OBSTETRICS

Flash glucose monitoring addition to self-monitoring of blood glucose and perinatal outcomes in gestational diabetes: a randomized controlled trial

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BACKGROUND: Self-monitoring of blood glucose represents the standard for glycemic monitoring in gestational diabetes mellitus, while the role of continuous glucose monitoring remains uncertain.

OBJECTIVE: To assess whether adjunctive flash glucose monitoring improves achievement of established self-monitored glucose targets compared with self-monitoring alone and to examine maternal and neonatal outcomes.

STUDY DESIGN: We conducted an open-label, single-center, randomized controlled trial comparing adjunctive flash glucose monitoring plus self-monitoring of blood glucose with self-monitoring of blood glucose alone. The prespecified primary outcome was the percentage of self-monitored glucose measurements within the established target range. Secondary outcomes included maternal and neonatal outcomes. Analyses followed the intention-to-treat principle.

RESULTS: A total of 205 women (median age, 32 years; median prepregnancy body mass index, 23.5 kg/m^2; median gestational age, 27 weeks) were randomized (102 to adjunctive flash glucose monitoring and 103 to self-monitoring alone). The percentage of self-monitored glucose measurements within target range was lower in the adjunctive flash monitoring group (89.5% vs 92.6%, P=.04). Median fasting and 1-hour postprandial self-monitored glucose concentrations were comparable between groups and within recommended targets. The incidence of large-for-gestational-age infants was lower in the flash monitoring group (3% vs 11%; P=.05; odds ratio, 0.27; 95% confidence interval, 0.07–0.99).

CONCLUSION: Adjunctive flash glucose monitoring did not improve glycemic outcome in this low-risk gestational diabetes population. However, it was associated with fewer large-for-gestational-age neonates, a secondary outcome that should be interpreted cautiously given the sample size and number of events.

Key words: continuous glucose monitoring (CGM), flash glucose monitoring (FGM), gestational diabetes (GDM), large-for-gestational-age (LGA), perinatal outcomes, self-monitoring of blood glucose (SMBG), small-for-gestational-age (SGA)

Introduction

Continuous glucose monitoring supports achievement of glycemic targets in pregnancies complicated by type 1 diabetes.[1,2] Moreover, it reduces the risk of large-for-gestational-age neonates and neonatal hypoglycemia.[3] In gestational diabetes mellitus (GDM), however, the benefit of continuous glucose monitoring vs self-monitoring of blood glucose for perinatal outcomes remains uncertain.[1,4] Earlier small or observational studies have suggested improvements in glycated hemoglobin and/or rates of large-for-gestational-age infants,[5–11] whereas others showed no benefit.[12–15] More recently, 5 large randomized controlled trials evaluating real-time continuous glucose monitoring yielded inconsistent effects on glycemic or perinatal outcomes,[16–20] leaving ongoing uncertainty.

To the contrary, only a few small studies have evaluated flash glucose monitoring in GDM.[5,7,8,14] Although it does not provide real-time glucose display or alerts, it is more accessible in some settings and allows on-demand review of current, past, and trend data. We therefore aimed to assess whether adjunctive flash glucose monitoring improves achievement of established self-monitored glucose targets compared with self-monitoring of blood glucose alone and examined maternal and neonatal outcomes.

Methods

Design and participants

This open-label, single-center randomized controlled trial was conducted at the tertiary medical center outpatient clinic between January 2023 and January 2025.

Eligible participants met the following inclusion criteria: age 18 to 40 years, diagnosis of GDM confirmed by an oral glucose tolerance test between the 24th and 28th gestational week, according to the criteria of the International Association of Diabetes and Pregnancy Study Groups,[21] and the willingness and ability to comply with the study protocol.

Exclusion criteria were: hemoglobin A1c >6.0% (>42.0 mmol/mol) or fasting glucose >108 mg/dL at enrollment, multiple pregnancy, systemic corticosteroid use for more than 14 days before enrollment, a history of bariatric surgery, and severe psychiatric illness requiring hospitalization within the past year. These glycemic thresholds were applied to reduce the likelihood of including women with preexisting or more pronounced dysglycemia and to include women with milder GDM phenotype, who can manage their GDM nonpharmacologically. Women with a prior history of GDM were excluded to avoid potential confounding from previous experience with glucose monitoring and glycemic management.

Randomization and interventions

Recruitment occurred during routinely scheduled outpatient diabetes visits for women newly diagnosed with GDM. For logistical reasons, randomization

0002-9378

https://doi.org/10.1016/j.ajog.2026.03.030

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AJOG at a Glance

Why was this study conducted?

Self-monitoring of blood glucose is standard care in gestational diabetes, but it remains unclear whether adding flash glucose monitoring improves glucose target achievement or pregnancy outcomes.

Key findings

The percentage of self-monitored glucose measurements within target range was slightly lower with the adjunctive flash monitoring. Fasting and postprandial capillary glucose levels were comparable between groups and within recommended targets. Adjunctive flash monitoring was associated with fewer large-for-gestational-age neonates.

What does this add to what is known?

In low-risk gestational diabetes population, adding flash glucose monitoring did not improve capillary glucose target achievement compared with self-monitoring of blood glucose alone. Still, it was associated with fewer large-for-gestational-age neonates. As this was a secondary outcome, this finding should be considered exploratory.

was performed by administrative schedule blocks (1−8 participants per block). The allocation sequence for these blocks was generated using the online tool Research Randomizer, with approximately 1:1 allocation across sessions. All follow-up visits were conducted individually. Written informed consent was obtained from each participant individually prior to study inclusion. Owing to the nature of the intervention, neither participants nor investigators were blinded to group assignments.

At baseline, participants received nutritional counseling. Recommendations included 3 main meals and 2 to 3 snacks per day, with 40% to 50% of total energy intake from carbohydrates, 30% from protein, and 20% from fats. Women were advised to distribute carbohydrate intake evenly throughout the day and to avoid meal skipping. Daily physical activity was strongly encouraged, with a recommended minimum of 30 minutes per day. Lifestyle recommendations were reinforced at each follow-up visit. All were instructed to perform 4 daily capillary blood glucose measurements: fasting and 60 minutes after each main meal using the One-Touch Verio (LifeScan, Malvern, Pennsylvania) glucose meter. Urinary ketone testing was recommended twice daily (morning and evening) to avoid excessive carbohydrate restriction, since it may increase the risk of higher dietary fat consumption, which may result in fetal overgrowth. If positive, participants were advised to increase carbohydrate intake or to adopt smaller, regularly-timed meals.[1] Weekly weight monitoring was recommended.

