

EVALUATION OF FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES

I. Gys, A. Op 't Eyndt, E. Bevilacqua, A. Wijnands, P. Declercq*, R. Zeevaert, G. Massa

Department of Paediatric Endocrinology and Diabetology, and *Clinical Laboratory, Jessa Ziekenhuis,
B 3500 Hasselt, Belgium

Disclosure statement: No conflicts of interest Contact : diabetes.kind@jessazh.be

INTRODUCTION & OBJECTIVES

The FreeStyle® Libre Flash Glucose Monitoring System (FSLFGMS, Abbott) measures glucose concentrations in the interstitial fluid for up to 14 days (1). It has been approved for use in children aged > 4 yrs in January 2016 and since August 1, 2016 it is reimbursed by the government in Belgium. Experience in children, however, is limited (2).



In the present study we evaluated the accuracy and usability of the FSLFGMS in children with type 1 DM and took note of local skin reactions.

PATIENTS & METHODS

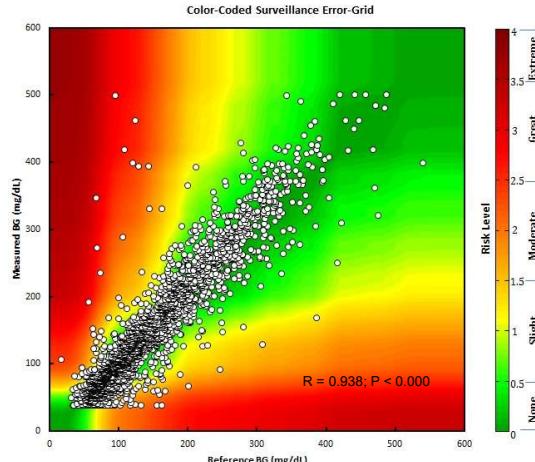
56 children with type 1 DM (36 girls), aged 4.7–17.5 yrs were included. Subjects wore a sensor on the back of their upper arm. For the first 14 days they regularly measured capillary blood glucose (BG) with their usual BG meter (Accu-Chek® Mobile (ACM), Roche (n=21), Contour® Next Link (CNL), Bayer (n=20); OneTouch® Verio® IQ (OTV), LifeScan (n=14)) followed by a sensor glucose scanning.

FSLFGMS readings were compared to BG measurements by surveillance error grid analysis (3). The mean absolute relative difference (MARD) was calculated. After 14 days subjects or their caregivers were asked to fill in a questionnaire on the usability of the FSLFGMS.

RESULTS

Result 1. Comparison by surveillance error-grid analysis of 2308 FSLFGMS readings paired with BG results

Degree of risk	Color	Hypo. %	Hyper. %	Total %
None	D. Green	44,02	26,00	72,14
Slight, lower	L. Green	12,35	7,41	19,76
Slight, higher	Yellow	2,47	3,12	5,59
Moderate, lower	L. Orange	0,48	1,17	1,65
Moderate, higher	D. Orange	0,39	0,22	0,61
Great, lower	L. Red	0,22	0,00	0,22
Great, higher	D. Red	0,04	0,00	0,04



Result 2. MARD analysis

	All (n=2287)	ACM (n=932)	CNL (n=685)	OTV (n=670)
Blood glucose (mg/dl)	155 (83)	154 (84)	148 (83)	163 (80)
Scan glucose (mg/dl)	162 (94)**	167 (97)**	162 (99)**	156 (84)**
MARD (%)	16.7 (14.6)	17.4 (15.3)	17.2 (13.9)	15.3 (14.4)*

* P < 0.02 OTV vs ACM & CNL; ** P < 0.001 blood glucose vs scan glucose

CONCLUSIONS

- Results show a fairly good agreement between the FSLFGMS readings and capillary BG measurements.
- Compared to ACM and CNL FSLFGMS overestimated BG creating a higher risk for hypoglycemia.
- As the MARD is relatively high we recommend not to take therapeutic decisions based on FSLFGMS readings.
- As many patients reported early detachment of the sensor special attention has to be paid to the wearing of the sensor.

Further studies are imperative in order to optimize the use of the FSLFGMS in the pediatric population.

REFERENCES

- Bailey T. The performance and usability of a factory-calibrated flash glucose monitoring system. Diabetes Technol Therap 2015;17:787-94.
- Campbell F et al. Clinical accuracy evaluation of Freestyle Libre Flash glucose monitoring system when used by children and young people with diabetes. 9th International ATTD Conference, Milan, 2016, Abstract 075.
- Klonoff DC et al. The surveillance error grid. J Diabetes Sc Technol 2014;8:658-72.

ACKNOWLEDGEMENT

The authors wish to thank Ch. Wakeman, dr. DC Klonoff and profs. Kovatchev and Breton for making available the the SEG analysis software program.

