Continuous glucose monitoring in the management of gestational diabetes in Switzerland (DipGluMo): an open-label, single-centre, randomised, controlled trial

Sofia Amylidi-Mohr, Giulia Zennaro, Sophie Schneider, Luigi Raio, Beatrice Mosimann, Daniel Surbek

Summary

Background In gestational diabetes, one of the key factors affecting perinatal outcomes is glycaemic control. We aimed to investigate the effect of real-time continuous glucose monitoring (rtCGM) on perinatal outcomes versus self-monitoring of blood glucose (SMBG).

Methods In this open-label, randomised, controlled trial, we recruited pregnant individuals aged 18–45 years with gestational diabetes, according to the International Association of Diabetes and Pregnancy Study Groups criteria, from a university hospital in Bern, Switzerland. Participants were randomly assigned (1:1) to the rtCGM intervention group or the SMBG control group. Randomisation was done centrally on the basis of pre-pregnancy BMI, previous gestational diabetes, family history of type 2 diabetes, and ethnicity. The primary endpoint was a composite of perinatal outcomes: large for gestational age, macrosomia, polyhydramnios, neonatal hypoglycaemia, and stillbirth. Key secondary outcomes were patient preference and maternal glycaemic control. Analyses were conducted on an intention-to-treat basis. This trial is registered with ClinicalTrials.gov, NCT05037526.

Findings Between Sept 29, 2021, and June 11, 2024, 302 pregnant women with gestational diabetes were included in the study and randomly assigned to one of the groups. 156 participants were assigned to the rtCGM intervention group and 143 were assigned to the SMBG control group completed the study. Primary outcome data were available for 297 (99%) of 299 participants. The composite outcome did not differ significantly between the two groups (odds ratio 1·02 [95% CI 0·63–1·66]). The only adverse events were skin changes, occurring in six (4%) participants in the rtCGM intervention group and in one (<1%) participant in the SMBG control group (blinded device).

Interpretation Our results show that the outcome in individuals with gestational diabetes is not improved by the use of rtCGM. However, individuals expressed a higher preference for the rtCGM device. This finding suggests that rtCGM could be offered to simplify the management of gestational diabetes. A cost-effectiveness study could address what method requires fewer resources. To our knowledge, this is the first randomised trial powered to evaluate the efficacy of rtCGM regarding pregnancy outcomes.

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For the German translation of the abstract see Online for appendix 1

Department of Obstetrics & Gynecology, Inselspital University Hospital of Bern, University of Bern, Bern, Switzerland (S Amylidi-Mohr MD, G Zennaro MD, S Schneider MD, Prof L Raio MD, Prof D Surbek MD); **Department of Obstetrics & Gynecology, University Hospital of Basel, Basel, Switzerland** (Prof B Mosimann MD)

Correspondence to: Dr Sofia Amylidi-Mohr, Department of Obstetrics & Gynecology, Inselspital University Hospital of Bern, Friedbuehlstrasse 19 3010 Bern, Switzerland **sofia.mohr@insel.ch**

Introduction

Gestational diabetes is the most common complication of pregnancy, with an incidence rate of up to 14%.[1,2] The American Diabetes Association describes gestational diabetes as diabetes diagnosed during pregnancy that is not clearly overt diabetes.[3] Despite tremendous effort and research, there is still no global consensus on gestational diabetes screening. Based on the results of the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study in 2008,[4] the International Association of Diabetes and Pregnancy Study Groups (IADPSG) recommended a universal one-step screening using the 75 g oral glucose test between 24 weeks and 28 weeks of gestation. Glycaemic control has a major role in the treatment of gestational diabetes.[5,6] Until 2017, glycaemic control in gestational diabetes was mainly based on the self-monitoring of blood glucose (SMBG).[7] However, this method has inconveniences, such as multiple finger pricking for a single glycaemia measurement and intermittent checking of glucose concentrations, which might lead to poor patient adherence.[8] In the past two decades, a new method for glycaemic control has evolved—real-time continuous glucose monitoring (rtCGM).[9] The main benefit of rtCGM is that, after insertion, the system analyses the actual glycaemia continuously.[10] There are ongoing debates about what type of glycaemia measurement method is the most effective for pregnant individuals diagnosed with gestational diabetes regarding pregnancy outcomes. It is hypothesised that rtCGM is superior to SMBG, due to improved glycaemic control. Use of rtCGM during pregnancy in patients with type 1 diabetes is associated with improved glycaemic control in the third trimester, lower birthweight, and reduced risk of macrosomia.[11]

Research in context

Evidence before this study

We searched PubMed for Articles published before Sept 30, 2024, without restriction on language or start date. We included the search terms ("Gestational diabetes Mellitus" OR "Gestational diabetes"), AND "pregnancy", OR "diabetes in pregnancy", AND "continuous glucose monitoring", AND ("trial or randomised controlled trial"). We identified six randomised trials that used intermittent or episodic continuous glucose monitoring in women with gestational diabetes. Four of the studies showed a better detection of hypoglycaemia and higher qualification to insulin therapy in the real-time continuous glucose monitoring (rtCGM) group. However, none of the studies used rtCGM continuously. Additionally, the results were not conclusive regarding the maternal and neonatal outcomes, most probably due to the small population studied. Therefore, the evidence was weak regarding the efficacy of continuous glucose monitoring and additional evidence from powered randomised trials is needed to inform choices of glucose monitoring.