The intervention group received a flash glucose monitoring device (first-generation FreeStyle Libre, Abbott Diabetes Care, Alameda, California) in addition to self-monitored glucose measurements. In the intervention group, the first sensor was applied at enrollment with assistance from the study team, including guidance on device setup and connection to the LibreLink smartphone application or dedicated reader; 3% of participants used the reader due to smartphone incompatibility. Women were instructed to wear sensors continuously from enrollment until delivery and to scan at least 4 times per day, at each self-monitoring of blood glucose measurement; however, additional scans were encouraged. Each scan displayed the current glucose value, anticipated glucose trending, and a graphical display of glucose trends over the preceding hours. Participants received counseling on the interpretation of postprandial excursions with corresponding dietary or physical activity adjustments. Participants in the control group performed glucose monitoring exclusively by self-monitoring of blood glucose. Clinical visits and remote consultations alternated every 2 weeks. Self-monitored glucose values and, in the intervention group, glucose sensor data were reviewed at each contact. Therapeutic decisions, including insulin initiation and titration, depended on self-monitored glucose values in both groups.

Insulin was initiated if capillary blood glucose measurements exceeded glycemic targets on ≥3 days per week.[22] Basal insulin was initiated if fasting self-monitored glucose exceeded 95 mg/dL, whereas prandial insulin was initiated if 1-hour postprandial self-monitored glucose exceeded 140 mg/dL.[1] Fasting hyperglycemia was treated with evening Neutral Protamine Hagedorn insulin (starting dose 6−8 units) and postprandial hyperglycemia with rapid-acting insulin (lispro, starting dose 4 units before meals), with dose titration every 2 days (2−4 units). Insulin was the only glucose-lowering medication used. Glycemia was managed exclusively by the diabetes unit.

Outcomes

The primary outcome was the proportion of self-monitoring blood glucose measurements, electronically transferred from glucose meters, which were within the predefined target range. Mean fasting and postprandial glucose concentrations were also analyzed. Participants were included in the primary outcome analysis if download data were available; no minimum number of readings was prespecified. Although self-monitoring of blood glucose has limited ability to detect postprandial excursions, nocturnal hyperglycemia, or overall glycemic variability, it was selected as the primary outcome measure for several reasons. First, it remains the standard method guiding therapeutic decisions in routine clinical practice.[1,2] Second, the flash glucose monitoring device used in this study has been reported to underestimate glucose

levels, particularly overnight,[23] and its accuracy may be reduced at the beginning and end of sensor wear.[24] We hypothesized that additional insight into glucose excursions afforded by flash glucose monitoring would inform participants' daily lifestyle decisions, resulting in improved 4-point self-monitoring of blood glucose profiles.

Secondary outcomes included perinatal outcomes and flash glucose monitoring metrics. Perinatal outcomes were based on the international consensus on core outcome sets for GDM research[25] and covered both neonatal and maternal outcomes. Neonatal outcomes included birthweight, large-for-gestational-age and small-for-gestational-age neonate, gestational age at birth, preterm delivery, neonatal hypoglycemia, stillbirth, neonatal death, and jaundice requiring phototherapy treatment. Large-for-gestational-age neonate was defined as a birthweight above the 90th percentile, whereas small-for-gestational-age was defined as a birthweight below the 10th percentile. Birthweight percentiles were derived by the Perinatal Institute's GROW Centile Calculator (Gestation Network Ltd, UK; version 2.1.6.1), following the approach used in the Continuous Glucose Monitoring in Women With Type 1 Diabetes in Pregnancy (CONCEPTT) trial.[26] Neonatal hypoglycemia was defined as a blood glucose concentration <47 mg/dL.[27] Maternal outcomes included hypertensive disorders in pregnancy (gestational hypertension, preeclampsia, and eclampsia), initiation of insulin therapy, gestational weight gain, mode of delivery, perineal trauma, and the need for blood transfusion. Gestational weight gain was categorized as inadequate, adequate, or excessive, based on prepregnancy body mass index.[28]

The flash glucose monitoring metrics assessed were mean glucose concentration, pregnancy-specific time in range (percentage of time spent with glucose between 63 and 140 mg/dL), time above that range, and time below that range.[1]

At the end of the study, participants completed an anonymous, study-specific satisfaction questionnaire evaluating their experiences with the flash glucose monitoring use.

Statistical analysis

Sample size was determined using the between-group difference reported in the Flash glucose monitoring in gestational diabetes mellitus (FLAMINGO) trial,[7] which represented the most comparable randomized evidence available at the time of study design. In that study, mean postprandial glycemia was 113.94 mg/dL (standard deviation, 8.13) in the intervention group and 109.52 mg/dL (standard deviation, 6.36) in the control group. Using this effect size, a total of 94 participants (47 per group) were estimated to provide 80% power at a 2-sided alpha level of 0.05. Assuming an attrition rate of approximately 30% due to withdrawal, or incomplete follow-up, the recruitment target was increased to 135 participants. In addition, participants in the present study exhibited low-risk GDM phenotype. Given the potentially smaller achievable between-group difference in a population with milder hyperglycemia, we conservatively increased the planned sample size to approximately 200 participants to ensure adequate statistical power.

Statistical analyses were performed using SPSS, version 27.0 (IBM Corp., Armonk, NY) and Python 3.12.7 in Jupyter Notebook (Anaconda Inc, Austin, TX). Normality of continuous variables was assessed using the Kolmogorov-Smirnov test. Normally distributed variables were compared using the Student's *t* test; non-normally distributed variables were analyzed using the Mann-Whitney U test. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. The primary outcome was analyzed on an intention-to-treat basis. As this was a randomized controlled trial, randomization was expected to balance measured and unmeasured confounders between groups; therefore, analyses were conducted unadjusted. Multivariable adjustment was not performed because of the limited number of neonatal outcome events and the risk of model overfitting. A 2-sided *P* value <.05 was considered statistically significant. Missing data were not imputed; analyses were performed on available cases, and the number of participants included in each analysis was reported in the tables.

