ORIGINAL ARTICLE

Use of Ambulatory Glucose Profile in Monitoring and Improved Control of Gestational Diabetes Mellitus When Compared to Self-monitoring of Blood Glucose

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Received: 25 September 2024; *Accepted:* 25 April 2025

Abstract

Introduction: Gestational diabetes mellitus (GDM) is hyperglycemia diagnosed for the first time during the second or third trimester of pregnancy. It often leads to neonatal complications. Effective management of GDM is crucial to mitigate such risks. This study evaluates the effectiveness of ambulatory glucose profile (AGP) vs self-monitoring of blood glucose (SMBG) in managing GDM.

Methods: This 18-month observational study was conducted at All India Institute of Medical Sciences, Raipur, India, involving 65 pregnant women diagnosed with GDM. Thirty-two patients wore the flash glucose monitoring system (AGP group) and 33 performed SMBG (SMBG group). Blood glucose levels were monitored using AGP and SMBG, with data collected on fasting, postprandial glucose levels, and hypoglycemic events till 15 days after enrollment. Statistical analysis was performed using IBM Statistical Package for the Social Sciences (SPSS) version 21.

Results: The AGP group showed significant reductions in blood glucose levels across all measured times. Mean blood glucose concentrations decreased significantly in both groups from enrollment till 15 days, with no significant intergroup differences. The AGP group had a higher mean time in range (92 vs 90%) and lower time above range (4 vs 6%) compared to the SMBG group. Hypoglycemic events were fewer in the AGP group.

Conclusion: AGP demonstrated superior effectiveness in managing GDM by providing continuous glucose monitoring, improving glycemic control, and reducing hypoglycemic events compared to SMBG. AGP is recommended for better glucose management in GDM patients.

Journal of The Association of Physicians of India (2025): 10.59556/japi.73.1064

Introduction

Gestational diabetes mellitus (GDM) is caused by glucose intolerance with onset or first recognition during pregnancy.[1] This metabolic disorder typically arises in the second or third trimester when the insulin requirements of the body increase significantly. The prevalence of GDM is widely influenced by genetic, demographic, and lifestyle factors. Globally, >14% of pregnancies are complicated by GDM.[2] However, this prevalence can be higher in certain populations, such as those with a higher incidence of type 2 diabetes mellitus (T2DM). For example, studies have shown that women of South Asian, African, and Hispanic descent are at a higher risk compared to Caucasian women.[3] In India, GDM has a high prevalence of 16.55%.[4] Additionally, factors such as obesity, advanced maternal age, and a family history of diabetes also contribute to the increased likelihood of developing GDM.[5]

Gestational diabetes mellitus often leads to several neonatal complications. Macrosomia arises from maternal hyperglycemia, leading to fetal hyperinsulinemia, thereby accelerating somatic growth.[6] This excessive fetal growth is associated with increased risks of birth injuries, such as shoulder dystocia, brachial plexus injury, and clavicular fractures. Moreover, infants of mothers with GDM are predisposed to preterm delivery, with resultant complications from immature organ systems, most notably the respiratory system. The heightened risk of respiratory distress syndrome in these neonates is attributed to the delayed production of surfactant, a crucial component for pulmonary function.[7] Postnatally, the sequelae of maternal hyperglycemia manifest as neonatal hypoglycemia, due to persistent hyperinsulinemia, posing risks for seizures and neurological impairments if not promptly managed.[8] These neonates also exhibit an elevated incidence of jaundice secondary to hyperbilirubinemia, and polycythemia, which can lead to hyperviscosity syndrome. Electrolyte disturbances, particularly hypocalcemia and hypomagnesemia, are additional concerns, potentially precipitating neuromuscular irritability and convulsions. Long-term health consequences for infants include an increased risk of obesity and metabolic syndrome, such as T2DM and cardiovascular diseases, later in life.[9] The intrauterine environment and genetic predisposition contribute to these risks.

