*

The FSLP FGM sensor is small, light, painless to insert and does not need recalibration [6]. Sensor insertion and retention problems are common. Data on glycaemic variability, TIR, and asymptomatic hypoglycaemia are useful for day to day management of children with type I DM. Evidence shows that low cost, accurate data, and data on demand are advantages of FGM, with lower mean absolute difference throughout 14 days [7,8]. Diabetes management in children involves glycemic variability, time in target range and other metrics, beyond HbA1c, blood glucose and hypoglycaemia for a better control [9].

Contributors: SAN, PV, SS: conceptualized and designed the study; SAN, RC: reviewed the literature; SAN, RVD, RC: data acquisition: SAN: data analysis and manuscript preparation. All authors were involved in revising it critically for intellectual content and reviewing the manuscript version submitted.
Funding: The sensors and reader used in this study, HbA1c measurements and glucometer strips for self-Monitoring of blood glucose were funded by PUNCH (Pediatricians United for Child Health) CHARITY, India.
Competing interests: None stated.

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