Ethics

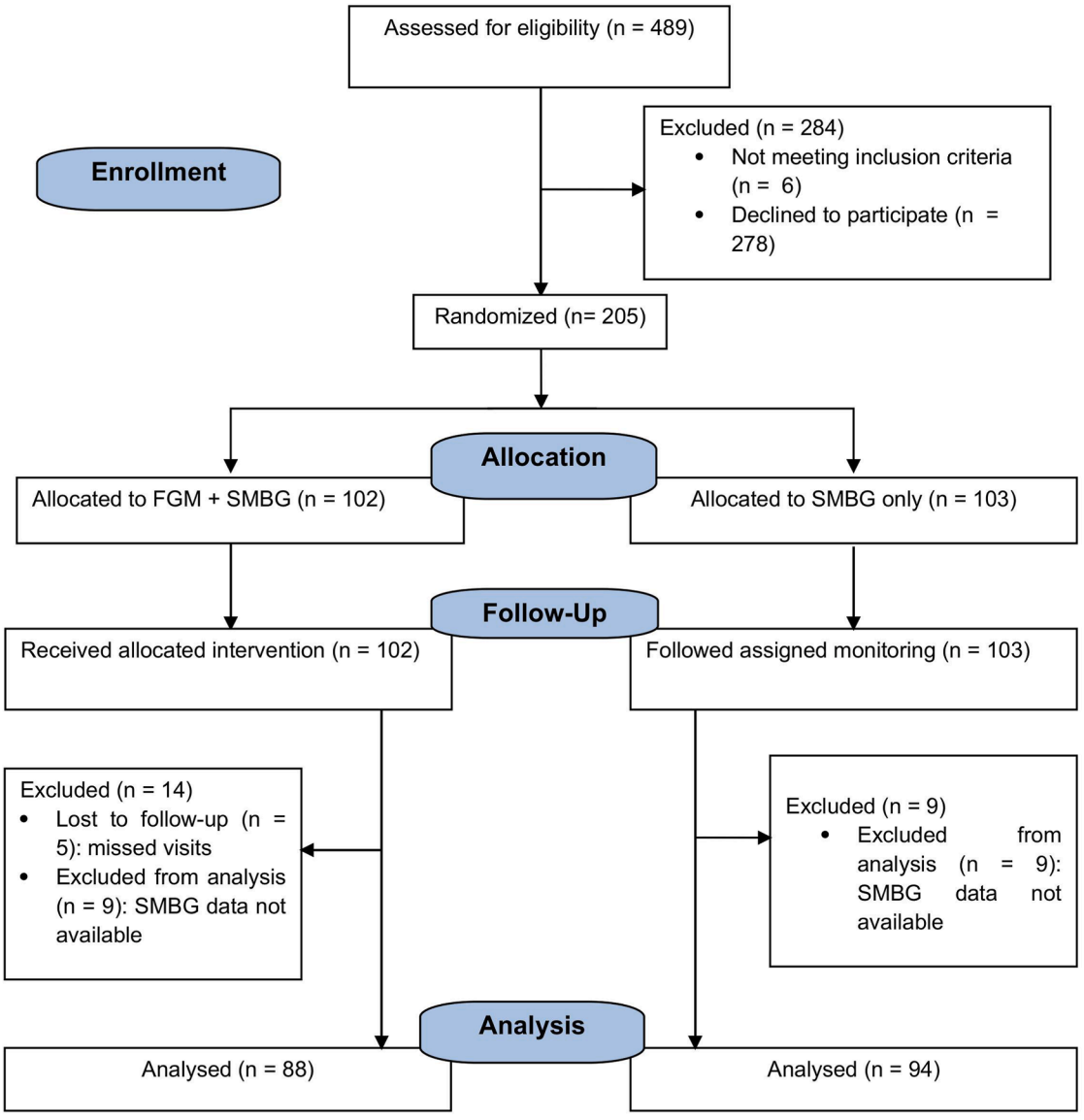
The study was approved by the National Medical Ethics Committee (reference number: 0120-449/2021/4) and conducted in accordance with the Declaration of Helsinki. The trial was registered retrospectively at ClinicalTrials.gov (Identifier: NCT06774404). The full study protocol was approved by the National Medical Ethics Committee before participant enrollment and remained unchanged after trial registration.

Results

From 489 women assessed for eligibility, 205 were randomized to adjunctive flash glucose monitoring plus self-monitoring of blood glucose (intervention group, n=102) or self-monitoring alone (control group, n=103) (Figure). Perinatal outcome data were available for 198 participants (99%), and self-monitored glucose data were obtained from 182 participants (91%), 9 missing from each group. Participants without available self-monitored glucose data were more likely to be active smokers (28% vs 6%, *P*<.01) and more likely to report occasional financial difficulties (27% vs 9%, *P*=.05), compared to those who provided self-monitored glucose data (Supplemental Table 1). Flash glucose monitoring data were available for 94 participants (97%); in 3% of participants, data could not be retrieved.

At baseline, there were no considerable differences between the groups (Table 1). In both groups, 66% of women met diagnostic criteria based on elevated fasting glucose values (Table 1). Preexisting medical conditions were reported in 31% of participants overall. The most common were polycystic ovary syndrome (n=16), thyroid disorders (n=16), asthma (n=10), endometriosis (n=5), and inflammatory bowel disease (n=3).

FIGURE
Consolidated Standards of Reporting Trials (CONSORT) flow diagram for the primary outcome



Glycemic outcomes

The intervention and control groups did not differ in the average number of self-monitored blood glucose measurements. The percentage of measurements within target range was lower in the intervention group than in the control group (89.5% vs 92.6%, *P*=.04; achieved power, 0.63) (Table 2, Supplemental Figure 1). However, there were no differences in median fasting or postprandial glucose concentrations between groups (Table 2).

Flash glucose monitoring–derived metrics showed a mean sensor glucose of 90 (86–94) mg/dL and pregnancy-specific time in range of 96% (94–98). Women scanned 4.0 (2.0–5.0) times per day (Table 2).