Effective management of GDM is essential in mitigating these adverse outcomes. Therapeutic strategies include meticulous glycemic control through dietary modifications, physical activity, and pharmacotherapy, including insulin administration when necessary.[10] Intensive treatment is crucial; however, overly stringent glycemic control in GDM can lead to hypoglycemia in up to 71% of cases.[11] While self-monitoring of blood glucose (SMBG) can help manage blood glucose levels, it often misses postprandial (PP) hyperglycemia and hypoglycemia due to the lack of 24-hour monitoring.[12] The National Institute for Health and Care Excellence (NICE) recommends testing blood sugar levels four to eight times daily, a challenging frequency to maintain.[13] Continuous glucose monitoring (CGM) systems offer a more comprehensive glucose profile without the discomfort of frequent finger pricks.[12] One of the most substantial benefits of CGM is its ability to provide real-time glucose monitoring. Unlike SMBG, which only provides snapshot readings at specific times, CGM offers a comprehensive view of glucose trends and fluctuations throughout the day and night. This continuous monitoring helps users understand how different factors such as food, exercise, and insulin affect their glucose levels, allowing for more precise adjustments in therapy. CGM systems also come with alerts and alarms that notify users of high or low glucose levels.[14] These real-time alerts enable timely interventions to prevent hyperglycemia or hypoglycemia,

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How to cite this article: Siddiqui MS, Kawale S, Rokkam R, *et al.* Use of Ambulatory Glucose Profile in Monitoring and Improved Control of Gestational Diabetes Mellitus When Compared to Self-Monitoring of Blood Glucose. J Assoc Physicians India 2025;73(8):15–20.

which is particularly beneficial during sleep or activities when frequent testing is not feasible. Studies have shown that CGM use can significantly reduce the frequency and severity of hypoglycemic events by providing early warnings and detailed glucose trends, whereas SMBG may miss detecting hypoglycaemia. Flash glucose monitoring (FGM) was introduced in 2014, which features a subcutaneous sensor that tracks glucose levels in real-time. The FreeStyle Libre Pro system, which can be used for up to 14 days without finger-prick calibration, offers detailed glucose data but lacks automatic alarms.[15]

The ambulatory glucose profile (AGP) is a transformative tool in diabetes management, which offers a standardized, single-page report that visualizes CGM data.[16] AGP simplifies the complex data from CGM systems into an easy-to-interpret format. It shows daily glucose patterns, variability, and target ranges. This user-friendly report enhances patient understanding and engagement by clearly indicating periods of hypoglycemia and hyperglycemia. For healthcare providers, AGP facilitates efficient analysis and personalized treatment planning, leading to better clinical outcomes.[17] Despite its advantages, the 24-hour glycemic profile using AGP has not been extensively studied in GDM patients in India. The current study aims to evaluate the glycemic profiles of GDM patients using AGP and its effectiveness in managing GDM at a tertiary healthcare center in Central India.

The primary objective of this study was to compare the effectiveness and safety of the AGP with the SMBG profile in the monitoring and control of GDM. Additionally, the study aimed to assess glycemic variability (GV) in GDM patients and the user acceptability of AGP among individuals with GDM, gauging patient comfort and satisfaction with this monitoring method.

Methods

Study Design and Setting

This hospital-based observational study was conducted over a period of 18 months at the All India Institute of Medical Sciences (AIIMS), Raipur. The study was performed at the Antenatal Care (ANC) clinic, Medicine Outpatient Department (OPD), and Endocrinology OPD of AIIMS Raipur.

Methodology

- We selected two groups of patients. The first group had an AGP sensor attached, and the second group was on SMBG monitoring as directed by their treating physician.
- The day patients were enrolled was counted as day 1 (D1). The patients were followed up on days 7 and 15.
- The first group of participants wore the AGP sensor (on the back of their upper arm) for 14 days. Throughout this period, participants were asked to perform usual premeal capillary blood glucose (SMBG) tests daily.
- The second group of participants was asked to perform usual premeal capillary blood glucose (SMBG) tests daily.
- At clinic visits on days 7 and 15, data from the device were uploaded, frequency of SMBG tests was reviewed, and any adverse events (AEs) experienced or concomitant medication changes done by the treating physician were recorded. On day 15, the reader sensors were removed.
- The second contact, i.e., the D7 of enrollment was considered as the point of intervention, when the treatment was revised based on the initial 7-day glucose readings of the patient. The changes were done by the treating physician. None of the interventions were done as part of our research protocol.

