LETTER TO THE EDITOR

FreeStyle Libre flash glucose monitoring system in pregnant woman with type 1 diabetes: a focus on accuracy

Milo Gatti[1] · Anna Maria Letizia Amato[2] · Daniela Bruttomesso[2]

Dear Editor,

The accuracy of FreeStyle Libre in pregnant women with T1DM is not well known. Here, we present our experience in a pregnant patient with type 1 diabetes (T1DM) [1] followed from the second trimester (13 + 5 weeks) to delivery (38 + 1 weeks), when she gave birth to a vital female child weighing 3410 g. 12 sensors belonging to six different lots were used. HbA1c was 6.2%, 5.8%, 4.3% and 4.8%, respectively, before the pregnancy, at 7-, 26- and 35-week gestation. Mean weekly insulin administration is reported in Fig. 1a. Accuracy was assessed by Consensus Error Grid (ConEG) analysis. Pearson correlation coefficient between capillary and interstitial glucose values was computed. Furthermore, the mean absolute relative difference (MARD = |capillary glucose − interstitial glucose|/ capillary glucose × 100) was calculated. Finally, we compared values achieved during the second trimester with those of the third and glucose levels 1 h after meals with remaining daily measurements. Percent coefficient of glucose variation ($\%CV = \left[(\text{SD of glucose})/(\text{mean glucose})\right] \times 100$) was also computed.

1995 paired capillary and sensor glucose measurements were performed in 169 days (mean 11.8 tests/day). The Pearson correlation coefficient between capillary and interstitial glucose values was 0.89 (95%CI 0.88–0.90;

✉ Daniela Bruttomesso
daniela.bruttomesso@unipd.it

1   Postgraduate School of Clinical Pharmacology and Toxicology, University of Milan, Milan, Italy

2   Division of Metabolic Diseases, Department of Medicine, University of Padova, Via Giustiniani 2, 35128 Padua, Italy
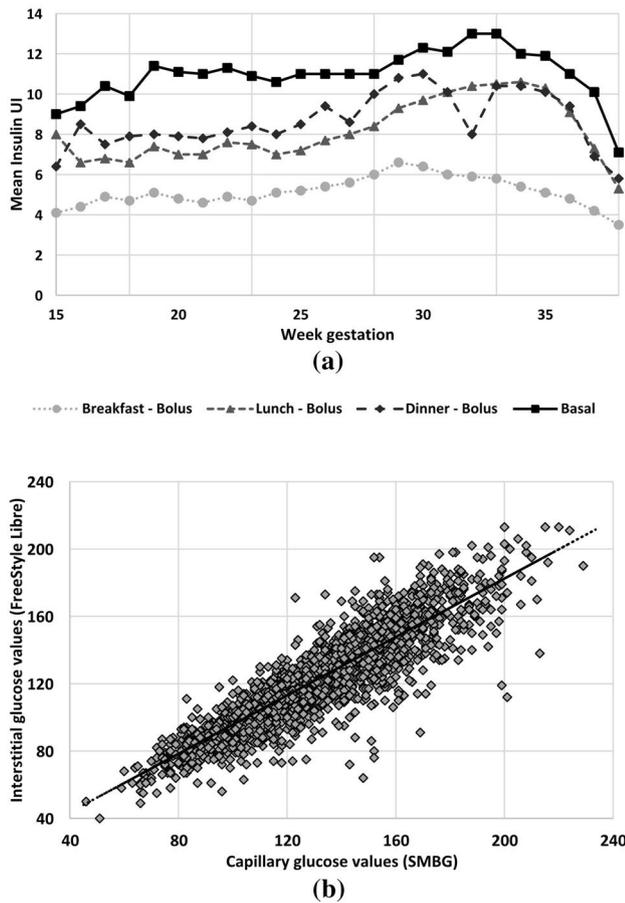
$p < 0.00001$—Fig. 1b). ConEG analysis found 91.7% of results in zone A and 99.8% in zones A and B (Table 1). The MARD was 8.55% ± 7.73%. 1878 (94.1%) of paired results ranged from 70 to 180 mg/dL, 96 (4.8%) were > 180 mg/ dL and only 21 (1.1%) were < 70 mg/dL. ConEG analysis showed 91.9%, 86.5% and 100% of results in zone A, respectively, for euglycemic, hyperglycemic and hypoglycemic values. 1014 paired measurements were performed in the second trimester (11.5 tests/day) and 981 in the third trimester (12.1 tests/day). During the third trimester, we found better accuracy than during the second according to both MARD (7.85% ± 7.05% vs 9.22 ± 8.28%; $p = 0.0001$) and ConEG analysis (94.8% vs 88.8% of results in zone A; $p = 0.000001$). Furthermore, a better glycemic control was achieved during the third trimester with fewer hypoglycemic and hyperglycemic events (2 vs 19 and 30 vs 66, respectively; $p < 0.000001$) and lower glucose variability, both for capillary (%CV 19.9 vs 25.3) and sensor measurements (%CV 20.9 vs 26.1). 496 paired measurements were performed 1 h after meals. ConEG analysis showed a significant lower accuracy of the values achieved 1 h after meal in comparison with the remaining daily measurements (87.5% vs 93.1% of results in zone A; $p = 0.00035$), with a MARD of 10.12% ± 8.78%.

