Poor Reliability and Poor Adherence to Self-Monitoring of Blood Glucose Are Common in Women With Gestational Diabetes Mellitus and May Be Associated With Poor Pregnancy Outcomes

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OBJECTIVE

To evaluate the compliance with self-monitoring of blood glucose (SMBG) and the reliability of diabetes logbooks in women with gestational diabetes mellitus (GDM), as well as the associated determinants and outcomes.

RESEARCH DESIGN AND METHODS

We prospectively selected French-speaking women with newly diagnosed GDM who had been referred to our diabetes management program and understood SMBG principles. At the next follow-up visit, we collected SMBG results from glucose meters and logbooks. We analyzed pregnancy outcomes.

RESULTS

Data were analyzed over 13 ± 3 days in 91 women. Only 61.5% had performed ≥80% of the required tests. Poor compliance was associated with a family history of diabetes, social deprivation, and non-European origin. The average time between pre- and postprandial tests was 141 ± 20 min, with 46.5% of women performing ≥80% of postprandial measurements 100–140 min after meals. Inadequate timing was associated with ethnicity and higher HbA_{1c} at baseline. A total of 23.1% of women had <90% matched values in diary and meter memory, and a poor concordance was associated with a family history of diabetes. Poor adherence was associated with more preeclampsia (12.2 vs. 1.9%, $P = 0.049$), and inadequate postprandial test timing with a higher HbA_{1c} at delivery (5.3 ± 0.4 vs. 5.0 ± 0.3% [34 ± 2 vs. 31 ± 2 mmol/mol], $P < 0.01$), despite more frequent insulin therapy.

CONCLUSIONS

Although women with GDM are considered to be highly motivated, SMBG adherence and reliability are of concern and may be associated with poor gestational prognosis, suggesting that caregivers should systematically check the glucose meter memory to improve GDM management.

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Tight glucose control improves outcomes in pregnancies complicated by gestational diabetes mellitus (GDM) (1,2). The goal of self-monitoring of blood glucose (SMBG) in patients with GDM is to provide timely and reliable measurement of blood glucose so that adequate treatment can be implemented (3,4).

However, little is known about the reliability of SMBG in women with GDM, with completion of only two small series (5,6). We considered this issue, as *1*) pregnant women are usually highly motivated and *2*) glucose control has to be rapidly achieved. Furthermore, GDM is a good model to assess SMBG compliance, as the number of tests during the first weeks of GDM management is identical in each subject (6/day), whereas it should be individualized afterward according to glucose control.

We hypothesized that the compliance and reliability of SMBG could improve pregnancy outcomes by reducing the time before potential insulin initiation, but our work was only powered for a pilot study.

RESEARCH DESIGN AND METHODS

Patients

Patients with newly diagnosed GDM were referred to our 1-day diabetes program including SMBG teaching. GDM was defined according to The International Association of the Diabetes and Pregnancy Study Groups recommendations (7), which have been endorsed in France (8). Patients were instructed how to accurately test and record SMBG data with a unique device model (Accu-Chek Active, Roche Diagnostics, Lyon, France) including a postprandial alarm. According to recommendations (4), we asked the subjects to test and record SMBG data up to the next planned visit 1–2 weeks later. We asked for blood glucose tests just before and 2 h after the beginning of each meal. Blood glucose targets were ≤5.3 mmol/L (95 mg/dL) before meals and ≤6.7 mmol/L (120 mg/dL) 2 h postprandial. Patients were informed that insulin therapy could be necessary if blood glucose targets were not achieved.

In this study, we prospectively selected women who were admitted to this program between January and June 2015. The inclusion criteria were *1*) French-speaking women and *2*) women with a good understanding at the end of the educational program of pre- and postprandial glucose targets and of how, when, and why SMBG had to be performed.

Clinical and Biological Data

Data were extracted from the electronic medical files. Our database was declared to the French-dedicated committee (Commission Nationale de l'Informatique et des Libertés, no. 1704392v0).

Women completed the EPICES questionnaire (Évaluation de la Précarité et des Inégalités de santé dans les Centres d'Examens de Santé), and psychosocial deprivation was defined as EPICES score ≥30.17 (9). Food insecurity, defined as the lack of food (sometimes or often) because of financial reasons, was assessed by asking the following question: "Considering your financial situation, which of these situations best describes your usual eating habits? (a) You eat all the food you want; (b) You have enough to eat, but don't always have a choice; (c) Sometimes you don't have enough to eat; and (d) Often you don't have enough to eat." The women who answered with b, c, or d were classified as food insecure (10).