Added value of this study

In our randomised controlled trial of 302 pregnant women with gestational diabetes, we randomly assigned participants during pregnancy to receive either rtCGM or standard self-monitoring of blood glucose (SMBG). We found no clinically relevant difference in neonatal and perinatal outcomes. Notably, the prevalence of large-for-gestational-age neonates and neonatal hypoglycaemia was similar in both groups. rtCGM did not demonstrate any glycaemic benefits over SMBG. Comparing the data between the rtCGM and the blinded continuous glucose monitoring device worn by the SMBGcontrol group, the main glycaemic parameters did not differ significantly. Nevertheless, the preference for the continuous glucose monitoring method was higher.

Implications of all the available evidence

In women with gestational diabetes, there was no significant difference in the perinatal and neonatal outcomes between those using rtCGM or SMBG. However, rtCGM seems to be more acceptable among pregnant women and could be useful in cases of non-adherence or to ease gestational diabetes management.

However, rtCGM use in gestational diabetes is controversial: some studies showed glycaemic benefits with improvements in neonatal outcomes and other studies did not support this finding.[12–15] Therefore, there is no consensus on rtCGM applications in patients with gestational diabetes, especially with regard to the timing and frequency.[8–10] We aimed to determine whether the rtCGM system would improve perinatal and neonatal outcomes compared with traditional SMBG in patients with gestational diabetes.

Methods

Study design and participants

We conducted an open-label, single-centre, randomised, controlled study that compared rtCGM and capillary SMBG in the prenatal care of patients with gestational diabetes. This trial is registered with ClinicalTrials.gov, NCT05037526. Participants were recruited from a single university hospital in Bern, Switzerland. The clinical study protocol was approved by the Ethics Committee of the Canton of Bern (2021-D0006). All participants gave written informed consent. Full details of the clinical study protocol and the statistical plan are provided in appendix 2 (pp 1–50).

See Online for appendix 2

We recruited individuals aged 18–45 years diagnosed with gestational diabetes between the 24 weeks and 28 weeks of gestation, presenting at our hospital for antenatal visits. The diagnosis of gestational diabetes was based on a general screening of our pregnant population with a one-step 75 g oral glucose tolerance test, according to IADPSG criteria.[4] Individuals were eligible if they had an abnormal test, a singleton pregnancy, and no fetal anomaly at the second trimester ultrasound. Individuals having started glucose monitoring and lifestyle intervention before 24 weeks of gestation were excluded.

Randomisation and masking

After enrolment, all participants received medical advice on diet and lifestyle according to our guidelines for gestational diabetes management and learned SMBG. Additionally, HbA_{1c} was evaluated. Eligibility required an HbA_{1c} value of less than 6·5% (48 mmol/mol). Eligible participants were randomised to receive rtCGM (intervention group; device G6; Dexcom International (San Diego, CA, USA) or SMBG (control group) throughout pregnancy. Monitoring methods were allocated (1:1) via a web-based system that used a computer-generated randomisation list (REDcap Database) and stratification by previous gestational diabetes, family history for type 2 diabetes, ethnicity, and BMI before pregnancy. A programming manager created the randomisation schedule, which was encrypted and maintained in the secure database. The study midwife team (SA-M SS, and GZ) executed participant enrolment and assignment.

Procedures

Sex was self-reported, and every individual who took part in the study was declared to be female. Data on ethnicity and race were collected via self-report and medical records. All participants followed routine care at our centre, with consultations by a diabetes specialist midwife or experienced obstetrician approximately every 2 weeks throughout pregnancy and 6–8 weeks after delivery. At enrolment, all participants received the same

guidance on dietary intervention and physical activity. Participants randomly assigned to the rtCGM intervention group were provided with an rtCGM system (G6 Dexcom International Sensor and Transmitter combined with a Smartphone App or with a Dexcom Receiver) throughout pregnancy. Participants were trained to use the study devices by our local diabetes specialist midwifes or study staff. During the wearing period, the participants received support for sensor replacement, understanding the readings, and reacting with diet and physical activity modification. rtCGM data were recorded and uploaded (via Dexcom Clarity software; Dexcom International) for diet adjustments or initiation with or without adjustment of insulin therapy at each routine visit. The glucose target range was 3·5–7·8 mmol/L. In the SMBG control group, participants tested capillary glucose concentrations six times daily (before and 1 h after meals) as advised before enrolment. This group used a blinded rtCGM device (G6 Dexcom International Sensor and Transmitter combined with a blinded Dexcom Receiver) at three timepoints: at enrolment (26–30 weeks of gestation), at 34–38 weeks of gestation, and directly postpartum, across 10 days each time. The sensor was applied to the individual and connected to a blinded transmitter, the data were downloaded from an indepedent study member not involved in the treatment after the application period. The blind device served the purpose to compare both the capillary and rtCGM values and the patient's satisfaction. The glucose targets in the control group were fasting and preprandial values of 5·3 mmol/L or less and 1-h postprandial values of 8·0 mmol/L or less.