Study Population

Sample Size

The sample size was calculated using the formula:

$$n = \frac{Z^2 PQ}{e^2}$$

Here, $Z = 1.96$, $P = 16.55$, $Q = 83.45$, and $e = 10\%$. Using this formula, the calculated sample size was 53. Accounting for a 10% nonresponse and refusal rate, the sample size was adjusted to 60, which was divided into two groups: (1) AGP and (2) SMBG.

Inclusion Criteria

Pregnant women aged >18 years, diagnosed with GDM according to the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria.

Exclusion Criteria

Women aged ≤18 year, with a preexisting diagnosis of type 1 diabetes mellitus (DM) or type 2 DM, history of allergic reactions to AGP materials, adhesives, chlorhexidine, or alcoholic antiseptic solutions, presence of local site infection or any abnormality, and who refused to provide consent were excluded from the study.

Operational Definitions

Gestational diabetes mellitus was diagnosed using the IADPSG criteria. These criteria include specific blood glucose thresholds during an oral glucose tolerance test (OGTT). According to these criteria, a fasting glucose level of 92 mg/dL or higher is indicative of GDM. Additionally, if the 1-hour glucose level reaches or exceeds 180 mg/dL, or if the 2-hour glucose level is 153 mg/dL or higher, the diagnosis of GDM is confirmed.

Target blood sugar levels were defined to ensure stable glucose management. For fasting blood sugar (FBS), the target was set at <95 mg/dL. For postprandial (PP) measurements, the target was <140 mg/dL at 1-hour PP and <120 mg/dL at 2-hour PP.

Glycemic variability, which measures fluctuations in blood glucose levels, was defined by the coefficient of variation (CV). The goal was to maintain a CV of <36% to ensure more stable blood glucose levels, reducing the risk of both hyperglycemia and hypoglycemia.

The primary metrics for managing blood glucose levels were time in range (TIR), time above range (TAR), and time below range (TBR). For TIR, which represents the percentage of time that blood glucose levels remain within the desired range, the target was set at >90%. For TAR, which measures the percentage of time that blood glucose levels are above the target range, the objective was to keep this value below 5%. Similarly, the target for TBR, which indicates the percentage of time that blood glucose levels fall below the target range, was also set at <5%.

Study Variables and Data Collection

A detailed history and clinical examination of the patients were recorded. Hemogram and metabolic profiles were documented. The AGP monitor (FreeStyle Libre Pro Flash Professional; Abbott Diabetes Care Ltd, Range Road, Witney, Oxon, UK) was applied to the back of the left upper arm for 14 days. Patients maintained a chart documenting the timing of major meals (breakfast, lunch, and dinner) while the AGP monitor was in place. Additionally, all women were instructed to perform SMBG four times a day (preferably seven times a day) and document the timings in their chart. Both AGP and SMBG were used for monitoring and control of GDM as per the study plan.

Data Analysis

The collected data were entered into a Microsoft Excel Sheet and analyzed using IBM SPSS version 21. Quantitative data were summarized using mean and standard

deviation (SD). The Chi-square test was used for comparison of categorical variables, while *t*-tests and Fisher's exact tests were applied for quantitative (continuous) variables as appropriate. A Likert scale was used for user questionnaires. Differences between variables were considered statistically significant when the *p*-value was <0.05.

Results

Demography and Baseline Clinical Details of the Participants

The participants were divided into two groups: (1) the AGP group ($n = 32$) and (2) the SMBG group ($n = 33$). The majority of patients were aged 26–30 years in both groups. The mean age was 28.93 ± 3.60 years in the AGP group and 29.06 ± 3.91 years in the SMBG group.

The mean FBS levels were 107.54 ± 13.03 mg/dL in the AGP group and 101.45 ± 8.68 mg/dL in the SMBG group. The mean 1-hour PP blood sugar levels were 190.74 ± 27.94 mg/dL in the AGP group and 179.60 ± 20.38 mg/dL in the SMBG group. The mean 2-hour PP blood sugar levels were 157.96 ± 23.60 mg/dL in the AGP group and 144.27 ± 22.81 mg/dL in the SMBG group.