We considered the following pregnancy outcomes: preeclampsia (blood pressure ≥140/90 mmHg on two measurements 4 h apart and proteinuria of at least 300 mg/24 h or ≥3 on dipstick testing in a random urine sample), caesarean section, preterm delivery (delivery before 37 completed weeks), and large- and small-for-gestational-age infants (large for gestational age, birth weight >90th percentile, and small for gestational age, <10th percentile, for a standard French population from 18,122 birth weights in the peri-urban districts of Paris and adjusted for gestation but not for fetal sex or ethnicity) (11). Of note, we did not find any association of fetal sex with GDM in our cohort (12), and customized birth weight percentiles adjusted for ethnicity are not available in France. HbA_{1c} (Dimension technology, Siemens Healthcare Diagnostics Inc., Newark, DE) was measured during the educational diabetes program day and on the day after delivery.

SMBG Data Collection

Just before the first scheduled visit after the educational program, the research technician (F.G.) duplicated SMBG logbook values and downloaded glucometer data using the software provided by the meter manufacturer (Roche Diagnostics). The diabetologist was blinded to the meter values, and the management decisions were therefore only based on self-reported SMBG values. The women were not aware that data would be compared. Noteworthily, all the data were analyzed after all the included women had delivered.

Compliance With SMBG Measurement

We first analyzed the compliance of women to pre- and postprandial SMBG. We considered that women were compliant if glucose meter data showed that they had performed at least 80% of both pre- and postprandial SMBG tests. We calculated the time between pre- and postprandial glucose tests using meter data. We defined as inadequate timing for postprandial SMBG when it was performed before 100 min or later than 140 min after the preprandial test.

Glucose Control

We analyzed glucose meter values and defined adequate preprandial and postprandial glucose control, respectively, as mean SMBG values ≤5.3 and 6.7 mmol/L.

Reliability of the Diabetes Logbook

We then analyzed the concordance between the logbook and the meter records (reliability of diary record). We adapted the terminology used by Given et al. (13,14). There were five categories of data (Fig. 1): *1*) underreported data were defined as meter values that were not reported in the logbook (omitted values), *2*) concordant data were defined as logbook values matching meter values, *3*) nonconcordant data were values in the diary that were different from those recorded in the meter, *4*) overreported data were defined as values added in the diary without the corresponding value in the meter (phantom values), and *5*) concordant empty data were defined as no meter measures and no self-reported value in the logbook.

The percentage of concordance was calculated as the proportion of concordant data first in these five categories (overall concordance) and second in the four first categories (not considering concordant empty data: concordance). In those four categories, we considered that women reported concordant data if at least 90% of paired logbook-meter data were concordant.

Finally, we determined the proportion of women who altered the results in a way that it would affect management, i.e., either insulin need or insulin dose adjustment. We considered as dissemblers the women who, more than three

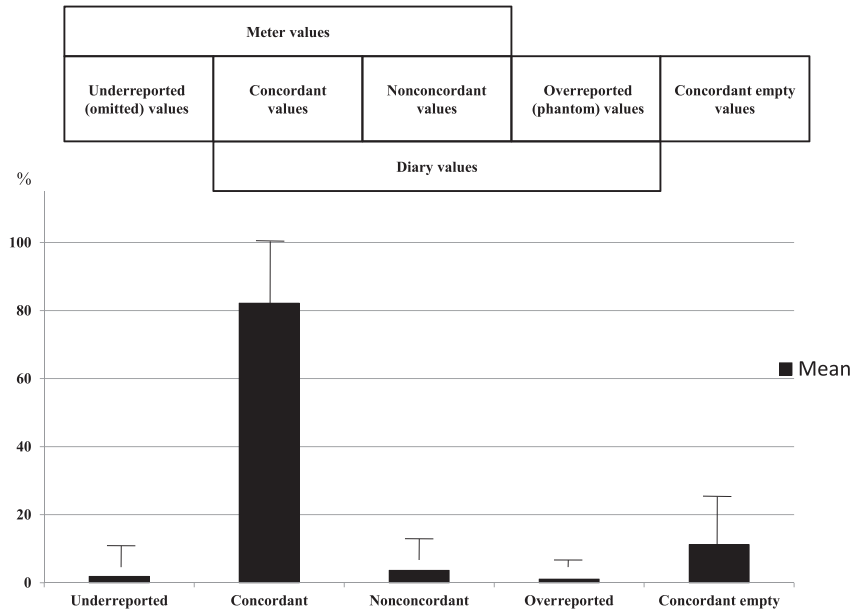

Figure 1—Diagrammatic comparison of meter and diary records.

times per week, underestimated their glucose values above the target (nonconcordant data) or did not report a high glucose value (underreported data).

