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ORIGINAL ARTICLE

New Innovation: Use of Flash Glucose Monitoring for Evaluating Glycaemic Variability, Patient Satisfaction and Clinical Utility in Pregnant Women with Diabetes

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Abstract

Aim Application of Flash glucose monitoring (FGM) system to evaluate glycaemic variability (GV), patient satisfaction and clinical utility in pregnant women with diabetes.

Methods This prospective study was conducted in a tertiary care teaching hospital on 70 pregnant women with diabetes where blood sugar levels were monitored by FGM and self-monitoring of blood glucose (SMBG).

Results FGM generated 19,950 readings versus 1470 readings by SMBG over 3 days. Glucose values measured by FGM and SMBG had significant positive correlation ($r > 0.89$; $p < 0.001$). Significant difference ($p < 0.001$) was present between minimum glucose values by FGM (52.49 ± 15.42 mg/dl) and SMBG (72.74 ± 18.30 mg/dl). FGM (20.9%) was able to pick exact duration of hypoglycaemia, while one-third of this duration was missed by conventional SMBG (14.7%; $p < 0.05$). Hypoglycaemic episodes were observed in 92.9% women by FGM as compared to 45.7% by SMBG ($p < 0.001$). No significant difference was observed in maximum glucose level or duration of hyperglycaemia by both methods. FGM identified hyperglycaemia in 74% women vs. 52% by SMBG ($p < 0.001$). GV calculated by using MODD by FGM was 118.4 ± 52.4 mg/dl and by SMBG was 83.2 ± 53.2 mg/dl ($p < 0.001$). 100% women preferred AGP vs. SMBG.

Conclusion This is the first study to evaluate FGM for GV and patient satisfaction in women with GDM. Significant correlation was observed in glucose values by FGM and SMBG. FGM was more sensitive in detecting GV and hypoglycaemic excursions as compared to SMBG. All women preferred FGM over SMBG. Use of FGM gave new insights in clinical management of challenging cases.

Keywords Diabetes in pregnancy · FGM · Glycaemic variability · SMBG

Introduction

Hyperglycaemia in pregnancy has far-reaching consequences for the mother and foetus not only in the perinatal period but also later on in life [1, 2]. To avoid these complications, it is essential to maintain normoglycaemia and minimise glycaemic variability during pregnancy. It is now known that "Glycemic pentad" essential for adequate control of glycaemia includes fasting glucose, postprandial glucose, HbA1c, glycaemic variability (GV) including episodes of hypoglycaemia and hyperglycaemia which influence the rate of microvascular complications [3].

Glycaemic variability is defined as the degree of glucose fluctuations in an individual over one day (intraday GV) or between different days (interday GV). It has been observed in the Diabetes Control and Complications Trial (DCCT) that in spite of similar HbA1c levels, patients treated with

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conventional methods showed a significantly higher rate of complications due to higher glycaemic variation [4]. Fluctuating glucose levels result in increased oxidative stress with endothelial damage, dyslipidaemia and increased rates of micro- and macrovascular complications [5] which may possibly result in macrosomia, sudden intrauterine death and other complications.

A woman with GDM or pregestational diabetes has to measure glucose levels 4–7 times/day by self-monitoring of blood glucose (SMBG) which gives only a snapshot of overall picture instead of reflecting the actual daily pattern besides being painful and inconvenient for the patient [1]. Flash glucose monitoring system (FGM) generates ambulatory glucose profile (AGP) report [6] and is a relatively new and simple technology which provides glucose values every 15 min and is being evaluated to titrate therapeutic intervention in patients suffering from type 1/type 2 diabetes [7–10]. To the best of our knowledge, there are no published data comparing FGM and SMBG for detecting GV, patient satisfaction and clinical utility in women with GDM.

Aim of the current pilot study was to apply FGM for evaluating glycaemic variability, patient satisfaction and clinical utility in comparison with the conventional SMBG in pregnant women with diabetes in pregnancy.

Materials and Methods

This prospective, observational, analytical study was conducted in Department of Obstetrics and Gynaecology in a tertiary care teaching Institute from November 2016 to March 2018 after obtaining permission from the Ethics Committee of Human Research (ECHR). All participants were recruited after taking a written informed consent.