In the AGP group, 28.1% ($n = 9$) patients were primigravida, and 71.9% ($n = 23$) were multigravida. In the SMBG group, 36.4% ($n = 12$) were primigravida, and 63.6% ($n = 21$) were multigravida. Among the multiparous women, 25% ($n = 8$) in the AGP group and 24.2% ($n = 8$) in the SMBG group had a history of GDM in a previous pregnancy. In the AGP group, 28.1% ($n = 9$) patients had a family history of DM, while in the SMBG group, 30.3% ($n = 10$) patients had a family history of DM. In the AGP group, one patient had hypertension, seven patients had hypothyroidism, and two patients had both conditions. In the SMBG group, one patient had hypertension, nine patients had hypothyroidism, and one patient had both conditions.

Diagnosis and Treatment

Most patients were diagnosed with GDM at 24–25 weeks of gestation. In the AGP group, 11 patients received medical nutrition therapy, while 21 patients received pharmacotherapy: 17 treated with insulin, 2 with insulin and metformin, and 2 with metformin alone. In the SMBG group, 12 patients received medical nutrition therapy, and 21 patients received pharmacotherapy: 17 treated with insulin, 2 with insulin and metformin, and 2 with metformin alone.

Measurement of Blood Glucose

In the AGP cohort, the mean blood glucose concentration prior to breakfast was 88.72 ± 12.93 mg/dL during the initial 7-day period (preintervention) and decreased significantly to 85.41 ± 5.87 mg/dL postintervention during the final 7 days ($p = 0.046$). The mean PP blood glucose level following breakfast was 114.10 ± 20.82 mg/dL in the first 7 days (preintervention) and significantly decreased to 106.37 ± 11.45 mg/dL postintervention ($p = 0.002$). Similarly, the mean PP blood glucose level after lunch was 120.03 ± 20.53 mg/dL preintervention and decreased significantly to 111.13 ± 10.40 mg/dL postintervention ($p = 0.001$). The mean PP blood glucose level following dinner was 125.65 ± 19.22 mg/dL preintervention and decreased significantly to 115.48 ± 10.36 mg/dL postintervention ($p = 0.001$). The findings are summarized in Table 1.

In the SMBG cohort, the mean blood glucose concentration before breakfast was 92.15 ± 9.65 mg/dL during the preintervention period and decreased significantly to 88.48 ± 5.47 mg/dL in the postintervention period ($p = 0.002$). The mean PP blood glucose level following breakfast was 114.57 ± 15.96 mg/dL preintervention and decreased significantly to 108.63 ± 10.62 mg/dL postintervention period ($p = 0.020$). Similarly, the mean PP blood glucose level after lunch was 117.63 ± 14.40 mg/dL preintervention and decreased significantly to 112.75 ± 8.64 mg/dL postintervention ($p = 0.012$). The mean PP blood glucose level following dinner was 124.27 ± 16.66 mg/dL preintervention and decreased significantly to 114.57 ± 10.98 mg/dL in the postintervention period ($p = 0.001$). The findings are summarized in Table 2.

Table 1: Comparison of the blood glucose in different timings between the first 7 days (preintervention) and last 7 days (postintervention) in the AGP group

Timing		*Mean*	*SD*	*t-value*	*p-value*
Before breakfast	Preintervention	88.72	12.93	1.98	0.046*
	Postintervention	85.41	5.87		
After breakfast	Preintervention	114.10	20.82	−2.50	0.002*
	Postintervention	106.37	11.45		
After lunch	Preintervention	120.03	20.53	2.67	0.001*
	Postintervention	111.13	10.40		
After dinner	Preintervention	125.65	19.22	2.40	0.001*
	Postintervention	115.48	10.36		

* Significant when $p < 0.05$

Table 2: Comparison of the blood glucose in different timings between the first 7 days (preintervention) and last 7 days (postintervention) in the SMBG group

Timing		*Mean*	*SD*	*t-value*	*p-value*
Before breakfast	Preintervention	92.15	9.65	3.67	0.002*
	Postintervention	88.48	5.47		
After breakfast	Preintervention	114.57	15.96	2.56	0.020*
	Postintervention	108.63	10.62		
After lunch	Preintervention	117.63	14.40	2.78	0.012*
	Postintervention	112.75	8.64		
After dinner	Preintervention	124.27	16.66	3.87	0.001*
	Postintervention	114.57	10.98		