Perinatal outcomes

The overall incidence of large-for-gestational-age neonates was low; the rate was numerically lower in the intervention group than in the control group (3% vs 11%; *P*=.05; odds ratio, 0.27; 95% confidence interval, 0.07–0.99) (Table 3, Supplemental Figure 2). The percentage of small-for-gestational-age neonates was similar in both groups (Table 3). Birthweight <2500 g was observed in 5 infants overall, and none had a birthweight below 2000 g. Polyhydramnios was reported in 5 cases (n=1 in the intervention group and n=4 in the control group). One intrauterine fetal demise occurred at 39 weeks of gestation in the intervention group; the cause remained unidentified.

The overall prevalence of maternal complications was low. Fourteen women (7%) received insulin treatment. All women received basal insulin; 3

TABLE 1
Baseline characteristics of study participants by randomization group and overall

Variable	All (n=200)	Intervention group (n=97)	Control group (n=103)	*P* value
Maternal age (y)	32 [28–35]	31 [28–34.5]	32 [29–36]	.26[a]
Parity[b,c]				.94[a]
Nulliparous, n (%)	119 (66)	59 (67)	60 (65)	
Multiparous, n (%)	61 (34)	29 (33)	32 (35)	
Prepregnancy BMI (kg/m^2)	23.5 [21.3–26.8]	23.5 [21.4–26.8]	23.5 [21.2–26.8]	.94[a]
BMI category prepregnancy				.99[d]
Underweight, n (%)	4 (2)	2 (1)	2 (1)	
Normal range, n (%)	114 (57)	55 (57)	59 (57)	
Overweight, n (%)	54 (27)	28 (29)	26 (25)	
Obesity, n (%)	28 (14)	12 (12)	16 (15)	
OGTT glucose concentration (mg/dL)				
0 min	95 [92–99]	95 [92–97]	94 [92–99]	.41[a]
60 min	193 [187–203]	196 [189–205]	192 [187–203]	.73[a]
120 min	166 [158–175]	167 [158–178]	166 [158–175]	.85[a]
Gestational age at inclusion (wks)	27 [26–28]	26 [26–28]	27 [26–28]	.93[a]
HbA1c at baseline (mmol/mol)	30 [28–32]	31 [28–32]	30 [28–32]	.19[a]
HbA1c at baseline (%)	4.9 [4.7–5.1]	5.0 [4.7–5.1]	4.9 [4.7–5.1]	
Family history of diabetes, n (%)	102 (51)	55 (57)	47 (45)	.12[e]
Active smoking at inclusion, n (%)	15 (7.5)	7 (7)	8 (8)	.88[e]
Preexisting comorbidity, n (%)	62 (31)	31 (32)	31 (30)	.78[e]
Education level[b,c]				.96[d]
Primary or less, n (%)	1 (0.6)	0 (0)	1 (1)	
Secondary education, n (%)	48 (27)	25 (28)	23 (25)	
Tertiary education, n (%)	131 (72)	63 (72)	68 (74)	
Self-reported financial situation[b,c]				.73[e]
No financial difficulties, n (%)	161 (89)	78 (89)	83 (90)	
Occasional financial difficulties, n (%)	19 (11)	10 (11)	9 (10)	

Data are expressed as median [interquartile range], mean (±SD), or number (percentage), as appropriate.

BMI, body mass index; *HbA1c*, hemoglobin A1c; *OGTT*, oral glucose tolerance test.

[a] *P* values represent comparisons between the 2 groups using the Mann-Whitney *U* test for continuous variables used as appropriate; [b] Data available for 180 women (88 in the FGM+SMBG group and 92 in the SMBG-only group); [c] Preexisting comorbidities included polycystic ovary syndrome, thyroid disorders, asthma, endometriosis, inflammatory bowel disease, psoriasis, celiac disease, cardiac conditions (arrhythmia, mitral valve prolapse, aortic regurgitation, and congenital heart defects), psychiatric disorders (depression), epilepsy, prolactinoma, central diabetes insipidus, gastroesophageal reflux disease, anemia, and prior thromboembolic events; [d] *P* values represent comparisons between the 2 groups using the Fisher's 2-sided test used as appropriate; [e] *P* values represent comparisons between the 2 groups using the $\chi 2$ test for categorical variables used as appropriate.

required additional prandial insulin, all in the intervention group (Table 3).

A total of 108 participants (53% in the intervention group and 55% in the control group) completed the anonymous patient satisfaction questionnaire. Participants in the intervention group reported low perceived device burden and indicated a preference for flash glucose monitoring in future pregnancies (Supplemental Table 2).

Comment

Principal findings

In this single-center randomized trial, adjunctive flash glucose monitoring did not improve achievement of self-monitored glucose targets compared with self-monitoring of blood glucose alone. Fasting and postprandial capillary glucose concentrations were comparable between groups and remained within recommended target ranges, although the percentage of self-monitored glucose measurements within target range was lower in the adjunctive flash monitoring group. A lower incidence of large-for-

TABLE 2
Glycemic outcomes by randomization group and overall

Variable	All (n=200)	Intervention group (n=97)	Control group (n=103)	*P* value
HbA1c at the last visit (mmol/mol)	32 [29–34]	32 [30–34]	32 [29–34]	.31[a]
HbA1c at the last visit (%)	5.1 [4.8–5.3]	5.1 [4.9–5.3]	5.1 [4.8–5.3]	
Change in HbA1c (mmol/mol)	T3 [0–3]	1 [0–3]	2 [0–3]	.32[a]
Change in HbA1c (%)	0.1 [0.0–0.3]	0.1 [0.0–0.3]	0.2 [0.0–0.3]	
Self-monitoring of blood glucose parameters	All (n=182)	Intervention group (n=88)	Control group (n=94)	
Median fasting glucose (mg/dL)	86 [83–92]	86 [83–92]	86 [81–95]	.27[a]
Median postprandial glucose (mg/dL)	112 [104–117]	113 [104–119]	110 [106–115]	.12[a]
% fasting glucose <95 mg/dL	90.7 [75.0–97.1]	87.8 [72.5–96.3]	92.6 [76.0–97.4]	.11[a]
% postprandial glucose <140 mg/dL	94.2 [89.1–98]	93.0 [87.5–97.7]	95.1 [90.7–97.5]	.07[a]
% of measurements in target overall	91.3 [86.8–96.0]	89.5 [85.2–95.2]	92.6 [87.4–96.4]	.04[a]
Number of overall measurements (n)	260 [181–306]	274 [187–310]	240 [181–298]	.18[a]
Number of measurements per day (n)	3.5 [2.9–3.9]	3.6 [2.8–3.9]	3.4 [2.9–3.8]	.40[a]
Proportion of monitored days (%)	95 [83–98]	95 [90–98]	93 [79–98]	.15[a]
Daily monitoring coverage (%)	79 [72–97]	83 [58–92]	74 [60–87]	.08[a]
Flash glucose monitoring parameters from randomization to delivery		Intervention group (n=94)		
Mean average sensor glucose (mg/dL)	NA	90 [86–94]	NA	
Time spent between 63 and 140 mg/dL (%)	NA	96.2 [94.4–98.2]	NA	
Time spent above 140 mg/dL (%)	NA	0.7 [0.2–1.5]	NA	
Time spent below 63 mg/dL (%)	NA	2.5 [0.9–4.1]	NA	
Number of scans per day (n)	NA	4.0 [2.0–5.0]	NA	

