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Novel Ambulatory Glucose-Sensing Technology Improves Glucose Profile, Patient Adherence and Detects Hypoglycemia Frequency and Duration in Children and Adolescents with type 1 diabetes

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Background

Glucose monitoring (GM) is a mainstay of diabetes control and management. Improving glycemic control is essential to prevent microvascular complications. However, adherence to GM can be a challenge in children and adolescents. Detecting hypoglycemia is essential for its prevention and treatment. The flash glucose monitoring device when scanned, produces a glucose result along with historic results with a 15-min frequency for up to 8 h. Its use resulted in reduction of the frequency of hypoglycemia in well controlled adults with type 1 diabetes (1). In another study on adults with tight diabetes control, use of Flash monitoring device was shown reduce hypoglcymia frequency and time spent in hypoglycemia (2).

Hypothesis

Due to the ease of use of the flash monitoring device and lack of the need of calibration, we hypothesize that patients' adherence to GM will be improved. In addition, we expect that the glucose profile will show improvement during the use of the device as patients will be more aware of their glucose profile and will more readily adjust their insulin dosages. Finally, as it can be a CGM tool, we expect to capture undetected hypoglycemia and assess its duration

Aim

We aim to study the impact of the flash ambulatory glucose monitoring in improving diabetes control, enhancing adherence and detecting hypoglycemia in children and adolescents with type 1 diabetes.

Methods

The study is prospective involving 3 hospital visits. Children and adolescents with diabetes were enrolled in the study which involved a period on conventional glucose self-monitoring followed by a similar period of monitoring using the flash glucose monitoring device (FreeStyle Libre). Average fasting and daily glucose, frequency of GM, frequency and duration of hypoglycemia were compared on conventional and the flash monitoring.

Visit 1

Consent is obtained from those who agreed to participate.
Patients are explained the aim and methods of the study
Demographic information including age, duration of diabetes, method of insulin delivery are recorded
Capillary HbA1c is recorded

Visit 2

Glucometers were downloaded and data of up to 6 weeks prior to the visit is stored.
Average daily glucose, fasting glucose, frequency of hypoglycemia detected and daily number of glucose checking are retrieved
Patients are trained on the use of the Flash monitoring device and had the first sensor inserted by one of a team of diabetes educators.

Visit 3

Patients are seen 2-4 weeks after the first visit. During this period, they would have worn 1-2 sensors.
Data is downloaded from the device reader and saved in the study records.
Average daily glucose, fasting glucose, number of daily scans by patients, number of diurnal and nocturnal hypoglycemia and average duration of hypoglycemia episode were retrieved from the downloaded data and saved.

Statistical methods

Non-parametric tests (Wilcoxon signed rank test for paired observations) were used to examine the difference between the parameters. P values below 0.05 were considered significant. Box plots were used to display distributions. Medians and Inter Quartile Ranges (IQR) were used as measures of location and dispersion. However, for the mean duration of hypoclycemia the mean and 95% CI was used for these measures.

Results

75 subjects were studied. Age mean (range) was 11.9 years (2-19). Mean (range) HbA1c was 8.2g% (5.9-10.2). 15 were on insulin pump therapy and 60 on multiple daily injection of insulin.
Significant difference was found between the median average of day glucose by glucometers compared with flash monitoring (P = 0.028).
Out of 44,688 hours monitored by Flash monitoring for all the study group. 1,185.6 hours were spent in hypoglycemia (2.7%).
68 (94%) and 65 (90%) patients had detected nocturnal and diurnal hypoglycemia respectively on Flash monitoring compared to 12 (16.6%) and 30 (41%) on glucometer testing (P< 0.00).
Mean (range) duration of hypoglycemia was 95 minutes (15-330).
Statistically-significant difference is found between the frequency of GM on Flash monitoring compared with glucometer testing (P < 0.001).

Table

Parameter	Glucometer Median (IQR)	Flash monitoring device Median (IQR)	P value
Day glucose average	218 (183-250)	206 (179-236)	0.028
Fasting glucose average	171 (141-200)	168 (132-200)	0.194
Number of patients detected diurnal hypoglycemia	30 (41%)	65 (90%)	
Number of patients detected nocturnal hypoglycemia	12 (16.6%)	68 (94%)	
Average frequency of monitoring/day	2.87 (1-6)	11.6 (3-44)	

Conclusion

Flash monitoring is a useful tool to improve glucose profile, adherence to GM and detecting hypoglycemia (diurnal and nocturnal) in children and adolescents with type 1 diabetes.

References

1) Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycemia in type 1 diabetes: a multicenter, non-masked, randomised controlled trial. The Lancet 2016; 388(10057):2254-2263.
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