As this was a pilot study, and no previous studies were available for comparison, sample size was calculated using an assumption of the correlation value. Sample size was calculated to be 70 with 95% confidence limit and 90% power by assuming correlation coefficient $r = 0.5$.

Selection Criteria: Diagnosed pregnant women with diabetes were recruited from the antenatal clinic of the hospital. Inclusion criteria were pregnant women with GDM or type 1 and type 2 DM having singleton pregnancy with period of gestation (POG) < 36 weeks. Women with multiple pregnancy, pregnancy complicated with other chronic medical illness, period of gestation (POG) ≥ 36 weeks and those who refused to participate in the study were excluded.

Study Methodology

On admission, detailed history and thorough clinical examination were performed. Recruited women were admitted, and complete workup was done as per hospital protocol. All participants underwent glucose monitoring by FGM system (FreeStyle Libre Pro) (Fig. 1) and SMBG. SMBG was done by finger prick capillary blood test using calibrated glucometer (ACCU-CHEK®) during the study period. Capillary blood test was done 7 times in a day- fasting, 2 h' post-breakfast, pre-lunch, 2 h post-lunch, pre-dinner, 2 h post-dinner and at 2 am. During this time, they were allowed to do all their routine activity including taking bath without any hindrance due to the inserted device or without causing any harm to the device itself.

FGM has been approved by FDA for continuous ambulatory glucose monitoring [11, 12]. It consists of a sensor and a reader. Sensor with a filament (5 X 0.4 mm^2) is applied over the arm by an applicator. Filament measures glucose levels in the interstitial fluid every 15 min over a period of 14 days. The sensor application is painless, and it is adherent to the skin like a sticker. It can be easily removed by gentle pulling. The AGP profile is downloaded by FGM reader which transfers the data in a graphical and numerical form that is easy to interpret and share.

The FGM graphs depict average blood glucose, percentage of time during which patient had glucose levels within

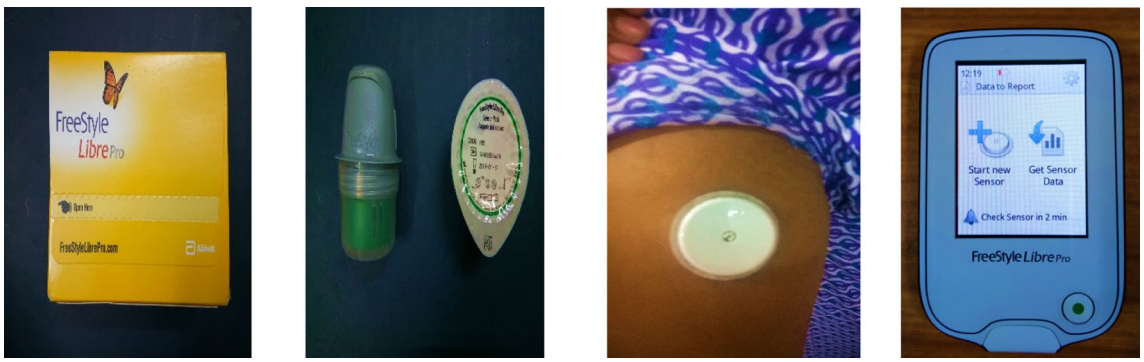

Fig. 1 FreeStyle Libre flash glucose monitoring system. **a** Flash glucose monitoring system. **b** Flash glucose monitoring applicator and sensor pack. **c** Flash glucose monitoring sensor. **d** Flash glucose monitoring reader

range, time duration below target and above target. Glucose levels at a particular time of the day can be retrieved and correlated with the patient's food diary, exercise, treatment.