Baseline data were noted at randomisation and included personal and family history of gestational diabetes or type 2 diabetes, respectively, BMI before pregnancy, and ethnicity. Trial visits took place when participants attended routine obstetric visits at approximately every 2 weeks starting from enrolment, during which the following parameters were recorded: gestational age, maternal weight, maternal blood pressure, insulin treatment and dose, proteinuria, quantity of amniotic fluid, and estimated fetal weight. For participants in the rtCGM intervention group, the following rtCGM metrics were also collected: mean sensor glucose, time in range, time above range, and time below range. HbA_{1c} measurements were taken at randomisation and the postpartum visit.

The following pregnancy and neonatal outcomes were recorded: date of delivery, occurrence of stillbirth, pre-eclampsia (office blood pressure ≥140/90 mm Hg with proteinuria, with or without new onset of symptoms of maternal organ dysfunction, and with or without fetal growth restriction), mode of delivery (vaginal, instrumental vaginal, or emergency or planned caesarean section), indication for induction, neonatal weight, gestational age at delivery, duration of stay at neonatal intensive care unit, neonatal morbidity (neonatal hypoglycaemia with plasma glucose <2·5 mmol/L, jaundice requiring phototherapy, respiratory distress requiring continuous positive airway pressure treatment), neonatal death (from delivery to 28 days after delivery), and presence of congenital anomalies.

During the postpartum period (6–8 weeks after delivery), the following parameters were recorded: maternal weight, HbA_{1c} concentration, and results of a 2 h 75 g oral glucose tolerance test.

Maternal adverse events were defined as any unwanted or unintended event during the trial, related or unrelated to the trial device. Maternal serious adverse events were defined as any event that resulted in any of the following: death, life-threatening experience, inpatient hospital admission for 24 h or longer or prolongation of existing hospital admission 24 h or longer, a persistent or significant disability or incapacity or presence of a congenital anomaly, and important medical events based on appropriate medical judgement. Potential harms evaluated as adverse events and serious adverse events were recorded from randomisation until 2 months after delivery. Serious adverse events were assessed throughout the trial by SA-M and GZ. Data on congenital anomalies were collected at delivery and assessed by an experienced obstetrician and neonatologist.

Participants were asked to complete a physical activity questionnaire at randomisation and 34 weeks of gestation, and a satisfaction questionnaire after birth.

All data were entered in a research electronic data capture database (REDCap database) by SA-M, GZ, SS. The database was developed for this trial only and accessed with a code.

Outcomes

The primary outcome was a composite of adverse pregnancy and neonatal outcomes, including the proportion of large for gestational age newborns (birthweight >90th and ≤95th centile), fetal macrosomia (birthweight >95th centile), incidence of polyhydramnios, rate of neonatal hypoglycaemia, and occurrence of stillbirth.

The birthweight centiles were based on the birthweight assessment algorithm of the fetal medicine foundation in London.[16] The maximal vertical pocket of amniotic fluid was measured and defined as polyhydramnios if it exceeded 8 cm. Fetal growth restriction was defined according the International Society of Ultrasound in Obstetrics and Gynecology practice guidelines (abdominal circumference/estimated fetal weight <3rd centile, or abdominal circumference/estimated fetal weight <10th centile plus the following: (1) uterine artery-pulsatility index >95th centile, (2) with or without abdominal circumference or estimated fetal weight crossing centiles >2 quartiles on growth centiles, and (3) with or without cerebral placental ratio <5th centile for the fetuses with late fetal growth restriction).[17]

Neonatal blood glucose was assessed after birth (as routinely performed in patients with gestational diabetes) and defined as hypoglycaemia if glucose concentration was less than 2·5mmol/L within 2–4 h after birth after birth and before feeding.

Prespecified secondary glycaemic and maternal outcomes were requirement of insulin (basal or bolus) therapy, insulin dose at visits, glucose monitoring profiles and rtCGM metrics, (glycaemic variability [coefficient of variation and SD of the rtCGM data], mean interstitial glucose and its SD, time in range, and questionnaires relating to satisfaction with the monitoring device). Additionally, HbA_{1c} values were defined at inclusion and postpartum, and the prevalence of persistent metabolic disorder was recorded based on a 75 g oral glucose tolerance test 6–8 weeks after birth.

Insulin therapy was considered if the glucose concentrations were higher than the recommended limit and nutrition or activity adaptations were fully utilised. In the case of repeated fasting glucose of more than 6·1mmol/L, we begun an insulin therapy directly in both groups. Alternative, in the control group, we initiated insulin treatment if 15% of the measurements were abnormal for more than 2 weeks and the nutritional adaptation did not improve glycaemic control. In the intervention group, we prescribed insulin if the time in range was less than 85%. Asymmetric macrosomia with an abdominal circumference of 75 centiles or more or maternal obesity (BMI ≥30 kg/m²) were additional indicators for insulin therapy.