Statistical Analyses

Continuous variables were expressed as means ± SD and compared by one-way ANOVA or the Mann-Whitney *U* test as adequate. The significance of differences in proportions was tested with the χ^2 test. Logistic regression was used for multivariate analyses based on models including the factors that were associated with compliance to SMBG and adequate postprandial SMBG timing, with a *P* value ≤0.10 in univariate analyses. Statistical analyses were carried out using SPSS software (SPSS, Chicago, IL). The level of significance for all tests was $P < 0.05$.

RESULTS

Characteristics of the Women

A total of 94 patients met the inclusion criteria. However, we could not report SMBG data for three of them: two women did not bring back their meter to hospital visits, and one was hospitalized and could not use her meter. Therefore, the results included only 91 women. Table 1 shows the characteristics of these women.

Compliance

Data were analyzed over 12.7 ± 2.9 days. A total of 78.0% of the subjects performed at least 80% of the required preprandial SMBG tests and 65.9% of them performed at least 80% of the required postprandial SMBG tests. Overall, 61.5% of the women were considered compliant. Poorly compliant women were more likely to have a family history of diabetes in first-degree relatives, not to be of French ethnicity, and to have social medical insurance dedicated to deprived individuals (Table 1). In multivariate analyses including all of these parameters, compliance was independently associated with family history of diabetes (odds ratio 0.38 [95% CI 0.15–0.98], *P* = 0.044). They were also more likely to have inadequate preprandial glucose control, delayed postprandial timing, and nonconcordant data in their logbook and their glucose meter (Table 1).

The mean time between pre- and postprandial glucose measurement was 141 ± 20 min. Figure 2 shows the distribution of women according to the mean time between pre- and postprandial tests. A total of 42 women (46.2%) had 80% adequate timing (between 100 and 140 min). Inadequate timing was associated with ethnicity (timing was inadequate in 22% of the women from France, 14.3% from the rest of Europe, 66.7% from North Africa, 72.7% from Sub-Saharan Africa, and 66.7% from other origins; *P* for trend 0.003), higher HbA_{1c} at the time of the educational program (women with inadequate vs. adequate timing: 5.3 ± 0.5% [34 ± 3 mmol/mol] vs. 5.1 ± 0.4% [33 ± 2 mmol/mol], respectively; *P* = 0.03). In multivariate analyses including both parameters, adequate postprandial timing was independently associated with French origin (odds ratio 3.93 [95% CI 1.09–14.26], *P* = 0.037). Inadequate timing was also associated with inadequate preprandial glucose control (34.0 vs. 4.8%, respectively, *P* = 0.001), lower compliance for SMBG testing (44.7 vs. 81%, $P < 0.001$), and lower concordance between logbook and glucose meter (90% of paired diary-meter glucose values: 61.7 vs. 92.9%, $P < 0.001$). These data are shown in Supplementary Table 1.

Concordance

Figure 1 illustrates the proportion of underreported data, concordant data, nonconcordant data, overreported data, and concordant empty data: 1.94 ± 6.5, 82.1 ± 18.1, 1.9 ± 6.5, 1.0 ± 3.0, and 11.5 ± 13.4%, respectively. Underreported values were always high blood glucose values and nonconcordant values were always underestimated compared with the meter values. Overall, 81.3% of the patients had at least 90% of paired logbook-meter glucose values.

When we excluded the concordant empty data, 76.9% of the patients had at least 90% of paired logbook-meter glucose values. These women (*n* = 70), as compared with those having <90% of concordant data (*n* = 21), were less likely to have a familial history of type 2 diabetes in first-degree relatives (38.2 vs. 71.4%, respectively, $P < 0.01$) and more likely to be compliant (at least 80% of SMBG tests: 71.4 vs. 28.6%, $P < 0.0001$) and to have adequate postprandial timing (57.4 vs. 14.3%, $P < 0.01$). Forty-two percent of the women with poor concordance were considered dissemblers. These data are shown in Supplementary Table 2. The mean number of concealed high meter glucose readings was 1.0 ± 2.2 per week. In total, 9.9% of the subjects were considered dissemblers, with more than three underreported, nonconcordant, or overreported values per week.