FGM system was applied for 5–14 days. Threshold of 70 mg/dl was considered as hypoglycaemia, and a value ≥ 140 mg/dl was set as hyperglycaemia as ADA recommends target plasma glucose level to be < 140 mg/dl after 1 hour post-meal [13]. After 3 days of sensor application, mean glucose value measured in the interstitial fluid by FGM and in capillary blood by SMBG; range of glucose values; and hypo- and hyperglycaemia events, duration and frequency of these events by both FGM and SMBG were compared. Frequency and duration of hypo/hyperglycaemia by FGM were depicted by actual glucose measurements. Frequency and duration of hypo/hyperglycaemia by SMBG were calculated by measuring the number of times the woman had episodes of hypo/hyperglycaemia out of 7 times for calculating frequency, and the same ratio was multiplied by 24 h for calculating the duration of hypo/hyperglycaemia in the absence of absolute values by SMBG. Glycaemic variability was measured using mean of daily difference (MODD) by FGM and SMBG. MODD is the mean of all valid absolute value differences between glucose concentrations measured at the same time of day on 2 consecutive days [14]. GV was also assessed by calculating the standard deviation (SD), mean amplitude of glycaemic excursion (MAGE), continuous overall net glycaemic action (CONGA) [14] using the EasyGV Version 9.0.2 Nathan R Hill software for the data collected by FGM.

As patient satisfaction plays a key role to treatment adherence and compliance, in this study, patient satisfaction was evaluated for user acceptability of flash glucose monitoring system (FGM) as compared to SMBG by using Likert scale. Grading was done on a 5-point scale with 5 indicating "excellent", 4 "very good", 3 "good", 2 "fair" and 1 "poor".

Statistical analysis was performed by the SPSS program for Windows, continuous variables were presented as mean ± SD, and categorical variables were presented as absolute numbers and percentage. *P* value of < 0.05 were considered as statistically significant.

Results

Mean age of women was 28.01 ± 4.8 years (range 19–42 years). Mean body mass index according to pre-pregnancy weight was 23.9 ± 2.4 kg/m^2 (range 19.4–30.4 kg/m^2).

Among the recruited participants, 3 (4.3%) women had type 1 DM, and 5 (7.1%) had type 2 DM, while the rest 62 (88.5%) had gestational diabetes. The baseline glycaemia and lipid profile at recruitment are depicted in Table 1.

Mean glucose values measured by SMBG and FGM over a day for 3 consecutive days are shown in Table 2, and 7-point corresponding glucose values measured over 3 days by FGM and SMBG are given in Table 3. A significant positive correlation ($r > 0.89$; $p < 0.001$) was seen between the glucose values measured by SMBG and FGM.

The mean of minimum glucose value over 3 days detected by FGM was 52.5 ± 15.4 mg/dl which was significantly lower ($p < 0.001$) as compared to the minimum value detected by SMBG (72.7 ± 18.3). The number of women with hypoglycaemia was 92.9% (65/70) by FGM as compared to 45.7% (32/70) by SMBG ($p < 0.05$). Duration of hypoglycaemia detected by SMBG over a period of 3 days was 14.7% which was significantly lower compared to duration detected by AGP (20.9%; $p < 0.001$).

The mean of maximum glucose value detected by FGM (173.4 ± 53.3) and by SMBG (157.7 ± 63.3) over 3 days was

Table 1 Baseline investigations

	Mean ± SD (*n* = 70)	Range
Haemoglobin (gm %)	11.57 ± 1.39	7.8–13.8
Random blood sugar (mg/dl)	135.40 ± 44.13	80–300
Fasting blood sugar(mg/dl)	107.15 ± 26.05	71–204
Postprandial blood sugar(mg/dl)	165.15 ± 63.53	89–390
HbA1c (%)	6.49 ± 1.43	4.75–15
S. Cholesterol (mg/dl)	192.63 ± 35.34	132–289
Triglycerides (mg/dl)	159.68 ± 51.75	86–355
LDL (mg/dl)	75.49 ± 26.97	30–142
HDL (mg/dl)	46.97 ± 7.266	18–58

Table 2 Comparison of mean glucose values by SMBG and FGM

Day	Mean glucose value (SMBG) (*n* = 70)	Mean glucose value (FGM) (*n* = 70)	*P* value
Day 1	112.2 ± 34.0	107.5 ± 36.5	0.427
Day 2	115.7 ± 35.8	114.2 ± 47.5	0.831
Day 3	115.5 ± 31.9	112.2 ± 35.3	0.571