Proportion of monitored days: % of days with ≥1 recorded glucose value from education to delivery; Daily monitoring coverage: % of recorded measurements relative to 4 recommended daily measurements (fasting and 3 1-hour postprandial). Data are expressed as median [interquartile range]. All *P* values represent comparisons between groups using the Mann-Whitney U test.

HbA1c, hemoglobin A1c; *NA*, not applicable.

[a] *P* values stand for comparisons between groups using the Mann-Whitney U test for continuous variables, as appropriate.

gestational-age neonates was observed in the intervention group; however, this secondary finding should be considered exploratory given the limited number of events.

Results in the context of what is known

Although blood glucose target achievement was higher in the control group, the absolute difference was small, and the achieved post hoc statistical power was modest. Importantly, mean fasting and postprandial self-monitored glucose concentrations in both groups were within recommended target ranges, suggesting that the observed difference is unlikely to be clinically meaningful. Similarly, in 4 of 5 largest trials, exploring potential benefits of continuous glucose sensor systems in GDM, no increase in time spent in target range was observed with sensor use.[16,17,19,20] Conversely, in the study by Valent et al,[18] that included participants with high-risk GDM (average prepregnancy body mass index 33 kg/m^2, 50% of women with early GDM diagnosis, 82% receiving insulin therapy), time spent in pregnancy target range was 5% higher in the continuous glucose monitoring group. In addition, in the subgroup of participants with glucose-lowering medication from the glycaemic control and pregnancy outcomes with real-time continuous glucose monitoring in gestational diabetes (GRACE) study,[16] higher time in range in the continuous glucose monitoring group was observed. Interestingly, there was no difference in time in range detected in the STEADY SUGAR study despite the high-risk GDM population (median prepregnancy body mass index 37 kg/m^2, early GDM diagnosis, 80% glucose-lowering medication use).[20] However, in that study, women with continuous glucose monitoring were less likely to spend more than 25% of time above the glucose target range. Participants in our cohort, however, were characterized by predominantly normal prepregnancy body mass index, low rates of excessive gestational weight gain, and a limited need for pharmacotherapy. These features reflect a low-risk and well-controlled gestational diabetes

TABLE 3
Perinatal outcomes by randomization group and overall

Perinatal outcomes	All (n=198)	Intervention group (n=96)	Control group (n=102)	*P* value
Maternal outcomes				
Total gestational weight gain (kg)	10 [6–13]	10 [6–12]	10 [7–14]	.18[a]
Gestational weight gain category				.60[b]
Adequate GWG, n (%)	79 (40)	40 (41)	39 (38)	
Insufficient GWG, n (%)	80 (40)	40 (41)	40 (39)	
Excessive GWG, n (%)	41 (20)	17 (18)	24 (23)	
Insulin therapy, n (%)	14 (7)	10 (10)	4 (4)	.10[c]
Basal-acting insulin, n (%)	14 (7)	10 (10)	4 (4)	.10[c]
Basal-acting insulin, IU/day	11 [10–16]	10 [8–20]	13 [11–16]	.75[a]
Rapid-acting insulin, n (%)	3 (2)	3 (3)	0 (0)	.11[c]
Rapid-acting insulin, IU/day	10 [8–10]	10 [8–10]	0	/
Gestational age at start of insulin therapy, wks	33 [31–34]	33 [30–34]	35 [32–36]	.18[a]
Gestational hypertension, n (%)	9 (5)	6 (6)	3 (3)	.32[c]
Preeclampsia, n (%)	2 (1)	1 (1)	1 (1)	1.0[c]
Postpartum hypertension, n (%)	10 (5)	6 (6)	4 (4)	.53[c]
Gestational age at delivery (wks)	39 [38–40]	39 [38–40]	39 [38–40]	.55[a]
Preterm birth (<37th week)	25 (13)	13 (13)	12 (11)	.87[b]
Induction of labor, n (%)	62 (31)	30 (32)	32 (31)	1.0[c]
Mode of delivery				
Vaginal delivery, n (%)	151 (77)	74 (79)	77 (75)	.87[c]
Cesarean section, n (%)	46 (24)	20 (21)	26 (25)	.50[c]
Maternal birth injuries (all), n (%)	47 (24)	28 (29)	19 (19)	.1[c]
Perineal laceration >grade 2	0	0	0	/
Need for blood transfusion, n (%)	2 (1)	1 (1)	1 (1)	1.0[c]
Shoulder dystocia, n (%)	1 (0.5)	1 (1)	0	.49[a]
Neonatal outcomes				
Birthweight (g)	3376 [3020–3698]	3405 [3005–3692]	3355 [3045–3700]	.72[a]
Birthweight, customized percentile (%)	46.5±27.8	42.3±28.3	48.5±30.1	.45[a]
Birthweight, national percentile (%)	52.4±27.9	51.9±27.5	52.8±28.3	.88[a]
Birth length, cm	51.0 [50.0–52.0]	51.0 [49.0–52.0]	51.0 [50.0–53.0]	.42[a]
Apgar score				
1 min	9 [9–9]	9 [9–9]	9 [9–9]	.50[a]
5 min	9 [9–9]	9 [9–9]	9 [9–9]	.57[a]
10 min	10 [9.5–10]	10 [10–10]	10 [9–10]	.26[a]
Large for gestational age (>90th percentile), n (%)	14 (7)	3 (3)	11 (11)	.05[c]
Birthweight >4000 g	17 (9)	5 (5)	12 (12)	.13[c]
Small for gestational age (<10th percentile), n (%)	30 (15)	15 (15)	15 (15)	1.0[c]
Extreme small for gestational age (<fifth percentile), n (%)	13 (7)	7 (7)	6 (6)	.78[c]
Jaundice, n (%)	16 (8)	10 (11)	6 (6)	.30[c]