* Significant when $p < 0.05$

The mean variation in fasting blood glucose levels from the preintervention to the postintervention period was 3.31 mg/dL in the AGP cohort and 3.66 mg/dL in the SMBG cohort, with an intergroup difference of 0.35 mg/dL. The mean change in PP blood glucose levels following breakfast from preintervention to the postintervention period was 7.72 mg/dL in the AGP cohort and 5.93 mg/dL in the SMBG cohort, resulting in an intergroup difference of 2.79 mg/dL. The mean change in PP blood glucose levels following lunch from preintervention to the postintervention period was 8.90 mg/dL in the AGP cohort and 4.87 mg/dL in the SMBG cohort, with an intergroup difference of 4.13 mg/dL. The mean variation in PP blood glucose levels following dinner from preintervention to the postintervention period was 10.17 mg/dL in the AGP cohort and 9.69 mg/dL in the SMBG cohort, resulting in an intergroup difference of 0.48 mg/dL. However, the intergroup variations were not statistically significant at any time interval. The findings are summarized in Table 3.

Time in Range

As shown in Table 4, in the AGP group, the mean time within the target range was 84% during the preintervention period and significantly increased to 92% postintervention ($p < 0.001$). The mean time below the target range was 3% during the preintervention period and decreased significantly to 2% during the postintervention period ($p = 0.008$). The mean time above the target range was 12% during the preintervention period and decreased significantly to 4% postintervention ($p < 0.001$).

Hypoglycemic Events

In the AGP group, three patients experienced symptomatic hypoglycemia, while eight patients experienced asymptomatic hypoglycemia. In contrast, in the SMBG group, four patients experienced symptomatic hypoglycemia, with no cases of asymptomatic hypoglycemia recorded. The results of the Chi-square test for hypoglycemic events in the AGP and SMBG groups are summarized in Table 5. In the AGP group, 9.37% of patients experienced symptomatic hypoglycemia compared to 12.12% in the SMBG group ($p = 0.01$). This indicates a significant difference in the occurrence of symptomatic hypoglycemia between the two groups.

Glycemic Variability

The GV (% CV) in the AGP group was calculated to be 16.81 ± 4.22 in the preintervention period and 14.15 ± 3.08 in the postintervention period. Paired *t*-test indicated a statistically significant difference between the preintervention and postintervention values ($p = 0.005$), suggesting an improvement in GV following the intervention (Table 6).

Table 3: Comparison of the mean change in the blood glucose at different times of measurement during preintervention and postintervention period between the AGP and SMBG groups

Timings		*Mean change*	*Difference*	*p-value*
Before breakfast	AGP	3.31	0.35	0.468
	SMBG	3.66		
After breakfast	AGP	7.72	2.79	0.646
	SMBG	5.93		
After lunch	AGP	8.90	4.13	0.216
	SMBG	4.87		
After dinner	AGP	10.17	0.48	0.971
	SMBG	9.69		

Table 4: Comparison of the various times between the first 7 days and last 7 days in the AGP group

Timing		*Mean*	*SD*	*p-value*
Time in target	Preintervention	0.84	0.10	<0.001*
	Postintervention	0.92	0.03	
Time below target	Preintervention	0.03	0.02	0.008*
	Postintervention	0.02	0.01	
Time above target	Preintervention	0.12	0.09	<0.001*
	Postintervention	0.04	0.03	

* Significant when $p < 0.05$

Table 5: Comparison of hypoglycemic events in AGP and SMBG groups

Hypoglycemic events	*Group AGP*		*Group SMBG*		*p-value*
	N = 32	*%*	*N = 33*	*%*	
Symptomatic	3	9.37	4	12.12	0.01*
Asymptomatic	8	25	0	0	

Chi-square test; *Significant when $p < 0.05$

Table 6: Comparison of glycemic variability in the AGP group

Coefficient of variability	*Mean*	*SD*	*p-value*
Preintervention	16.81	04.22	0.005*
Postintervention	14.15	03.08	

Paired *t*-test; *Significant when $p < 0.005$

User Acceptability

In the AGP group, 10.34% of the patients responded with "agree" (indicating that the device was almost painless) regarding the acceptability of the device. A significant majority, 89.66%, responded with "strongly agree" (indicating that the device was painless) for the acceptability of the device. Notably, none of the patients provided responses of "neither agree nor disagree" (indicating slight pain), "disagree" (indicating moderate pain), or "strongly disagree" (indicating severe pain) on the user acceptability questionnaire that was given to them. No AEs were observed with the AGP monitor.