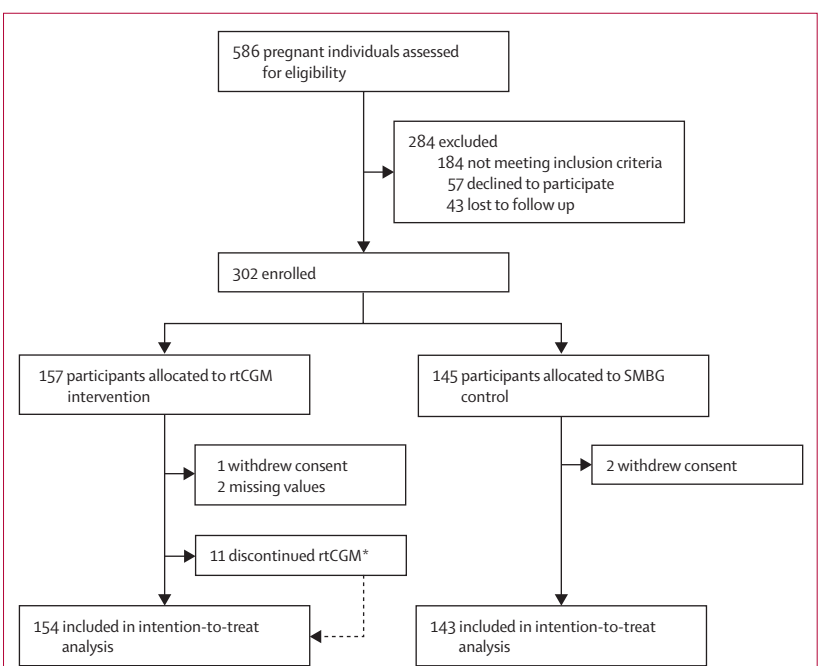

Figure 1: **Trial profile**
rtCGM=real-time continuous glucose monitoring. SMBG=self-monitoring blood glucose. *11 participants showed non-adherence to study procedures because of skin irritation or dissatisfaction and therefore discontinued wearing the rtCGM sensor and proceeded with SMBG but were included in the primary analysis per intention to treat.

Statistical analysis

To reduce the proportion of adverse outcomes from 49% in the control group to 32% in the intervention group (data from our observational cohort study)[18] and to achieve a power of 80% at a two-sided alpha-level of 0·05 and considering a drop out of 5%, 302 participants were recruited. Baseline data are presented and stratified by glucose monitoring allocation. Categorical variables are presented as numbers (%) and numerical variables as median (IQR) or mean (SD) as appropriate. Continuous data were compared using a t-test. The primary analysis compared the two groups on the aforementioned composite fetal, neonatal, and maternal outcomes. Overall p values correspond to the Kruskall-Wallis test and χ^2 test, or the exact Fisher test when the expected frequencies were less than five in some cells. To predict the primary outcome, univariable and multivariable logistic regression was performed. The predictor variable was the study group alone and the study group adjusted for covariates. Results are presented as odds ratios (ORs) with corresponding 95% CIs and p values. $p<0·05$ was considered statistically significant. Analyses reflect an intent-to treat paradigm, in which all data were analysed according to randomised treatment assignment. All evaluations were done using the statistical software R and IBM SPSS Statistics for Windows, Version 29.0.2.0.

The trial was overseen by an independent data safety monitoring board.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Sept 29, 2021, and June 11, 2024, 586 pregnant women with gestational diabetes were assessed for eligibility and 302 participants were randomly assigned to the rtCGM intervention group (n=157) or the SMBG control group (n=145). Three participants withdrew their consent before the baseline assessments, leaving 156 in the rtCGM group and 143 in the SMBG group. 11 (4%) participants showed non-adherence to study procedures because of skin irritation or dissatisfaction; therefore, these participants discontinued wearing the rtCGM sensor and proceeded with SMBG (figure 1). These participants were included in the primary analysis per intention to treat.

At baseline, randomly assigned participants in the rtCGM intervention group had a mean age of 33·46 years (SD 4·64), mean HbA_{1c} of 5·10% (SD 0·39), mean BMI of 25·80 kg/m² (SD 5·09), and mean gestational age of

27·71 weeks (SD 1·84). Participants in the SMBG control group had a mean age of 32·91 years (SD 5·23), mean HbA_{1c} of 5·04% (SD 0·32), mean BMI of 25·71 kg/m² (SD 5·02), and mean gestational age of 27·69 weeks (SD 1·72). Any minor imbalances in baseline characteristics between participants in the rtCGM intervention group and the SMBG control group were within the expected bounds for random allocation (table 1). HbA_{1c} datasets were incomplete because of missing HbA_{1c} values (196 [66%] of 299 participants declined blood sampling by inclusion). In both groups, the postnatal HbA_{1c} values were significantly higher than the prenatal values (appendix 2 p 51).

The proportion of completed prenatal visits was high. Participants using rtCGM completed slightly more scheduled visits than the SMBG control group (mean 8·51 [SD 2·8] visits *vs* 8·04 [SD 2·6] visits), however the difference was not significant.

We obtained primary outcome data for all but two individuals; the primary analysis includes data for 297 (99%) of 299 individuals. The comparison of the two groups regarding the primary outcome (composite of pregnancy and neonatal outcomes) showed no significant difference between the groups (56 [36%] of 154 in the rtCGM intervention group *vs* 50 [35%] of 143 in the SMGB control group; univariable OR 1·06 [95% CI 0·66–1·71]; p=0·80; table 2). In table 2 each of the variables included in the composite outcome are presented. After adjusting for the stratification variables, the two groups did not significantly differ (multivariable OR 1·02 [95% CI 0·63–1·66]; figure 2). When comparing the association between the stratification variables and the risk for an adverse pregnancy outcome, obesity and previous gestational diabetes lead independently to a higher rate of neonatal complications, as expected. Surprisingly, overweight was not associated with a higher adverse outcome incidence (figure 2).