(continued)

TABLE 3
Perinatal outcomes by randomization group and overall *(continued)*

Perinatal outcomes	All (n=198)	Intervention group (n=96)	Control group (n=102)	*P* value
Newborn hypoglycemia, n (%)	0	0	0	/
NICU admission, n (%)	4 (2)	1 (1)	3 (3)	.62[c]
Stillbirth, n (%)	1 (0.5)	1 (1)	0	.49[c]
Neonatal death, n (%)	0	0	0	/

Gestational weight gain category as per the Institute of Medicine guidelines. Birthweight, customized percentile (%) using Perinatal Institute's GROW Centile calculator. Data are expressed as median [interquartile range], mean (±SD), or number (percentage), as appropriate.

GWG, gestational weight gain; *NICU,* neonatal intensive care unit.

[a] *P* values stand for comparisons between groups using the Mann-Whitney U test for continuous variables, as appropriate; [b] *P* values stand for comparisons between groups using the χ^2 test for categorical variables used, as appropriate; [c] *P* values stand for comparisons between groups using the Fisher's 2-sided test, as appropriate.

phenotype, in which the potential for further improvement in glucose target achievement may have been inherently limited. Altogether, these data suggest that continuous monitoring systems may be particularly useful in high-risk GDM populations.

Of note, in our study, a lower incidence of large-for-gestational-age neonates was observed in the intervention group despite the lack of demonstrated glycemic benefit and low-risk GDM population. This finding suggests that flash glucose feedback may influence dietary and lifestyle behaviors in ways not captured by routine self-monitoring of blood glucose, as shown in previous studies,[7,13] for example, by decreasing carbohydrate intake. However, given the limited number of events and the secondary nature of this outcome in our trial, this finding should be considered hypothesis-generating rather than definitive evidence of clinical benefit and requires confirmation in adequately powered trials, specifically designed to evaluate these endpoints. Our observation is, however, similar to findings from GRACE[16] and STEADY SUGAR studies,[20] both of which reported reduced rates of large-for-gestational-age neonates in association with continuous glucose monitoring despite similar glycemic parameters between the groups. In contrast, DipGluMo[17] found no differences in perinatal outcomes, underscoring heterogeneity in study populations and management strategies. A possible explanation is the intensive blood glucose monitoring in its control group (6 measurements daily), exceeding that of comparable studies and potentially improving outcomes.[17]

Participants in our intervention group scanned on average only 4 times daily despite encouragement to scan more frequently. Although lower than levels shown effective in nonpregnant diabetes populations,[29] this engagement may have been sufficient in GDM, where glucose levels and excursions are typically less pronounced. The unexpectedly low scan frequency, despite repeated encouragement, raises concerns about effective engagement with real-time glucose monitoring in GDM. As the degree of interaction with sensor data is less apparent in this setting, it may nonetheless substantially influence glycemic and perinatal outcomes.

The incidence of small-for-gestational-age neonates was similar between groups in our cohort, but overall rates were higher than expected. However, the incidence of extreme SGA (<fifth percentile) was low, and only a small number of infants had birthweight <2500 g, with none below 2000 g. Comparable observations have been reported in other trials.[16,17] As no between-group difference was observed, this finding does not appear to be related to the intervention but highlights the importance of individualized glycemic management in generally mild and well-controlled GDM.

Average sensor glucose was lower in our intervention group than those reported in recent randomized trials[16–20] and was comparable to values described in women with normal glucose tolerance during pregnancy.[30,31] However, direct comparisons should be made cautiously, as differences in population characteristics, treatment strategies, and monitoring devices may influence reported metrics. In particular, studies evaluating the device used in our trial during pregnancy have reported generally good agreement with capillary measurements,[32,33] but occasional underestimation of glucose values has also been described.[34,35] Although therapeutic decisions in our trial were based on capillary glucose values, thereby minimizing potential clinical impact of sensor underestimation, device-related variability should be considered when comparing sensor-derived metrics across studies.

Reported satisfaction with flash glucose monitoring use was high in our cohort, similarly to previously reported.[5,6,36] However, the relatively low response rate limits the interpretation of these findings substantially.

Clinical implications

Self-monitoring of blood glucose remains the cornerstone of GDM management, as reflected also by the latest guidelines[1] and international consensus statement.[2] In our low-risk population, adjunctive flash glucose monitoring did not improve the attainment of established self-monitored glycemic targets. Although a lower incidence of large-for-gestational-age neonates was noted in the intervention group, this secondary finding should be interpreted cautiously.

Research implications

Further research is needed to define sensor-derived glycemic targets associated with optimal perinatal outcomes, including acceptable time above target range and their relevance in early-diagnosed GDM. More broadly, additional studies should evaluate the potential of glucose sensor technology in reducing the burden of GDM across the continuum of care, from diagnosis through pregnancy and into the postpartum period, particularly in populations facing socioeconomic challenges.

Strengths and limitations

Our study has certain strengths. The trial included a well-characterized and relatively homogeneous cohort of women diagnosed with GDM between 24 and 28 weeks of gestation, all of whom had normal glycemic parameters in early pregnancy. This approach minimized inclusion of women with previously unrecognized prediabetes or overt diabetes and reduced diagnostic heterogeneity related to mildly elevated fasting glucose in early pregnancy.[37] The randomized design reduced the risk of selection bias and supported internal validity. The intervention was initiated from GDM diagnosis and continued until delivery, allowing assessment of glucose monitoring throughout routine clinical care. In addition, flash glucose monitoring is widely used in contemporary diabetes management, which enhances the clinical relevance of the findings. The requirement for active scanning to obtain glucose data also enabled actual device engagement assessment.

