

Continuous glucose monitoring versus blood glucose self-monitoring in patients with gestational diabetes mellitus managed via diet control: a prospective pilot study

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Objectives: To compare agreement between continuous glucose monitoring (CGM) and self-monitoring of blood glucose and to assess the acceptance and satisfaction of CGM among Chinese women with gestational diabetes mellitus (GDM) in Hong Kong.

Methods: Chinese women diagnosed with GDM after 28 weeks of gestation and managed via diet control were recruited at Kwong Wah Hospital, Hong Kong, between January 2025 and June 2025. Participants were instructed to wear a CGM sensor for 15 days. Additionally, they were instructed to perform self-monitoring of blood glucose via finger prick four times per day on 4 separate days. Fasting glucose levels in the morning and postprandial glucose levels 2 hours after each meal were recorded. Participants' knowledge, application, usage, and acceptance and satisfaction of CGM were assessed using an 18-item questionnaire. Satisfaction with CGM was also assessed using the validated Chinese version of the Glucose Monitoring Satisfaction Survey.

Results: In total, 50 Chinese women diagnosed with GDM after 28 weeks of gestation and managed via diet control were included in the analysis. A total of 711 paired measurements were collected. Agreement between CGM and self-monitoring measurements was good, with a concordance correlation coefficient of 0.836. The linear-mixed-effects-based Bland-Altman plot showed a mean bias between the two methods of 0.069 mmol/L. Deming regression yielded an intercept of -0.046 and a slope of 1.017, indicating minimal fixed and proportional bias. The mixed-effects model showed a precision ratio of 0.626. The mean absolute relative difference was 8.04%. Parkes error grid analysis indicated that 100% of paired measurements were in zone A or B. Overall, 83.7% were satisfied with CGM and accepted its use for glucose monitoring during pregnancy when the sensor was provided free of charge.

Conclusion: Agreement between CGM and self-monitoring measurements was good in Chinese women with GDM. CGM can be used as an adjunct to self-monitoring with finger pricks, which should be performed at least weekly to cross-check agreement. Most women with GDM accepted and were satisfied with CGM.

Keywords: Blood glucose self-monitoring; Continuous glucose monitoring; Diabetes, gestational; Patient satisfaction

Introduction

Gestational diabetes mellitus (GDM) is characterised by glucose intolerance resulting in hyperglycaemia during pregnancy¹. Women with GDM have a higher risk of adverse maternal and fetal outcomes, including macrosomia, preterm delivery, neonatal respiratory distress syndrome, neonatal intensive care unit admission, and

Caesarean section². The prevalence of GDM has increased over the past few decades³, owing to rising rates of obesity and advanced maternal age^{4,5}. In Hong Kong, the incidence

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of GDM in 2016 was 32.5%, based on the World Health Organization 1999 criteria⁶. At Kwong Wah Hospital, Hong Kong, the incidences in 2025 were 24.1% for GDM, 4.2% for diabetes mellitus in pregnancy, and 1.9% for pre-existing diabetes mellitus.

Glycaemic control is essential to reduce GDM-related complications. Self-monitoring of blood glucose via finger prick is the standard practice in Hong Kong⁷. The National Institute for Health and Care Excellence guidelines recommend daily testing of fasting and postprandial blood glucose levels in pregnant women with GDM managed via diet control⁸. However, finger pricking can cause discomfort and inconvenience, potentially reducing adherence to glycaemic monitoring⁹.

Continuous glucose monitoring (CGM) is a small device attached to the upper arm to enable real-time or intermittent monitoring of glucose concentrations in interstitial fluid¹⁰, thereby facilitating reductions in mean glycated haemoglobin levels, mean glucose levels, and hypoglycaemic episodes, while improving patient satisfaction, among patients with types 1 and 2 diabetes mellitus^{11–13}. Satisfaction with CGM is high among Western pregnant women^{14,15}. A physiological time lag in glucose diffusion from the vascular space to the interstitial fluid can lead to discrepancies between self-monitored and CGM glucose levels¹⁶. Physiological changes during pregnancy, such as increased blood volume and hormonal fluctuations, may affect sensor performance. This study aimed to compare agreement between CGM and self-monitoring of blood glucose and to assess the acceptance and satisfaction of CGM among Chinese women with GDM in Hong Kong.