Discussion

There is a growing demand for advanced tools to monitor and regulate alterations in 24-hour blood glucose levels. Among the first continuous, albeit invasive, monitoring systems introduced are the continuous glucose monitoring system (CGMS) and FGM system. The CGMS facilitates periodic recording of comprehensive blood glucose profiles and important statistics for diabetic patients. Given the availability of this technology, it is essential to evaluate its accuracy, reproducibility, and ability to detect critical glycemic events as well as blood glucose patterns. In a systematic review, Aggarwal et al. analyzed 26 clinical and 12 economic studies and revealed that CGMS effectively reduces hypoglycemic events and improves glucose and HbA1c levels, while also impacting direct and indirect management costs.[18] Another systematic review by Majewska et al. found that CGM provides better glycemic control than SMBG and improves qualification for insulin therapy. However, most studies do not show CGM's impact on neonatal outcomes, indicating a need for further research.[19]

In this study, significant reductions in mean blood glucose levels were observed postintervention compared to preintervention across various meal timings in both the SMBG and AGP groups. For instance, before breakfast, mean blood glucose levels decreased significantly in both the AGP and SMBG groups. Similar reductions were noted after breakfast, lunch, and dinner in both groups. However, there was no significant difference in the mean change in blood glucose levels between the AGP and SMBG groups across different meal timings. These findings suggest that while both AGP and SMBG interventions effectively reduced mean blood glucose levels across various meal timings, there was no significant advantage of one method over the other in terms of mean blood glucose level reduction. Thus, our study demonstrated that both AGP and SMBG are effective in detecting and managing hyperglycemia in GDM patients. The detailed data provided by AGP allow for the comprehensive assessment of hyperglycemic episodes. Conversely, the frequency of SMBG recordings plays a crucial role in identifying hyperglycemic episodes, often missed due to less frequent testing.

Alfadhli et al. conducted a prospective open-label randomized controlled study at the Maternity and Children Hospital, Medina, Saudi Arabia, evaluating the impact of a real-time continuous glucose monitoring system (RT-CGMS) as an educational tool in 130 pregnant women diagnosed with GDM. Participants were randomized into two groups: (1) SMBG alone and (2) SMBG with RT-CGMS application shortly after diagnosis. Despite improvements in glucose variability metrics, the study found no significant enhancements in overall glycemic control or pregnancy outcomes with RT-CGMS use.[20] Lane et al. conducted a randomized controlled trial to assess whether RT-CGMS improves glycemic control over intermittent SMBG in GDM. They reported that despite RT-CGM providing continuous feedback, there was no significant difference in mean sensor glucose levels between the groups after 4 weeks. Additionally, there were no notable differences in glycemic target achievement, maternal, or neonatal outcomes. However, patients perceived CGM, particularly real-time feedback, as beneficial for managing GDM, suggesting its role as a motivational tool.[21] These findings are similar to those reported in the current study.

However, some studies indicate that AGP may be more effective in managing hyperglycemia. Yogev et al. assessed the utility of CGM in managing insulin therapy for GDM. They reported that adjustments based on CGM data improved glycemic control, highlighting its potential in managing diabetic pregnancies effectively.[22] García-Moreno et al. reviewed 457 studies and included six randomized clinical trials involving 482 patients in their meta-analysis. The findings indicate that CGM use led to lower HbA1c levels at the end of pregnancy, reduced gestational weight gain in mothers, and lower birth weights in infants compared to blood glucose monitoring (BGM).[23]