In both groups, all important perinatal and neonatal outcome variables were almost identical. The absolute gestational weight gain did not differ significantly in the two groups (12·1 kg [SD 9·4] in the rtCGM intervention group *vs* 11·7 kg [5·5] in the SMBG control group; table 3). The prevalence of major obstetric complications such as pre-eclampsia (seven [5%] of 154 participants in the rtCGM intervention group *vs* five [3%] of 143 participants in the SMBG control group; OR 1·31 [95% CI 0·45–3·72]), fetal growth restriction (11 [7%] of 154 participants in the rtCGM intervention group *vs* ten [7%] of 143 participants in the SMBG control group; 1·02 [0·45–2·49]), and premature birth (four [3%] of 154 participants in the rtCGM intervention group *vs* two [1%] of 143 participants in the SMBG control group; 1·82 [0·43–9·99]) did not differ significantly in the two groups (table 3). Their low incidences preclude further interpretation of the results. Similarly, induction of labour and caesarean section rate, as well as neonatal admission in the neonatal intensive care unit and need of respiratory support, showed resemblance in the two groups (table 3).

With regard to the glycaemic profile of the participants, it was difficult to compare the rtCGM data between the two groups. The control group used the blinded device at a maximum of three timepoints (at inclusion, in the 34–38 weeks of gestation, and postpartum) compared with

	All (n=299)	rtCGM intervention group (n=156)	SMBG control group (n=143)
Maternal age, years	33·22 (4·93)	33·46 (4·64)	32·91 (5·23)
Gestational age at inclusion, weeks	27·72 (1·82)	27·71 (1·82)	27·69 (1·73)
Ethnicity and race			
White	202 (68%)	104 (67%)	98 (69%)
African	36 (12%)	21 (13%)	15 (10%)
Asian	30 (10%)	15 (10%)	15 (10%)
Hispanic	18 (6%)	9 (6%)	9 (6%)
Mixed	9 (3%)	4 (3%)	5 (3%)
Previous gestational diabetes	71 (24%)	40 (26%)	31 (22%)
Family history for diabetes (first degree relative)	65 (22%)	39 (25%)	26 (18%)
BMI before 20 weeks of pregnancy, kg/m²	25·73 (5·02)	25·80 (5·12)	25·71 (5·01)
Normal (<25 kg/m²)	159 (53%)	82 (53%)	77 (54%)
Overweight (25 to <30 kg/m²)	79 (26%)	41 ((26%)	38 (27%)
Obesity (≥30 kg/m²)	59 (20%)	31 (20%)	28 (20%)
75 g oral glucose tolerance test, mmol/L			
Fasting glucose	5·29 (0·49)	5·35 (0·54)	5·23 (0·41)
1-h glucose*	9·90 (1·68)	10·26 (1·89)	9·60 (1·45)
2-h glucose*	8·51 (1·67)	8·58 (1·87)	8·45 (1·49)
HbA_{1c} at enrolment, %†	5·07% (0·36)	5·10% (0·39)	5·04% (0·32)
HbA_{1c} at enrolment, mmol/mol	31·00 (2·38)	32·00 (2·46)	32·00 (2·13)
Preexisting maternal morbidity	54 (18%)	25 (16%)	29 (20%)
Systolic blood pressure, mm Hg‡	111·62 (9·57)	111·81 (9·48)	111·33 (9·71)
Diastolic blood pressure, mm Hg‡	71·78 (6·96)	72·01 (6·64)	71·41 (7·28)

Data are mean (SD) or n (%). Data were collected at enrolment or randomisation (up to 10 days after enrolment). rtCGM=real-time continuous glucose monitoring. SMBG=self-monitoring blood glucose. *Value was not determined when fasting glucose was ≥5·1 mmol/L. 1-h glucose was available in 89 participants and 2-h glucose in 88 participants. †HbA_{1c} value at enrolment was only available in 196 of 299 participants. ‡Blood pressure values were only available in 208 participants.

Table 1: **Baseline characteristics of participants**

	All (n=299)	rtCGM intervention group (n= 156)	SMBG control group (n=143)	p value
≥1 primary outcome event	106/297 (36%)	56/154 (36%)	50/143 (35%)	0·90
Large for gestational age neonate	30/299 (10%)	16 (10%)	14 (10%)	1·00
Macrosomia	14/299 (5%)	9 (6%)	5 (3%)	0·51
Polyhydramnios	77/299 (26%)	42 (27%)	35 (24%)	0·73
Stillbirth	0	0	0	..
Neonatal hypoglycaemia	18/297 (6%)	9/154 (6%)	9/143 (6%)	1·00

Data are n (%) or n/N (%) unless otherwise specified. Differences in N are due to missing data. Data analysis was done in all randomised participants with available data for the corresponding outcome, based on the group to which they were initially allocated. rtCGM=real-time continuous glucose monitoring. SMBG=self-monitoring blood glucose.