Methods

Chinese women diagnosed with GDM after 28 weeks of gestation and managed via diet control were recruited at Kwong Wah Hospital, Hong Kong, between January 2025 and June 2025. Women with pre-existing diabetes mellitus, diabetes mellitus in pregnancy, GDM requiring insulin therapy, or in the first or second trimester of gestation were excluded. The cut-off of 28 weeks of gestation corresponds to the timing of the oral glucose tolerance test (for fasting and 2-hour plasma glucose levels), which is selectively offered to women with identified risk factors; most GDM cases are identified at this time. GDM was defined as a fasting plasma glucose level of ≥ 5.1 mmol/L or a 2-hour plasma glucose level of ≥ 8.5 mmol/L¹⁷.

Participants were instructed to wear a CGM sensor (FreeStyle Libre 2 Plus; Abbott Diabetes Care, United

Kingdom) for 15 days. Additionally, they were instructed to perform self-monitoring of blood glucose via finger prick (Contour Plus Elite blood glucose meter and Contour Plus blood glucose test strips; Ascensia Diabetes Care Holdings AG, Switzerland) four times per day on 4 separate days. Fasting glucose levels in the morning and postprandial glucose levels 2 hours after each meal were recorded.

Participants' knowledge, application, usage, and acceptance and satisfaction of CGM were assessed using an 18-item questionnaire. Items were rated as yes/no or on a five-point Likert scale ranging from strongly disagree (1) to strongly agree (5). Satisfaction with CGM was also assessed using the validated Chinese version of the Glucose Monitoring Satisfaction Survey^{18,19}, which comprises four domains: openness, emotional burden, behavioural burden, and worthwhileness. The maximum score for each domain is 5; higher scores indicate greater domain-specific outcomes.

The sample size was based on similar studies in the literature^{20–22}. Agreement between the two methods was assessed using the concordance correlation coefficient. Fixed and proportional biases were evaluated using Deming regression. A linear-mixed-effects-based Bland-Altman plot was constructed to visualise systematic bias, with adjustments for repeated measurements and within-participant variability. A precision ratio was calculated using a mixed-effects model to compare the variance of random error terms between the two methods. The mean absolute relative difference was calculated to determine average percentage error. Parkes error grid analysis was conducted to evaluate clinical safety (no or little effect on altering clinical action or outcome) by categorising paired measurements into risk zones (A to E)²³. All statistical analyses were performed using R software (version 4.5.1).

Results

In total, 50 Chinese women diagnosed with GDM after 28 weeks of gestation and managed via diet control were included in the analysis (Table 1). Of these, 45 completed all measurements, and five experienced sensor dislodgement (between days 7 and 13). A total of 711 paired measurements were collected; glucose levels ranged from 3.1 to 12.3 mmol/L for the self-monitoring method and from 3.3 to 10.5 mmol/L for the CGM method. The mean number of CGM scans per person was 33 ± 30 per day. In self-monitoring, 76.3% of fasting glucose levels and 74.8% of 2-hour postprandial glucose levels met the recommended targets of < 5.3 mmol/L and < 6.8 mmol/L, respectively⁷.

Table 1. Characteristics of participants (n=50).