This study has several limitations. First, the primary glycemic outcome was based on capillary glucose measurements obtained through self-monitoring. However, this approach may not fully capture glycemic patterns detectable with flash glucose monitoring and may thus be less suitable for detecting potential benefits. Conversely, sensor-derived glycemic outcomes may be affected by usually intermittent sensor use in the control group, potentially biasing glycemic parameters toward more favorable results. Second, in our study, neither participants nor investigators were blinded to group allocation, which may have influenced behavior, particularly in the intervention group. Third, approximately 10% of self-monitored glucose data were missing, however, with similar proportions in both groups, reducing concern for differential attrition between treatment arms. Nevertheless, missing glucose data were more common among participants who were active smokers and those reporting financial difficulties. This suggests that missingness may not have been entirely random and may reflect underlying socioeconomic or behavioral factors associated with study engagement. Although the overall proportion of missing data was modest, we cannot exclude the possibility that analyses based on available data may slightly over-represent participants with greater health engagement or socioeconomic stability. Fourth, participants assigned to flash glucose monitoring received additional education on the interpretation of sensor data, which may have reinforced behavioral change beyond the effect of glucose monitoring itself. Fifth, the absence of documented neonatal hypoglycemia likely reflects local selective screening practices rather than a true absence of biochemical hypoglycemia. Also, although randomization minimizes confounding, the relatively small number of events for certain neonatal outcomes precluded adjusted analyses, and residual confounding cannot be entirely excluded. Finally, participants were recruited from a single tertiary center and represented a relatively homogeneous population, characterized by high educational attainment, stable socioeconomic conditions, and predominantly normal prepregnancy body mass index, which may limit generalizability to populations with higher baseline metabolic risk. At the same time, the majority of women treated at our[38] and some other centers[39–41] represent a lower-risk GDM population, so our results may also be relevant in everyday clinical practice.

Conclusion

In this randomized trial, adjunctive flash glucose monitoring did not improve the achievement of established self-monitored glucose targets. Although the incidence of large-for-gestational-age neonates was numerically lower in the intervention group, this secondary finding should be interpreted cautiously given the small number of events. The role of flash glucose monitoring in routine GDM care remains to be defined and will depend on clear evidence regarding clinically meaningful sensor-derived glucose targets. ■

References

1. American Diabetes Association Professional Practice Committee for Diabetes*. 15. Management of diabetes in pregnancy: standards of care in diabetes-2026. Diabetes Care 2026;49(Supplement_1):S321–38.
2. Benhalima K, Durnwald C, Sweeting A, et al. Application of continuous glucose monitoring and automated insulin delivery technologies for pregnant women with type 1, type 2, or gestational diabetes: an international consensus statement. Lancet Diabetes Endocrinol 2026;14:157–77.
3. Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre International randomised controlled trial. Lancet 2017;390:2347–59.
4. Burk J, Ross GP, Hernandez TL, Colagiuri S, Sweeting A. Evidence for improved glucose metrics and perinatal outcomes with continuous glucose monitoring compared to self-monitoring in diabetes during pregnancy. Am J Obstet Gynecol 2025;233:162–75.
5. Won S, Kim HJ, Park JY, et al. Quality of life in women with gestational diabetes mellitus and treatment satisfaction upon intermittently scanned continuous glucose monitoring. J Korean Med Sci 2025;40:e46.
6. Bastobbe S, Heimann Y, Schleußner E, Groten T, Weschenfelder F. Using flash glucose monitoring in pregnancies in routine care of patients with gestational diabetes mellitus: a pilot study. Acta Diabetol 2023;60:697–704.
7. Majewska A, Stanirowski PJ, Tatur J, et al. Flash glucose monitoring in gestational diabetes mellitus (FLAMINGO): a randomised controlled trial. Acta Diabetol 2023;60:1171–7.
8. Paramasivam SS, Chinna K, Singh AKK, et al. Continuous glucose monitoring results in lower HbA_{1c} in Malaysian women with insulin-treated gestational diabetes: a randomized controlled trial. Diabet Med 2018;35:1118–29.
9. Lai M, Weng J, Yang J, et al. Effect of continuous glucose monitoring compared with self-monitoring of blood glucose in gestational diabetes patients with HbA1c<6%: a randomized controlled trial. Front Endocrinol 2023;14:1174239.
10. Yu F, Lv L, Liang Z, et al. Continuous glucose monitoring effects on maternal glycemic control and pregnancy outcomes in patients with gestational diabetes mellitus: a