Table 2: **Effect of glucose monitoring method on variables of the primary composite outcome (large for gestational age neonate, macrosomia, polyhydramnios, stillbirth, and neonatal hypoglycaemia)**

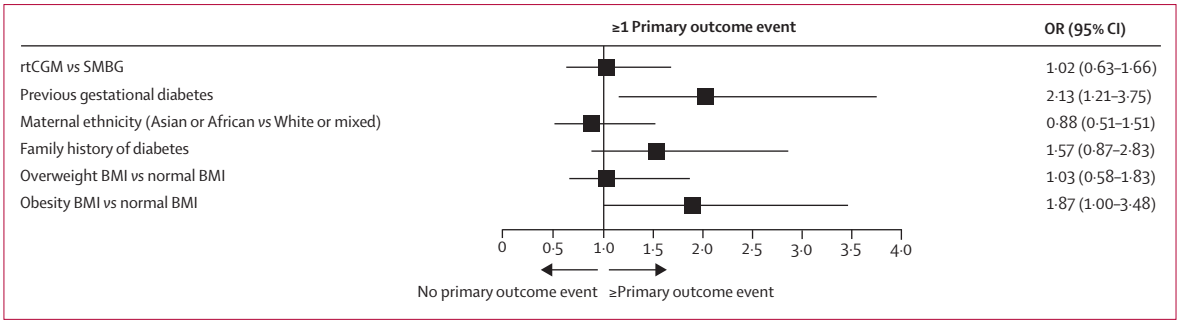

Figure 2: **Associations of glucose monitoring method, ethnicity, previous gestational diabetes, family history for diabetes, and BMI with the primary outcome in participants with gestational diabetes**

Forest plot presents the ORs (95% CI) of any adverse pregnancy outcome included in the composite primary outcome. Normal BMI=<25 kg/m². Obesity BMI=≥30 kg/m². OR=odds ratio. Overweight BMI=25 to <30 kg/m². rtCGM=continuous glucose monitoring. SMBG=self-monitoring blood glucose.

	All (n=298)	rtCGM intervention group (n=155)	SMBG control group (n=143)	p value	Univariable OR (95% CI)
Gestational age at delivery, weeks	38·8 (1·3)	38·7 (1·5)	38·9 (1·0)	0·38	..
Absolute gestational weight gain in pregnancy, kg	11·9 (7·8)	12·1 (9·4)	11·7 (5·5)	0·65	..
Premature rupture of membranes	4 (1%)	3 (2%)	1 (1%)	0·62	2·81 (0·41–36·98)
Fetal growth restriction*	21 (7%)	11 (7%)	10 (7%)	>0·99	1·02 (0·45–2·49)
Pre-eclampsia†	12 (4%)	7 (5%)	5 (3%)	0·77	1·31 (0·45–3·72)
Spontaneous premature birth	6 (2%)	4 (3%)	2 (1%)	0·68	1·82 (0·43–9·99)
Mode of delivery					
Vaginal birth	148 (50%)	83 (54%)	65 (45%)	0·16	1·38 (0·87–2·20)
Vaginal operative birth	25 (8%)	9 (6%)	16 (11%)	0·09	0·48 (0·19–1·09)
Caesarean section	125 (42%)	63 (41%)	62 (43%)	0·64	0·89 (0·55–1·43)
Shoulder dystocia	6 (2%)	3 (2%)	3 (2%)	>0·99	0·89 (0·21–4·02)
Induction of delivery	124 (42%)	59 (38%)	65 (45%)	0·24	0·73 (0·47–1·18)
Neonatal intensive care unit admission	9 (3%)	5 (3%)	4 (3%)	>0·99	1·16 (0·34–3·86)
Need for respiratory support	12 (4%)	9 (6%)	3 (2%)	0·14	2·89 (0·77–10·08)

Data are mean (SD) or n (%) unless otherwise specified. One participant overall, one participant in the rtCGM group, and one participant in the SMBG group had missing data. Data analysis was done in all randomised participants with available data for the said outcome, based on the group to which they were initially allocated. rtCGM=real-time continuous glucose monitoring. SMBG=self-monitoring blood glucose. *Defined as fetal weight of less than 3rd centile or at least two of three of the following: (1) abdominal circumference/fetal weight=Less than 10th centile; (2) uterine artery-pulsatility=more than 95th centile; and (3) abdominal circumference/estimated fetal weight crossing centiles more than two quartiles on growth centiles. †Defined as from the international Society for the Study of Hypertension in Pregnancy.

Table 3: **Effect of glucose monitoring method on perinatal and neonatal outcomes**

the intervention group that used the device continuously at a mean of 67·3 days (SD 4·9), with a mean of active sensor time of 92·5% (SD 6·1). Unfortunately, in the control group a high number (61 [43%] of 143 participants) refused at least one continuous glucose monitoring session due to personal reasons, which resulted in an imbalance of the data. To partially compare the glycaemic profiles, we matched the two groups according to the wearing periods (table 4). At enrolment, we did not find a significant difference in time in range or mean glucose value. Nevertheless, in the later pregnancy the time in range of the SMBG control group was significantly higher than that in the rtCGM intervention group (96·9% [SD 3·0] *vs* 92·2% [7·1]; p=0·02; table 4). There were no severe hypoglycaemia episodes reported in either of the groups.