	Value*
Age, y	34.8±4.2
Ethnicity	
Chinese	50 (100.0)
Non-Chinese	0
Education level	
Primary	0
Secondary	16 (32.0)
Tertiary or above	34 (68.0)
Pre-pregnancy body mass index, kg/m ²	23.6±3.1
Parity	
Nulliparous	31 (62.0)
Multiparous	19 (38.0)
Type of pregnancy	
Singleton	50 (100.0)
Twin	0
Gestational age at recruitment, wk	30.1±1.0
Oral glucose tolerance test	
Fasting glucose, mmol/L	4.9±0.4
2-hour postprandial glucose, mmol/L	9.0±1.1
Glycated haemoglobin, %	5.5±0.4

* Data are presented as mean±standard deviation or No. (%) of participants

Agreement between CGM and self-monitoring measurements was good, with a concordance correlation coefficient of 0.836 (lower 95% confidence limit, 0.813). The linear-mixed-effects-based Bland-Altman plot showed a mean bias between the two methods of 0.069 mmol/L (95% limits of agreement, -1.146 to 1.285 mmol/L, $p=0.1995$, Figure 1). Deming regression yielded an intercept of -0.046 (95% prediction interval, -0.363 to 0.264) and a slope of 1.017 (95% prediction interval, 0.961-1.073), indicating minimal fixed and proportional bias. The mixed-effects model showed a precision ratio of 0.626 (95% confidence interval, 0.333-1.176). The mean absolute relative difference was 8.04%. Parkes error grid analysis indicated that 94.7% of paired measurements were in zone A and 5.3% were in zone B (Figure 2).

Among participants with a pre-pregnancy body mass index (BMI) <25 kg/m² (n=35), 94.3% of paired measurements were in zone A and 5.7% were in zone B.

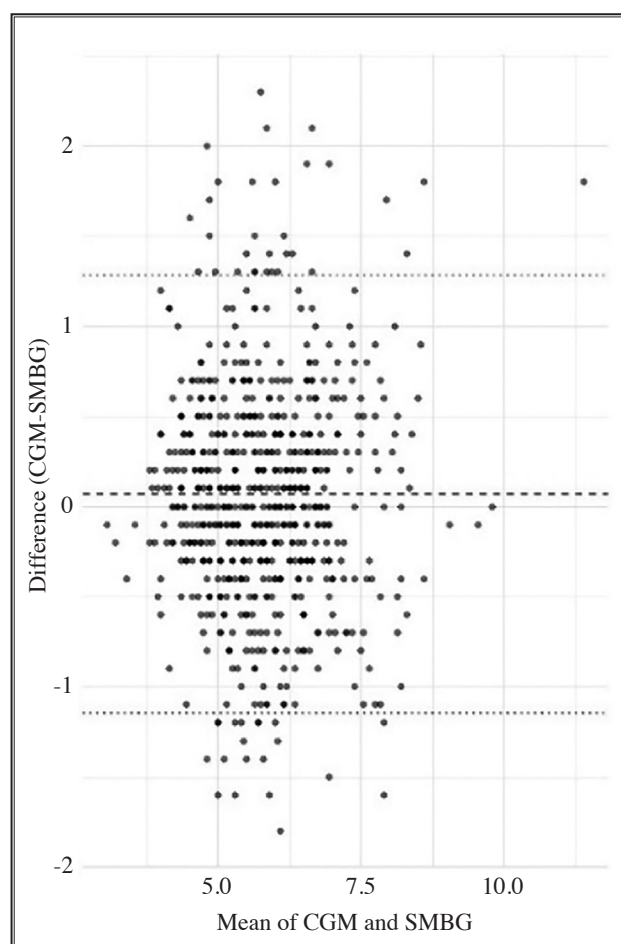


Figure 1. Linear-mixed-effects-based Bland-Altman plot to assess agreement between continuous glucose monitoring (CGM) and self-monitoring of blood glucose (SMBG) measurements.

Among participants with a pre-pregnancy BMI ≥ 25 kg/m² (n=15), 95.6% of paired measurements were in zone A and 4.4% were in zone B (Figure 2). The mean absolute relative differences were 8.2% among participants with a pre-pregnancy BMI of <25 kg/m² and 7.7% among participants with a pre-pregnancy BMI ≥ 25 kg/m².

Among 49 of the participants, 53.1% had heard of CGM previously; 34.7% had considered using it during pregnancy; 98% considered the CGM device easy to apply; 85.7% reported that CGM was less painful; and 89.8% agreed that CGM was more convenient, compared with self-monitoring via finger pricks (Table 2). Notably, 93.9% felt that CGM increased their awareness of glucose levels, and 83.7% reported that they maintained tighter dietary control. Overall, 83.7% were satisfied with CGM and accepted its use for glucose monitoring during pregnancy when the sensor was provided free of charge; 71.5% indicated a preference for CGM.