prospective cohort study. J Clin Endocrinol Metab 2014;99:4674–82.
11. Liang X, Fu Y, Lu S, et al. Continuous glucose monitoring-derived glycemic metrics and adverse pregnancy outcomes among women with gestational diabetes: a prospective cohort study. Lancet Reg Health West Pac 2023;39:100823.
12. Wei Q, Sun Z, Yang Y, Yu H, Ding H, Wang S. Effect of a CGMS and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: a randomized controlled trial. Sci Rep 2016;6:19920.
13. Alfadhli E, Osman E, Basri T. Use of a real time continuous glucose monitoring system as an educational tool for patients with gestational diabetes. Diabetol Metab Syndr 2016;8:48.
14. Voormolen DN, DeVries JH, Sanson RME, et al. Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): a multicentre randomized controlled trial. Diabetes Obes Metab 2018;20:1894–902.
15. Scifres CM, Mead-Harvey C, Nadeau H, et al. Intensive glycemic control in gestational diabetes mellitus: a randomized controlled clinical feasibility trial. Am J Obstet Gynecol MFM 2019;1:100050.
16. Linder T, Dressler-Steinbach I, Wegener S, et al. Glycaemic control and pregnancy outcomes with real-time continuous glucose monitoring in gestational diabetes (GRACE): an open-label, multicentre, multinational, randomised controlled trial. Lancet Diabetes Endocrinol 2026;14:50–61.
17. Amylidi-Mohr S, Zennaro G, Schneider S, Raio L, Mosimann B, Surbek D. Continuous glucose monitoring in the management of gestational diabetes in Switzerland (DipGluMo): an open-label, single-centre, randomised, controlled trial. Lancet Diabetes Endocrinol 2025;13:591–9.
18. Valent AM, Rickert M, Pagan CH, Ward L, Dunn E, Rincon M. Real-time continuous glucose monitoring in pregnancies with gestational diabetes: a randomized controlled trial. Diabetes Care 2025;48:1581–8.
19. Ehrhardt N, Fonda SJ, Mandava P, Abdalla G, Fay E. A randomized controlled trial of real-time continuous glucose monitoring (RT-CGM) for self-management of gestational diabetes. Am J Obstet Gynecol MFM 2026;8:101878.
20. Elkind-Hirsch K, Armatta M, Griffen C, et al. Continuous glucose monitoring in early gestational diabetes improves maternal and neonatal outcomes—The steady sugar trial. Diabetes Obes Metab 2026;28:691–700.
21. International Association of Diabetes and Pregnancy Study Groups Consensus Panel. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care 2010;33:676–82.
22. American Diabetes Association. 13. Management of diabetes in pregnancy: standards of medical care in Diabetes—2018. Diabetes Care 2018;41(Supplement_1):S137–43.
23. Fokkert MJ, van Dijk PR, Edens MA, et al. Performance of the FreeStyle libre flash glucose monitoring system in patients with type 1 and 2 diabetes mellitus. BMJ Open Diabetes Res Care 2017;5:e000320.
24. Tsoukas M, Rutkowski J, El-Fathi A, et al. Accuracy of FreeStyle libre in adults with type 1 diabetes: the effect of sensor age. Diabetes Technol Ther 2020;22:203–7.
25. Egan AM, Bogdanet D, Griffin TP, et al. A core outcome set for studies of gestational diabetes mellitus prevention and treatment. Diabetologia 2020;63:1120–7.
26. Meek CL, Corcoy R, Asztalos E, et al. Which growth standards should be used to identify large- and small-for-gestational age infants of mothers with type 1 diabetes? A pre-specified analysis of the CONCEPTT trial. BMC Pregnancy Childbirth 2021;21:96.
27. McKinlay CJD, Alsweiler JM, Ansell JM, et al. Neonatal glycemia and neurodevelopmental outcomes at 2 years. N Engl J Med 2015;373:1507–18.
28. Gilmore LA, Redman LM. Weight gain in pregnancy and application of the 2009 IOM guidelines: toward a uniform approach. Obesity (Silver Spring) 2015;23:507–11.
29. Lameijer A, Lommerde N, Dunn TC, et al. Flash glucose monitoring in the Netherlands: increased monitoring frequency is associated with improvement of glycemic parameters. Diabetes Res Clin Pract 2021;177:108897.
30. Durnwald C, Beck RW, Li Z, et al. Continuous glucose monitoring—derived differences in pregnancies with and without adverse perinatal outcomes. Obstet Gynecol 2024;144:684–96.
31. Carlson AL, Beck RW, Li Z, et al. Glucose levels measured with continuous glucose monitoring in uncomplicated pregnancies. BMJ Open Diab Res Care 2024;12:e003989.
32. Scott EM, Bilous RW, Kautzky-Willer A. Accuracy, user acceptability, and safety evaluation for the FreeStyle libre flash glucose monitoring system when used by pregnant women with diabetes. Diabetes Technol Ther 2018;20:180–8.
33. Lyu L, Huang Y-L, Huang Y, Wu Z-Y, Ping F, Li Y-X. Performance of flash continuous glucose monitoring and glycemic marker correlations in Chinese pregnant women with non-type 1 diabetes. World J Diabetes 2025;16:106967.
34. Heindrichs A, Radermecker R, Paquot N, Philips J-C. Evaluation of the accuracy of FreeStyle® Libre™ during gestational diabetes: is this device acceptable for decision making? Acta Diabetol 2020;57:1519–22.
35. Sola-Gazagnes A, Faucher P, Jacqueminet S, et al. Disagreement between capillary blood glucose and flash glucose monitoring sensor can lead to inadequate treatment adjustments during pregnancy. Diabetes Metab 2020;46:158–63.
36. Pikee S, Khushbu K, Anupam P, Manju P, Sachin J. New innovation: use of flash glucose monitoring for evaluating glycaemic variability, patient satisfaction and clinical utility in pregnant women with diabetes. J Obstet Gynecol India 2021;71:136–42.
37. Raets L, Beunen K, Benhalima K. Screening for gestational diabetes mellitus in early pregnancy: what is the evidence? J Clin Med 2021;10:1257.
38. Munda A, Indihar BŠ, Okanovič G, Zorko K, Steblovnik L, Barlovič DP. Maternal and perinatal outcomes during the COVID-19 epidemic in pregnancies complicated by gestational diabetes. Slovenian J Public Health 2023;62:22–9.
39. Zhang Y, Chen L, Ouyang Y, et al. A new classification method for gestational diabetes mellitus: a study on the relationship between abnormal blood glucose values at different time points in oral glucose tolerance test and adverse maternal and neonatal outcomes in pregnant women with gestational diabetes mellitus. AJOG Glob Rep 2024;4:100390.
40. Eleftheriades M, Chatzakis C, Papachatzopoulou E, et al. Prediction of insulin treatment in women with gestational diabetes mellitus. Nutr Diabetes 2021;11:30.
41. Saros L, Vahlberg T, Pellonperä O, Tertti K, Laitinen K. Diet intake and adherence to recommendations in women with gestational diabetes mellitus. Eur J Clin Nutr 2025;79:676–84.

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Received Dec. 29, 2025; revised March 23, 2026; accepted March 26, 2026.

The authors report no conflict of interest.

The research was supported by the University Medical Center Ljubljana through 2 tertiary institutional research projects: number 20230134 and number 20240251. No other external funding source, company, or organization had any role in the design, conduct, analysis, or reporting of this study.

A short oral presentation of this study was given at the Annual Meeting of the European Association for the Study of Diabetes (EASD), on September 17, 2025 in Vienna, Austria.

Date of registration: December 4, 2024.

Clinical trial identification number: NCT06774404.

URL of the registration site: https://clinicaltrials.gov/study/NCT06774404?cond=Diabetes

Date of initial participant enrollment: January 24, 2023.

The study was approved by the National Medical Ethics Committee (reference number: 0120-449/2021/4) on January 3, 2022.

Minor methodological amendments were made after ethics approval, without changes to predefined outcomes or study procedures (the full study protocol and all amendments are available in the Supplemental Material).

The dataset generated and analyzed during the present study is available from the corresponding author upon reasonable request.

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