In both groups, even after lifestyle intervention (including diabetic diet and regular physical activity) a very high number of participants were prescribed insulin therapy (overall 146 [48%] of 302 participants). We found a slightly increased proportion of participants assigned in the rtCGM intervention group were prescribed insulin therapy (either basal or bolus analogues; 80 [55%] of 156 participants *vs* 66 [45%] of 143 participants; OR 1·24 [95% CI 0·79–1·96]; appendix 2 p 52). However, participants in the SMBG control group started insulin by a significant earlier mean gestational age than those in the rtCGM intervention group (31·8 [± 3·2] weeks of gestation *vs* 30·6 [± 3] weeks of gestation; p=0·02; appendix 2 p 52). No participants in our cohort received metformin or other antidiabetic drugs.

Recognised rtCGM frustrations affected more participants in the rtCGM group (51 [33%] of 156 participants) than those in the SMBG control group (32 [22%] of 143 participants), most certainly because of the usage duration (appendix 2 p 51). The most common adverse events in both groups were skin reactions and

discomfort, occurring in six (4%) of 156 participants in the rtCGM intervention group and 11 (8%) of 143 participants in the SMBG control group. Interestingly, in the control group, only one participant had a visible skin reaction.

After giving birth, the participants in the rtCGM intervention group and those in the SMBG control group who used the blinded rtCGM device were asked to complete a satisfaction questionnaire regarding the two monitoring methods. The questionnaire was asked to be completed by the participants with a point scale from 1–10, with 10 being the most preferable. In both groups, the participants would have chosen the rtCGM method if they had the choice (8·5 score *vs* 8·0 score; p=0·47). Additionally, participants in the rtCGM group (score 8·7) found the use of the sensor significantly easier than the capillary measurement (score 7·2; p=0·001; appendix 2 p 53).

	rtCGM intervention group (n=156)	SMBG control group (n=143)	p value
Total included postpartum	n=156	n=82*	
Interstitial glucose, mmol/L	5·8 (0·3)	5·8 (0·5)	0·95
Coefficient of variation, %	19·6% (3·3)	21·7% (3·2)	0·13
SD of glucose readings, mmol/L	1·1	1·2	0·19
Time in range, %	92·6% (5·0)	88·7% (7·0)	0·12
Time above range, %	7·5% (8·2)	7·7% (5·8)	0·86
Time below range, %	0·6% (1·4)	1·2% (2·6)	0·08
Continuous glucose monitoring usage, days	67·3 (4·9)	14 (4·9)	0·011
Continuous glucose monitoring usage, %	93·6% (4·6)	..	..
Total included at enrolment	n=156	n=122*	..
Interstitial glucose, mmol/L	6·0 (0·77)	5·9 (0·59)	0·52
Coefficient of variation, %	16·5% (3·5)	17·4% (3·2)	0·27
Time in range, %	91·0% (13·1)	92·0% (5·4)	0·67
Time above range, %	8·6% (13·2)	6·8% (5·7)	0·45
Time below range, %	0·4% (3·3)	1·1% (0·9)	0·16
Continuous glucose monitoring usage, days	8·0 (2·5)	8·1 (2·6)	0·85
Continuous glucose monitoring usage, %	99·1% (5·1)	89·3% (6·5)	0·43
Total included at 34–38 weeks of gestation	n=156	n=110*	..
Interstitial glucose, mmol/L	5·9 (0·52)	6·2 (0·71)	0·13
Coefficient of variation, %	18·3% (3·2)	18·2% (4·0)	0·93
Time in range, %	92·2% (7·1)	96·9% (3·0)	0·02
Time above range, %	7·2% (7·3)	11·3% (12·6)	0·23
Time below range, %	0·6% (0·8)	0·6% (1·6)	0·90
Continuous glucose monitoring usage, days	10·3 (1·4)	9·1 (1·2)	0·01
Continuous glucose monitoring usage,%	97·1% (4·1)	96·9% (3·0)	0·65

Data are mean (SD) unless otherwise specified. rtCGM=real-time continuous glucose monitoring. SMBG=self-monitoring blood glucose. *Continuous glucose monitoring data in the SMBG group were obtained using blinded sensors at baseline, at 34–36 weeks of gestation, and postpartum. The rtCGM group used a real-time sensor from baseline to 3–8 days postpartum.

Table 4: **Continuous glucose monitoring measures**

Discussion

In this randomised controlled trial, perinatal and neonatal outcomes in participants with gestational diabetes randomly assigned to rtCGM during pregnancy did not differ significantly compared with those of the control participants. Specifically, we found no significant difference in the proportion of large for gestational age infants, macrosomia, neonatal hypoglycaemia, and stillbirth occurrence. However, patient preference was in favour of the rtCGM system, as assessed by a specific questionnaire.

In the past years, technological advances have made rtCGM devices more user-friendly and easier to implement into clinical practice. A few studies have been conducted investigating the effect of rtCGM in the management of gestational diabetes.[10,13–15,19] The largest randomised study in solely patients with gestational diabetes was a trial by Wei and colleagues[20] that compared SMBG alone with SMBG with rtCGM in 120 women with gestational diabetes. Unlike our study, lower maternal weight gain was observed when the rtCGM was used during the second trimester rather than during the third trimester. Additionally, the rtCGM group had a lower proportion of large for gestational age neonates and lower HbA_{1c} concentrations than the SMBG group; however, these differences were not statistically significant either. Alfadhli and colleagues[14] also randomly assigned 130 women with gestational diabetes in Saudi Arabia either to rtCGM for 3–6 days with SMBG or to SMBG alone. Despite the small duration of rtCGM, the authors did not see a marked difference in glycaemic control or perinatal outcomes.