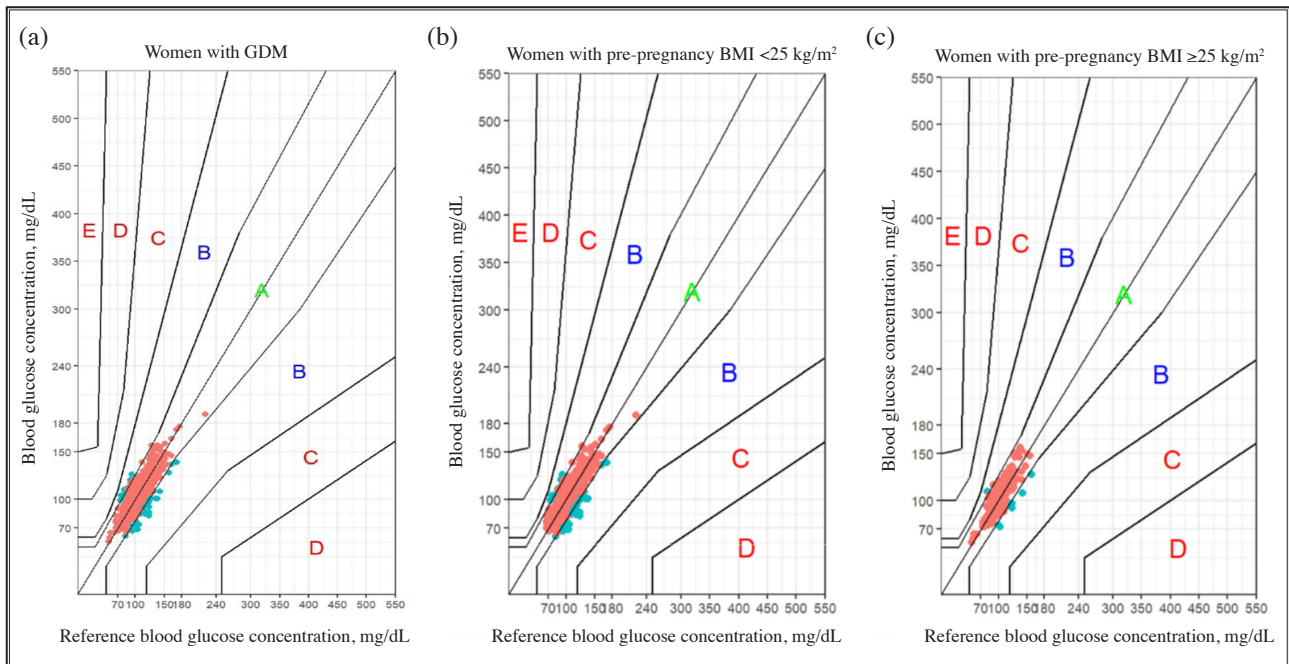


Figure 2. Parkes error grids comparing continuous glucose monitoring and self-monitoring of blood glucose measurements in (a) women with gestational diabetes mellitus (GDM) managed via diet control ($n=50$), (b) women with pre-pregnancy body mass index (BMI) $<25 \text{ kg/m}^2$ ($n=35$), and (c) women with pre-pregnancy BMI $\geq 25 \text{ kg/m}^2$ ($n=15$). Zone A includes pair measurements that are clinically accurate and have no effect on clinical action. Zone B represents altered clinical action with little or no effect on clinical outcome. Zone C represents altered clinical action that is likely to affect clinical outcome. Zone D represents altered clinical action that poses clinically significant risk. Zone E represents altered clinical action with potentially dangerous consequences.