Table 3 Comparison of 7-point corresponding mean glucose value by SMBG and FGM

Time	Mean ± SD glucose value SMBG (*n* = 70)	Mean ± SD glucose value FGM (*n* = 70)	*P* value
Fasting	93.9 ± 34.2	94.3 ± 35.6	0.954
2 h after breakfast	114.7 ± 38.2	110.5 ± 41.9	0.531
Before lunch	103.5 ± 45.9	100.2 ± 48.6	0.683
2 h after lunch	123.9 ± 40.0	122.9 ± 40.26	0.885
Before dinner	102.6 ± 30.1	100.4 ± 35.6	0.705
2 h after dinner	126.4 ± 50.5	123.5 ± 52	0.737
2 am	97.8 ± 66.5	96.9 ± 77.9	0.943

comparable ($p=0.115$)). A number of women with episodes of hyperglycaemia were more by FGM (74.3%; 52/70) as compared to SMBG (52.9%; 37/70; $p<0.001$). The duration of hyperglycaemic episode over 3 days detected by FGM was 14.3% and by SMBG was 15.7% ($p=0.658$).

Glycaemic variability using MODD by FGM (118.4 ± 52.4 mg/dl) was significantly higher than SMBG (83.2 ± 53.2 mg/dl; $p<0.001$)). Other methods used to calculate GV using FGM were SD 1.9 (range 0.5–7.2), COGNA 4.5 (range 2.4–8.7), MAGE 4.9 (1.3–18.6).

On assessing patient satisfaction, FGM was preferred over SMBG and was rated as "excellent" by 68 and "very good" by 2 pregnant diabetic women, while SMBG was graded as "fair" by 66 and "poor" by 4 women. The reasons given for lower grading of SMBG were due to anxiety, inconvenience, pain and timing of glucose monitoring. No side effect was observed in any patient related to the FGM system.

Antenatal complications associated with the 70 recruited women with hyperglycaemia are depicted in Table 4. Out of 70, 42 (60%) delivered vaginally, while 28 (40%) had LSCS due to foetopelvic disproportion, prolonged or unsatisfactory progress of labour, meconium stained liquor or malpresentation.

Mean birth weight was 2.90 ± 0.62 kg ranging from 0.6 to 3.9 kg. Out of 70 women, 68 women had live birth, whereas 2 had intrauterine demise, and 2 babies had neonatal deaths. Respiratory distress was observed in 3 (4.29%) neonates, 1 (1.43%) had sepsis, 8 (11.43%) had hypoglycaemia, 8 (11.43%) developed hyperbilirubinemia, and 6 had congenital anomaly.

FGM graph of 4 interesting cases is illustrated in Fig. 2 to depict the clinical utility of having FGM monitoring to identify periods of intraday and interday GV, hypoglycaemia and hyperglycaemia in women with GDM, type 2 and type 1 DM.

Case 1 GDM controlled on MNT had relatively normal average glucose values on SMBG, but GV was apparent with the use of FGM during the same day (intraday GV) and also over different days (interday) which were missed by SMBG.

Case 2 Type 2 DM with hypoglycaemia, the episodes of hypoglycaemia were seen as high glucose excursions, thus displaying very high interday GV. FGM was useful in patient education and for adjusting diet and insulin therapy to reduce GV in this case.

Case 3 Type 1 DM with diabetic ketoacidosis. FGM measures interstitial glucose levels between 40 and 500 mg/dl. During DKA, her blood glucose levels exceeded this limit and normalised after intensive management in medicine ICU.

Case 4 GDM with hypoglycaemia who was being over treated with MNT + Metformin from private practitioner. This woman had asymptomatic hypoglycaemia for 90–100% time as demonstrated by FGM but because a stillbirth in previous pregnancy patient was not willing to stop Metformin and took an inadequate diet. After showing her the daily FGM graph, she was counselled regarding persistent hypoglycaemia and its deleterious effects on the baby, and finally, Metformin was stopped, and diet was improved.

Table 4 Antenatal complications

Parameter	Cases($n=70$)	%
PIH	16	22.86%
Hypothyroidism	17	24.28%
Intrahepatic cholestasis of pregnancy	8	11.43%
Polyhydramnios	4	5.71%
Oligohydramnios	3	4.29%
Premature rupture of membranes	2	2.86%
Foetal growth restriction	1	1.43%
Anaemia	21	30.0%
Deranged Doppler	2	2.86%
Antepartum eclampsia	1	1.43%

Discussion

Grade of maternal hyperglycaemia is the most deterministic of foetomaternal risks. Most patients with diabetes are in need of improved glucose control as pregnancy requires more detailed glucose information than is provided by conventional methods like SMBG.