In the AGP group, there was a significant increase in the mean TIR in the postintervention period (92%) compared to that of preintervention (84%), alongside reductions in TBR and TAR. In contrast, TIR calculation was not feasible in the SMBG group. This demonstrates the advantage of AGP in assessing glycemic profile, which can be detrimental to both the patient and fetus. They often go unchecked in SMBG-managed patients but can be effectively addressed through AGP profiling. Regarding hypoglycemia, three patients in the AGP group and four in the SMBG group experienced symptomatic hypoglycemia (blood glucose < 60 mg/dL), all occurring at night and in patients receiving insulin. AGP detected eight additional asymptomatic hypoglycemia cases, managed through dietary and insulin dose modifications. This demonstrates the efficacy of AGP in identifying asymptomatic and nocturnal hypoglycemic episodes, which are often missed by SMBG. In a randomized trial, Ólafsdóttir et al. studied the impact of CGM on hypoglycemia in diabetes patients using multiple daily insulin injections (MDIs). Results showed a significant reduction in nocturnal hypoglycemia (48% for <70 mg/dL and 65% for <54 mg/dL) and daytime hypoglycemia. CGM use also improved hypoglycemia-related confidence in social situations and overall life quality, with participants feeling more capable of detecting and responding to low glucose levels.[24]

Assessing GV in the current study was possible in the AGP group, with mean GV decreasing from 16.81% CV during the preintervention period to 14.15% CV postintervention. While definitive GV targets for GDM are yet to be established, our findings suggest lower GV in GDM patients compared to type 1 and type 2 DM. AGP provides a comprehensive glycemic profile, aiding GV assessment, whereas SMBG's data sufficiency depends on testing frequency. User acceptability of CGM in the AGP group was high, with 89.66% of patients rating it as painless and no adverse reactions reported. This aligns with the study by Scott et al., who highlighted the FreeStyle Libre System's acceptability among pregnant women with diabetes. This study evaluated the accuracy, clinical safety, and acceptability of the system in pregnant women with diabetes. Sensor glucose values were compared to SMBG values taken at least four times daily. Results showed as high as 99.8% of sensor readings. User feedback indicated high satisfaction, and no device-related AEs were reported, demonstrating the safety and accuracy of the system for pregnant women with diabetes.[25] Similarly, Pikee et al. reported a preference for FGM over SMBG among patients. They assessed the FGM system for GV, patient satisfaction, and clinical utility in pregnant women with diabetes. They reported that FGM detected more hypoglycemic episodes (92.9 vs 45.7%) and identified hyperglycemia in more women (74 vs 52%) compared to SMBG.

All participants preferred FGM, highlighting its sensitivity and patient satisfaction.[26]

Limitations of the Study

The study has a few limitations that may impact its generalizability and reliability. The relatively small sample size limits the applicability of the findings to a broader population, and the single-center setting at AIIMS Raipur may not reflect different patient demographics and clinical practices elsewhere. Additionally, the study did not control for all potential confounding variables, and the technological limitations of the AGP device could affect data accuracy. The effectiveness of SMBG heavily depends on participant adherence, which can vary widely.

Conclusion

This study compares the effectiveness of AGP and SMBG in managing gestational GDM. Both monitoring methods significantly improved glycemic control, with notable reductions in fasting and PP blood glucose levels. The AGP group demonstrated a more significant reduction in blood glucose levels postintervention compared to the SMBG group, particularly after meals, although the intergroup differences were not statistically significant. The AGP group's mean time within the target glucose range increased from 84% to 92%, indicating better overall glucose management compared to the SMBG group. Additionally, the AGP group had a more substantial decrease in the time spent above the target glucose range, which suggests improved control over hyperglycemia. Moreover, the study highlights the practical advantages of AGP, such as CGM without frequent finger pricks, which enhances patient compliance and comfort. The real-time data and trend analysis provided by AGP help in making timely adjustments to the treatment regimen, potentially reducing the risk of AEs associated with GDM. However, both methods showed efficacy in reducing the incidence of hypoglycemia, with AGP also identifying asymptomatic hypoglycemia episodes that SMBG might miss. AGP appears to offer a more comprehensive and patient-friendly approach to glucose monitoring in GDM management, potentially leading to better clinical outcomes. These findings support the integration of AGP into routine GDM care, particularly in settings where continuous monitoring can provide significant benefits over traditional SMBG methods.

Acknowledgment

Authors acknowledge the expert English editing and writing assistance from Papyruscript Private Limited (https://www.papyruscript.com/), Delhi, India.

Sources of Support

The AGP machine was provided by the General Medicine Department. The study did not receive any external funding.

Conflict of Interest

None.

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