Regarding the Glucose Monitoring Satisfaction Survey, the overall satisfaction score was 3.7 ± 0.32 , the openness score was 3.65 ± 0.53 , the emotional burden score was 2.75 ± 0.53 , the behavioural burden score was 1.94 ± 0.42 , and the worthwhileness score was 3.9 ± 0.49 . One participant developed serious adverse events (severe pre-eclampsia, abruptio placentae, and intrauterine fetal death) that were unrelated to the two monitoring methods.

Discussion

CGM measurements demonstrated good agreement with self-monitoring measurements, with high trueness (minimal systematic bias) and good precision (consistent reproducibility). According to the International Organization for Standardization 15197:2013 specifications for glucose monitoring systems, at least 99% of paired measurements must fall within zones A and B of the Parkes error grid to meet the required accuracy criteria²⁴. A study in the United States showed that 99.8% of paired measurements fell within zones A and B of the Parkes error grid (76.9% in zone A and 22.9% in zone B)²⁵. In the present study, 100% of paired measurements fell within zones A and B, indicating clinical accuracy and safety with no or little

effect on altering clinical action or outcome.

The mean absolute relative differences for various CGM systems typically range from 10% to 12%²⁶. Reported values were 12.9% in healthy male adults, 13.2% in adults with type 1 diabetes, 11.4% in adults with type 1 or type 2 diabetes, and 15.9% in women with GDM^{21,25,27,28}. In our participants with GDM, the mean absolute relative difference was 8.04%. Measurements at 2 hours postprandially provided a reasonable estimation of blood glucose levels, given the physiological time lag in glucose diffusion from capillary blood to interstitial fluid. Further research is needed to determine whether shorter or longer postprandial measurement intervals can yield a lower mean absolute relative difference and higher correlation.

Participants with pre-pregnancy BMI <25 or $\geq 25 \text{ kg/m}^2$ did not significantly differ in terms of paired measurements within zones A and B of the Parkes error grid between CGM and self-monitoring methods, consistent with a finding among women with pre-pregnancy BMI <30 or $\geq 30 \text{ kg/m}^2$ in a study²⁵. Both the mean absolute difference and Parkes error grid demonstrated similar levels

Table 2. Knowledge, application, usage, and acceptance and satisfaction of continuous glucose monitoring (CGM) among participants (n=49).

Question	No. (%) of participants				
	No	Yes			
Knowledge					
I have heard of a CGM device before	23 (46.9)	26 (53.1)			
I have considered using a CGM device for glucose monitoring during pregnancy	32 (65.3)	17 (34.7)			
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I previously had a good understanding of the CGM device	6 (12.2)	16 (32.7)	20 (40.8)	6 (12.2)	1 (2.0)
Application					
The CGM sensor was easy to apply	0	0	1 (2.0)	31 (63.3)	17 (34.7)
I did not experience pain when applying the CGM sensor to my skin	0	4 (8.2)	7 (14.3)	15 (30.6)	23 (46.9)
Applying a CGM sensor was less painful than a routine finger prick	0	2 (4.1)	5 (10.2)	9 (18.4)	33 (67.3)
Usage					
The CGM sensor was comfortable to wear	0	3 (6.1)	5 (10.2)	32 (65.3)	9 (18.4)
The CGM sensor did not interfere with my daily activities	0	3 (6.1)	6 (12.2)	23 (46.9)	17 (34.7)
Obtaining a glucose reading with the CGM sensor was more convenient than a finger prick	1 (2.0)	1 (2.0)	3 (6.1)	15 (30.6)	29 (59.2)
I used the CGM sensor to measure my glucose level more frequently than finger pricks	0	0	2 (4.1)	15 (30.6)	32 (65.3)
I had greater awareness of my glucose level when using the CGM sensor	0	0	3 (6.1)	20 (40.8)	26 (53.1)
I had tighter dietary control when using the CGM sensor	0	0	8 (16.3)	25 (51.0)	16 (32.7)
Acceptance and satisfaction					
I accept using CGM to monitor my glucose level during pregnancy	1 (2.0)	0	7 (14.3)	20 (40.8)	21 (42.9)
I would like to continue using CGM during pregnancy	0	2 (4.1)	14 (28.6)	24 (49.0)	9 (18.4)
I prefer CGM over self-monitoring of blood glucose (ie, finger prick)	1 (2.0)	5 (10.2)	8 (16.3)	19 (38.8)	16 (32.7)
Overall, I am satisfied with the CGM device	1 (2.0)	3 (6.1)	4 (8.2)	25 (51.0)	16 (32.7)
I would recommend CGM to other pregnant women	1 (2.0)	3 (6.1)	9 (18.4)	19 (38.8)	17 (34.7)
Each CGM sensor costs around \$600 in Hong Kong; I am willing to purchase the CGM sensor again	2 (4.1)	10 (20.4)	25 (51.0)	10 (20.4)	2 (4.1)