The study included 70 pregnant women of which 62 had GDM, 3 had type 1 DM and 5 had type 2 DM where FGM and SMBG was done simultaneously for 3 days. FGM system generated 19,950 readings (95 readings/day × 3 days' × 70 patients) as compared to 1470 readings obtained by SMBG (7 readings/day × 3 days × 70 patients).

Mean glucose values measured by FGM and SMBG over 3 consecutive days and corresponding seven-point glucose values pre- and post-meal by both methods were comparable and showed good correlation ($r>0.89$; $p<0.001$). Yu et al. [15] and Alfadhli E et al. [16] found no difference in mean glucose levels between CGMS and SMBG, which is consistent with this study.

Mean of minimum glucose value detected by FGM was significantly lower than SMBG. FGM was able to pick exact duration of hypoglycaemia, while one-third of this was missed by conventional SMBG. SMBG missed hypoglycaemia in 33/70 (47.1%; $p<0.05$) women. AGP and SMBG were both able to pick up comparable values of maximum plasma glucose and time duration of hyperglycaemic phase. FGM was able to detect hyperglycaemia in 74% women, while SMBG could pick up hyperglycaemia in only 52% cases.

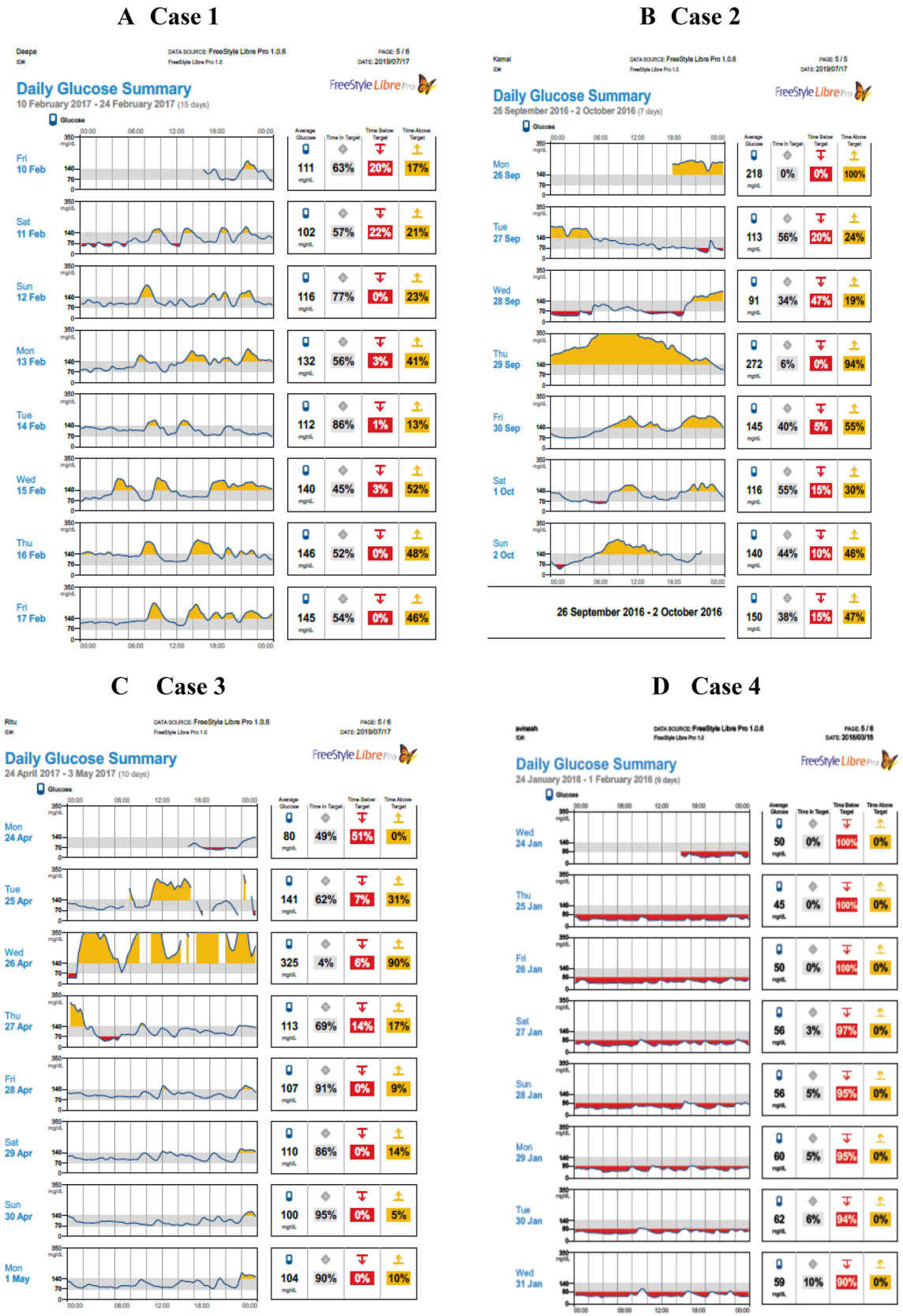

Fig. 2 AGP representation of 4 cases. **a** Case 1. Intraday and interday glycaemic variability in GDM**. b**. Case 2. Interday glycaemic variability in type 2 DM**. c**. Case 3. Diabetic ketoacidosis in type 1 DM**. d**. Case 4. Hypoglycaemia in GDM

As post-meal hyperglycaemia is a typical manifestation in GDM. Kestila et al. [17] demonstrated that the optimal timing of postprandial glucose measurement in GDM varies according to the composition of each meal, and hence, single SMBG measurement can miss the highest peak values. The advantage of FGM is that post-meal hyperglycaemia can be evaluated as a continuum, the hyperglycaemic peak occurred within 60–90 min postprandial in this study.

Yu et al. [15] and Alfadhli E et al. [16] found a significant difference in the glycaemic variability between SMBG and CGMS. MODD has been used in this study to compare GV by FGM and SMBG. MODD by SMBG (83.2 ± 53.2 mg/dl) was significantly lower than by FGM (118.4 ± 52.4 mg/dl; p value < 0.001). FGM helps to pick exact number and duration of asymptomatic and nocturnal hypo- and hyperglycaemic episodes which may be missed by SMBG. This is useful information, and when correlated with meal, exercise, stressors or insulin therapy on a daily basis, modification of therapeutic intervention and