Prognosis

We could not report outcomes during pregnancy for five women because they did not deliver in our hospital. Supplementary Table 3 shows behaviors and care during pregnancy and pregnancy outcomes according to SMBG compliance, postprandial timing, and concordance. Women

Table 1—Characteristics of women by compliance with SMBG

	Total cohort	Poor compliance	Good compliance	*P*
n	91	35	56	
Age (years)	33.2 ± 5.1	33.2 ± 5.1	31.9 ± 4.9	0.236
Pregravid BMI (kg/m^2)	26.0 ± 5.4	25.1 ± 6.0	26.4 ± 5.1	0.298
BMI categories				0.923
Normal	40 (44.0)	15 (42.9)	25 (44.6)	
Overweight	29 (31.9)	12 (34.3)	17 (30.4)	
Obese	22 (24.2)	8 (22.9)	14 (25.0)	
Personal history of GDM				0.870
No GDM	43 (75.4)	17 (73.9)	26 (76.5)	
Diet-treated GDM	13 (22.8)	6 (26.1)	7 20.6)	
Insulin-treated GDM	1 (1.8)	0 (0)	1 (2.9)	
Family history of type 2 diabetes	41 (46.1)	21 (61.8)	20 (36.4)	0.019
Parity (*n*)	2.1 ± 1.1	2.3 ± 1.4	1.9 ± 1.0	0.103
Nulliparity	33 (38.4)	11 (33.3)	22 (41.5)	0.448
Ethnicity				0.048
France	18 (20.9)	5 (15.2)	13 (24.5)	
Europe	7 (8.1)	0 (0)	7 (13.2)	
North Africa	30 (34.7)	13 (39.4)	17 (32.1)	
Sub-Saharan Africa	12 (14.0)	8 (66.7)	4 (7.5)	
Other	19 (22.1)	7 (21.2)	12 (22.6)	
Smoking before pregnancy	9 (10.5)	5 (15.2)	4 (7.5)	0.263
Regular social insurance	36 (39.6)	9 (25.7)	27 (48.2)	0.033
Psychosocial insecurity	37 (40.7)	15 (42.9)	22 (39.3)	0.736
Food insecurity	20 (22.0)	9 (25.7)	11 (19.6)	0.496
GDM				
Time of positive GDM screening (WG)	21.7 ± 8.1	22.7 ± 7.7	21.1 ± 8.4	0.393
Early screening	66 (76.7)	25 (73.5)	41 (78.8)	0.568
Time of early screening (WG)	11.4 ± 4.1	11.6 ± 3.5	11.3 ± 4.5	0.728
Early fasting plasma glucose (mg/dL)	91 ± 12	91 ± 9	90 ± 2	0.756
Late screening				
Time of late screening (WG)	26.4 ± 2.6	27.1 ± 2.8	26.0 ± 2.4	0.092
Late fasting plasma glucose (mg/dL)	90 ± 11	88 ± 10	91 ± 12	0.366
1-h plasma glucose (mg/dL)	170 ± 31	175 ± 32	168 ± 30	0.398
2-h plasma glucose (mg/dL)	139 ± 36	146 ± 42	135 ± 32	0.262
Type of GDM				0.670
Early GDM	30 (33.0)	13 (37.1)	17 (30.4)	
GDM	57 (62.6)	20 (57.1)	37 (66.1)	
Overt diabetes during pregnancy	4 (4.4)	2 (5.7)	2 (3.6)	
SMBG data at first follow-up visit				
Adequate preprandial glucose control	72 (79.1)	24 (68.6)	48 (85.7)	0.050
Adequate postprandial glucose control	20 (22.2)	10 (29.4)	10 (17.9)	0.201
Adequate postprandial timing	42 (47.2)	8 (23.2)	34 (61.8)	<0.001
Good concordance	70 (76.9)	20 (57.1)	50 (89.3)	<0.001
Dissembler	9 (9.9)	6 (17.1)	3 (5.4)	0.067

Data are *n* (%) or mean ± SD unless otherwise indicated. Women were considered to be compliant if glucose meter data showed that they had performed at least 80% of both pre- and postprandial SMBG tests. WG, weeks of gestation.

with poor compliance were more likely to experience preeclampsia than women with good compliance (12.1 vs. 1.9%, respectively, $P = 0.049$). Women with inadequate versus adequate postprandial SMBG timing were more likely to be treated with insulin at the end of the educational program (28.9 vs. 7.1%, $P = 0.007$) and overall during pregnancy (63.0 vs. 35.7%, $P = 0.01$), and they had a higher HbA_{1c} level at delivery (5.3 ± 0.4% [34 ± 2 mmol/mol] vs. 5.0 ± 0.3% [31 ± 2 mmol/mol], $P = 0.002$).