The accuracy of FreeStyle Libre in pregnant women with T1DM has thus far been reported in just 24 cases and just over 2 weeks [2]. To our knowledge, this is the first time accuracy of FreeStyle Libre was assessed over a very long time during pregnancy. Strong positive correlation between interstitial and capillary glucose levels was reported in our patient throughout the analysis period, despite the wide variability in insulin requirement and in hormone levels. FreeStyle Libre sensor provides

(a)

····●···· Breakfast - Bolus   --▲-- Lunch - Bolus   — ◆ —Dinner - Bolus   —■— Basal

(b)

Fig. 1 **a** Mean insulin administration for each week gestation. **b** Scatter plot correlating capillary glucose (on *x*-axis) and interstitial glucose (on *y*-axis) measurements. A strong positive correlation was reported ($r = 0.89$; $p < 0.00001$)

Table 1 Consensus error grid analyses comparing FreeStyle Libre sensor results to capillary SMBG results

Consensus error grid	Total ($n = 1995$)	II trimester ($n = 1014$)	III trimester ($n = 981$)
Zone A	1830 (91.7%)	900 (88.8%)	930 (94.8%)
Euglycemia	1726 (86.5%)	826 (81.5%)	900 (91.7%)
Hypoglycemia	21 (1.1%)	19 (1.9%)	2 (0.2%)
Hyperglycemia	83 (4.1%)	55 (5.4%)	28 (2.9%)
Zone B	161 (8.1%)	111 (10.9%)	50 (5.1%)
Euglycemia	148 (7.4%)	100 (9.9%)	48 (4.9%)
Hypoglycemia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hyperglycemia	13 (0.7%)	11 (1.0%)	2 (0.2%)
Zone C	4 (0.2%)	3 (0.3%)	1 (0.1%)
Euglycemia	4 (0.2%)	3 (0.3%)	1 (0.1%)
Hypoglycemia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hyperglycemia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Zone D	0 (0.0%)	0 (0.0%)	0 (0.0%)
Zone E	0 (0.0%)	0 (0.0%)	0 (0.0%)

information about glucose trend at each scan, helping to guide challenging treatment decisions and to improve glucose control, as suggested by decreased HbA1c levels and few hypoglycemic and hyperglycemic events (less than 6%) in our patient. We found a better accuracy of the device during the third trimester in comparison with second, possibly linked to the lower glucose variability. Underestimation of glucose values 1 h after meal by FreeStyle Libre has been reported [3]. Accordingly, we found a lower accuracy of values produced 1 h after meals compared to the remaining measurements.

FreeStyle Libre system could improve glucose control and clinical outcome in T1DM pregnant women. Further larger studies are required.

Compliance with ethical standards

References

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