alterations in dietary habits can be planned accordingly. Yu et al. [15] observed significantly shorter duration of hypoglycaemia and hyperglycaemia in CGMS group after four weeks of intervention as compared to the conventional group. The disadvantages of CGMS are that it is costly and invasive and needs considerable skills for effective use by the physicians, while FGM is painless, lower cost and more user friendly for the patient as well as the physician.

This study highlights the importance of continuous ambulatory glucose measurements in pregnant diabetic women. Robust AGP data might provide understanding about the poor outcomes observed in various studies of GDM with apparently good control of GDM throughout pregnancy. Several episodes of hypo- and hyperglycaemia which are missed by SMBG may be responsible for the adverse pregnancy outcomes like intrauterine death and macrosomia. Intrauterine hyperglycaemia may result in metabolic imprinting of the foetus and may be responsible for foetal origin of adult diseases[2] like childhood obesity, impaired glucose tolerance, type 2 DM, hypertension and metabolic syndrome.

The limitations of this study were that as there were no previous studies comparing efficacy of FGM and SMBG for GV and other glycaemia parameters, we had to compare our results with previous studies done with CGMS and SMBG. Also, as this was a pilot study, the sample size was calculated using an assumption of the correlation value.

Future studies may be planned to correlate GV with adverse foetomaternal outcome and also to evaluate AGP as a potential tool to educate the patient and motivate them to achieve a better glycaemic control during pregnancy by altering diet, exercise or insulin therapy.

Conclusion

Based on the findings of the study, it was observed that FGM has better clinical utility to detect GV, episodes and duration of asymptomatic or nocturnal hypoglycaemia. FGM had the added advantage of higher patient satisfaction compared to SMBG by avoiding repeated pricking, inconvenience and anxiety to the patient.

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Compliance with Ethical Standards

Conflict of interest Authors have no conflict of interest in the findings of this study.

Ethical Approval This study was initiated after approval from the Ethics Committee of Human Research of the Institute.

Humane and Animal Rights All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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