CONCLUSIONS

SMBG is an integral part of GDM care. We report here for the first time that, during the first 2 weeks after GDM care initiation, only 61.5% of the patients performed at least 80% of the required daily SMBG tests. Usually reported barriers to SMBG include costs for the meters and strips, lower socioeconomic status, stigma of testing in public places, pain, and inconvenience (15,16). We report here that noncompliant women, compared with compliant women, were more likely to have a family history of diabetes in first-degree relatives. We might guess that they were less anxious about diabetes. They could also have used their relative's glucose meter, but this is unlikely, as most did not live with a first-degree relative with diabetes. We also found that poor compliance with SMBG testing was more frequent in women from Sub-Saharan Africa and was associated with social insurance dedicated to people with social deprivation. Social deprivation may be only part of the explanation,

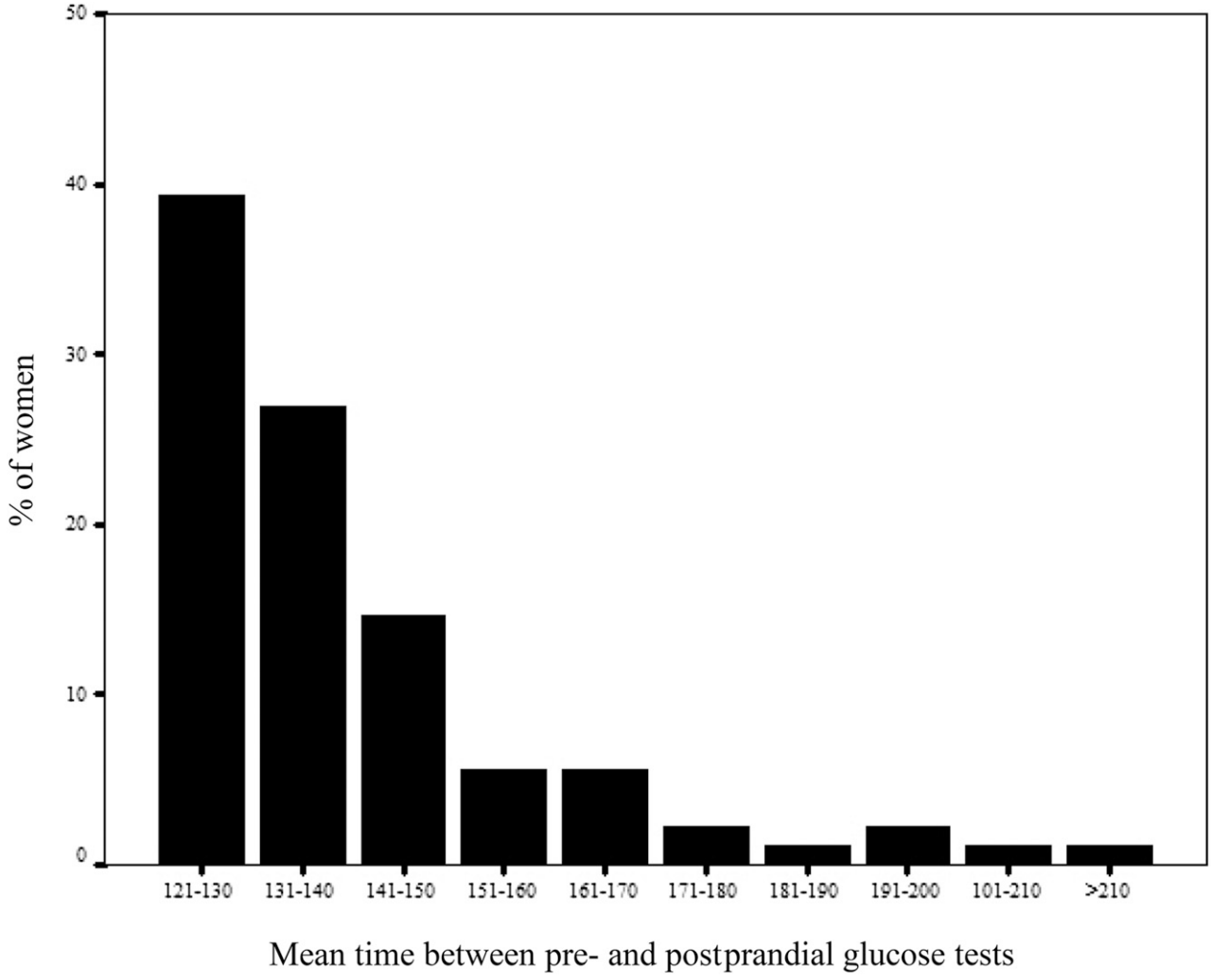

Figure 2—Delay between pre- and post-prandial glucose values in the meter. The women were asked to perform postprandial SMBG measurement 120 minutes after the beginning of the meal.

as neither the EPICES score nor food insecurity was associated with poor adherence.