It is difficult to make a direct comparison between published studies and ours, as most have only used short intervals of rtCGM or had a small sample size not powered to assess a potential difference in perinatal and neonatal outcomes.[20] However, the latest meta-analysis of randomised studies indicated that women using rtCGM exhibit slightly improved glycaemic control at the end of pregnancy without a decrease in mean fasting or postprandial glucose levels.[19] These findings do not line up with our results. Nevertheless, as in our study, no significant differences in maternal hypertensive disorders, neonatal macrosomia, large for gestational age neonates, neonatal hypoglycaemia, or other adverse outcomes were identified. Previous studies have used diverse criteria for defining the primary outcome, gestational age at screening, and treatment thresholds. Particularly for gestational diabetes, there is no international consensus for diagnosis. For example, a diagnosis early in pregnancy mirrors a different metabolic state than a diagnosis in the third trimester of pregnancy. Pooling results from studies with heterogeneous methodologies could introduce bias and reduce the reliability of the synthesised estimates.[21] Thus, we emphasise the need for an individual participant data meta-analysis, which allows harmonisation of definitions and standardised statistical approaches.

Our trial has several strengths. First, the sample size for the pregnancy trial was large enough to provide statistical power for a range of clinically relevant

maternal and neonatal outcomes. Second, our trial has a robust randomised controlled design. Participants were included and randomly assigned in pregnancy, only 11 discontinued treatment allocation, and the amount of missing data was low overall, with complete data on the primary outcome and with most data obtained from more than 99% of the individuals included. Bias related to missing data was considered low regarding the primary outcome and the majority of secondary outcomes. However, it is a limitation that the prespecified secondary outcome of rtCGM metrics could only partially be compared in the two groups. Unfortunately, 43% (61 of 143) of the participants in the SMBG control group declined the use of the blinded rtCGM device. Additionally, our study was conducted at a single university hospital, which introduces limitations in terms of broader applicability. This is due to the relatively homogeneous study population, as well as potential variability in treatment preferences and technical skills among a limited number of clinicians. However, all major ethnicities were represented in our study population, signifying a representative sample of the overall population. Despite this ethnic diversity, our cohort exhibited a lower average BMI compared with populations in other studies of women with gestational diabetes.[19,20] In Switzerland, we conduct a universal screening for gestational diabetes independently of risk factors as proposed by the American diabetes Association, and our data align with other national studies. Our data are consistent with findings from other national studies;[2,3,18] importantly, both groups in our study were diagnosed using identical criteria and managed according to the same clinical guidelines and treatment regimens. Thus, the comparison of the groups remains robust despite the monocentric design of the study. Our study also examined patient-reported satisfaction measures. The satisfaction questionnaire results indicate an obvious preference for the rtCGM method compared with SMBG. In the rtCGM group, the use of the rtCGM device was considered to be easier than the capillary method learned before inclusion. These findings should be interpreted with caution owing to low patient numbers returning the questionnaire after giving birth and wearing the blinded rtCGM device.

Compared with the existing literature,[22] our rates of skin intolerance reactions, such as redness, desquamation, pruritus, and sores, were low: 4% (n=6) in the rtCGM group and <1% (n=1) in the control group. Indeed, only one participant in the SMBG control group had visible signs of an eczema, but there were others (n=10, 7%) who reported pruritus and pain. Interestingly, the occurrence of major obstetric complications and the neonatal admission rate to neonatal intensive care unit was impressively low in both groups of this high-risk cohort. Regardless of the glucose monitoring method used, participants demonstrated high adherence to management, as reflected by their attendance at the scheduled antenatal visits. Additionally, participants in the SMBG control group measured the capillary glucose up to six times a day. This might have contributed to the positive outcomes observed, as frequent monitoring likely resulted in more effective glycaemic control. We are aware that this number of antenatal visits generates high health costs; thus, we think the rtCGM method has the potential to be used as an effective telemedicine. However, exploring this possibility is beyond the scope of our study.

In conclusion, our study suggests no benefits of rtCGM over SMBG in terms of glucose control. The use of rtCGM does not change the proportion of women with gestational diabetes requiring medical treatment, nor did the device have a significant influence on obstetric or neonatal outcomes. Nonetheless, rtCGM might offer a valuable alternative to finger-prick testing without compromising pregnancy outcomes. Notably, participants reported greater satisfaction with rtCGM, and it was the preferred method for most.

Contributors

SA-M conceived the idea, designed the study, and developed it further with DS, LR, GZ, SS, and BM. SA-M was responsible for securing the grants. SA, GZ, and SS led participant recruitment and provided technical support to the clinicians. SA-M and GZ conducted the analysis with input from DS. All authors contributed to the drafting and revision of the manuscript, and approved the final version, and SA-M had final responsibility for the decision to submit for publication. SA-M, GZ, and DS vouch for the accuracy and completeness of the data and for the adherence of the study protocol. SA-M and DS oversaw the conduct of the trial, had full access to all the data, and take full responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

Individual participant data that underlie the results reported in this Article will be available from 9 months to 36 months after the publication of this Article. The dataset generated during or analysed during the current trial are available from the corresponding author on reasonable request.

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