of agreement and clinical safety; however, the sample size for the subgroup analysis was small.

When the CGM sensor was provided free of charge, overall user acceptance and satisfaction were high. Most participants found the device easy and convenient to use and less painful than finger pricks; these advantages may improve adherence. Most participants reported improved glucose awareness and dietary control with CGM use. Real-time feedback may empower women to make more informed lifestyle and dietary choices to manage GDM. However, only 24.5% of participants were willing to pay for CGM, indicating that cost may be a major barrier to

continued use.

Regarding the Glucose Monitoring Satisfaction Survey, the overall satisfaction score of 3.7 and the emotional burden score of 2.75 were higher than scores reported in Western patients with type 1 diabetes, whereas the behavioural burden score of 1.94 was similar²⁹. Although CGM is generally well accepted, it may contribute to increased anxiety and frustration related to glucose control.

The present study had several limitations. The sample size was relatively small, and no formal sample size calculation was performed; thus, this pilot study provides

feasibility data only. Nonetheless, data completeness was high. The sample comprised women with GDM managed via diet control; those receiving insulin or oral hypoglycaemic agents may exhibit different agreement profiles due to medication pharmacokinetics. Both CGM and self-monitoring measurements, along with their corresponding timestamps, were self-reported and may have introduced bias. Performance and satisfaction findings associated with the FreeStyle Libre 2 sensor may not be generalisable to other CGM brands. The Parkes error grid was used to assess the clinical safety of CGM; however, it was originally developed to evaluate point-of-care glucose measurements in non-pregnant populations with diabetes and may not be fully applicable to women with GDM, for whom no venous blood reference standard was available. We did not assess other CGM-derived metrics such as time in range, time above range, hypoglycaemic episodes, or their associations with obstetric outcomes. A randomised controlled trial showed that outcomes were not improved by CGM, compared with self-monitoring, among women with GDM; however, preference for CGM was higher³⁰. This finding may be attributable to the similarly intensive glucose monitoring provided in both groups.

Conclusion

Agreement between CGM and self-monitoring measurements was good in Chinese women with GDM. CGM can be used as an adjunct to self-monitoring with finger pricks, which should be performed at least weekly to cross-check agreement. Most women with GDM accepted and were satisfied with CGM.

Contributors

CWL and WCL designed the study. CWL and

WYL acquired the data. CWL and CKW analysed the data. CWL drafted the manuscript. All authors critically revised the manuscript for important intellectual content. All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

As an editor of the journal, WL Lam was not involved in the peer review process. The other authors have disclosed no conflicts of interest.

Funding/support

This study was funded by the Kowloon Central Cluster Research Grant (reference: KCC/RC/G/2425-B01).

Data availability

All data generated or analysed during the present study are available from the corresponding author on reasonable request.

Ethics approval

This study was approved by the Central Institutional Review Board of Hospital Authority (reference: CIRB-2024-172-2). The patients were treated in accordance with the tenets of the Declaration of Helsinki. The patients provided written informed consent for all treatments and procedures and for publication.

Acknowledgement

We thank Kwong Wah Hospital Clinical Research Centre and Mr Steven Lau, Biostatistician from the Centre for Clinical Research and Biostatistics of The Chinese University of Hong Kong, for their advice.

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