Peak plasma glucose levels during pregnancy occur between 60 and 90 min after eating (3,4,15). In our series, postprandial SMBG tests were delayed in >50% of the women. The long delay we found may be clinically relevant: delayed testers had worse preprandial glucose control, whereas postprandial glucose control was similar, with a probable underestimation of postprandial glucose values due to delayed testing. However, a limit of our study is that time from the premeal test may not be equivalent to time from the start of the meal.

The concordance between meter and logbook values was inadequate in our series: 23.1% of the women exhibited <90% of paired diary-meter glucose values. Our results are, however, better than in type 1 and type 2 diabetes. Indeed, ~50% of adult diaries were considered as inaccurate in this population in a recent review (13). This is in agreement with the greater motivation of pregnant women, for whom SMBG is required only for a short period of time.

We could find only two little series analyzing SMBG reliability in pregnant women with diabetes (5,6). One study showed inaccurate reporting in 22% of 49 women with GDM (6). In an earlier study including 21 women with GDM, the average underreporting score and the average overreporting score were both 23% (5). It looks to be difficult to compare our study and the latter ones, as all analyzed results in very different ways.

The comparison of intensified SMBG with conventional blood glucose management (17) or less intensified SMBG (18–20) has shown controversial results regarding pregnancy outcomes during GDM. However, SMBG helps to reduce the frequency of macrosomia (20). Whether the level of compliance and the SMBG reliability have prognostic implication is, however, unknown. We found that women with poor compliance were more likely to experience preeclampsia, without difference in neonatal outcomes, and that those with inadequate postprandial SMBG timing had higher HbA_{1c} at delivery despite a higher rate of insulin therapy. Furthermore, preprandial glucose control was associated with compliance and adequate postprandial SMBG timing. These new data in a low sample size should alert caregivers but need to be confirmed in larger prospective series. Nevertheless, association does not mean causality. Patients who performed SMBG more strictly may

adhere more tightly to treatment programs as a result of better comprehension of treatment and improved adherence to the advised diet (21). Stress and social support may be confounders, as they were reported to be related to compliance to dietary recommendations (22). Finally, Sub-Saharan African origin and low socioeconomic status have been proven to be important risks factors for preeclampsia (23,24) and may constitute confounding factors considering the association between compliance and preeclampsia.

Our study has some limitations. We carried out our analyses during a short period of time, when the number of daily tests was similar in all women. However, repeated longitudinal measures of SMBG were similar across different periods of pregnancy in women with type 1 and type 2 diabetes (22). Our results may not be generalizable, and we could have had worse results if we had included women who, after evaluation, had not entirely understood how to manage SMBG or who poorly understood the French language. Furthermore, we did not evaluate some parameters that may impact compliance to and reliability of SMBG, such as health beliefs, behavioral intentions, psychological factors (22), and fear of inadequate glucose control. On the contrary, we had the opportunity to include parameters dealing with psychosocial deprivation including dedicated social insurances and precariousness EPICES score.

In this study, we show that we need to improve motivation of women with GDM for SMBG, especially those with family history of diabetes for compliance and those not from France for adequate postprandial timing. We also should trust SMBG diaries with caution. This information was not previously available and has therapeutic and prognostic consequences. We can adjust patient education with a supportive approach developing empowerment. The lack of meter-logbook agreement suggests that the real reason for monitoring was not understood by many patients, raising issues about motivation, perceived need, wishes to impress health care providers, denial of poor glucose control, and probably fear of insulin therapy. Finally, using the memory of blood glucose meters or automatically generated diary from glucose meters should improve the assessment of blood glucose control and guide clinical management and therefore might improve prognosis. In clinical practice, we suggest that the reliability of logbooks be checked by exploring glucometer memories as a matter of routine. For research purposes, our results claim for logbooks to be abandoned and electronic data considered.

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