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Do patients with gestational diabetes mellitus and their own blood glucose meter have better pregnancy outcomes than those not using a glucose meter?

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Abstract

To compare pregnancy outcomes between patients with gestational diabetes mellitus (GDM) with and without their own blood glucose meter.

We conducted a retrospective-cohort study of 835 women with GDM at the Second Hospital of Tianjin Medical University, Tianjin, China from 1 January 2016 to 31 December 2018. Perinatal outcomes of these patients were monitored and collected in the Tianjin Maternal and Child Health System. Each patient was advised by a certified clinical nutritionist regarding dietary analysis and lifestyle recommendations. All pregnant women with GDM were divided into the following 2 groups according to whether they had their own blood glucose meter: women with self-measured blood glucose levels with a routine obstetric examination in the study group (n=424); and those with non-self-measured blood glucose levels with a double obstetric examination in the control group (n=411). Maternal and fetal pregnancy outcomes were compared between these 2 groups. According to different self-management modes, the women were also divided into eight subgroups to compare blood sugar control and compliance with recommended insulin therapy.

The cesarean section rate was significantly lower in the study group than in the control group ($P<.05$). The prevalence of large-for-gestational age ($P<.05$) and macrosomia was significantly lower in the study group than in the control group (both $P<.05$). The prevalence of appropriate-for-gestational age was significantly higher in the study group than in the control group ($P<.05$). Birth weight was significantly lower in the study group than in the control group ($P<.05$). The mean times for blood sugar control and from the doctor recommendation for insulin treatment to the patient compliance in the study group were significantly shorter than those in the control group (both $P<.05$). The proportion of insulin required in the study group was significantly lower than that in the control group ($P<.05$). There were no significant differences in the time of controlling blood sugar and compliance among the 4 subgroups of the study group. However, subgroups with a dietary diary in the control group were better.

Self-monitoring blood sugar plus a routine obstetric examination can help patients with GDM control blood sugar, even without dietary diaries and treadmills. In addition to increasing the number of obstetric examinations, recording dietary diaries is helpful for controlling blood sugar in patients with GDM who are unwilling to measure blood sugar by themselves.

Abbreviations: GDM = gestational diabetes mellitus, LGA = large-for-gestational age, OGTT = oral glucose tolerance test, PG = plasma glucose, SGA = small-for-gestational age.

Keywords: gestational diabetes mellitus, perinatal outcome, self-monitoring, therapeutic compliance

1. Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance recognized for the first time during pregnancy.[1] GDM is 1 of most common endocrine disorders during gestation, affecting up to 20.3% of pregnancies, since implementation of the 2-child policy in China was announced in October 2015 (data from the Tianjin Maternal and Child Decision System).

GDM is associated with many types of perinatal complications, such as preeclampsia, preterm delivery, macrosomia, an increased cesarean delivery rate, and birth injury.[2–4] The increasing prevalence of GDM provides new challenges for antenatal care centers and midwifery institutions.

Almost all pregnant women in Tianjin are routinely required to undertake blood glucose measurement at 24 to 28 gestational weeks according to the requirements of the guidelines. The time frame for effective interventions to prevent complications from GDM is usually limited to the third trimester of pregnancy. Additionally, women with GDM require frequent visits to antenatal care centers or midwifery institutions. These frequent visits cause considerable stress to the patients and health care systems, considering the increasing incidence of GDM, with their frequently limited resources.[5,6]

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The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are publicly available.

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Strict glycemic targets, early screening, and management for GDM decrease the incidence of diabetes-related complications. Approximately 70% to 85% of patients with GDM can control blood glucose levels with lifestyle modification alone.[7–9] This requires patients to be actively engaged in self-management to achieve optimal perinatal outcomes. Self-management of GDM includes physical activity, a healthy diet, weight management, and self-monitoring of blood glucose.[10] Most pregnant women with GDM can accept 1 or more suggestions, such as exercise, diet control, and a dietary diary. However, some patients have low acceptance of self-monitoring, especially daily self-monitoring of blood sugar levels. Even if these patients increase the frequency of outpatient visits, there are still blind areas for blood sugar monitoring.[11]

Therefore, this study aimed to review a self-management model and perinatal outcomes of pregnant women with GDM undergoing an obstetric examination and delivery in the Second Hospital of Tianjin Medical University 3 years after the second birth policy was released. We also examined the necessity of self-monitoring blood sugar and a safe, effective, and acceptable self-management model.

2. Methods

2.1. Participants and study design

We conducted a retrospective-cohort study of 835 women with GDM who were at The Second Hospital of Tianjin Medical University, Tianjin, China from 1 January 2016 to 31 December 2018. Women with GDM were identified from the medical records department for analysis. International Classification of Diseases, 10th Revision codes for GDM were used to identify the sample. The data were extracted from the Tianjin Maternal and Child Decision System and validated from the medical records. These methods were used to accurately collect out-patient obstetric examination records, in-hospital delivery information, and the pregnancy outcome. Ethics approval was obtained from The Second Hospital of Tianjin Medical University and Tianjin Women's and Children's Care Center Ethics Committee. **The inclusion criteria were** a single pregnancy, the patient visited the obstetric clinic when required, and GDM was present, but there was no preexisting diabetes mellitus, with complete biometric records for the fetuses and mothers.

All of the pregnant women in our study who suffered from GDM were diagnosed by 1-step GDM screening using a 2-hours 75-gram oral glucose tolerance test (OGTT) at 24 to 28 weeks of gestation. The diagnosis of GDM was made according to the International Association of the Diabetes and Pregnancy Study Groups criteria as follows: fasting plasma glucose (PG) levels $\geq$5.1 mmol/L ($\geq$92 mg/dL), 1-h PG levels $\geq$10.0 mmol/L ($\geq$180 mg/dL), or 2-hours PG levels $\geq$8.5 mmol/L ($\geq$153 mg/dL).[12]

Each patient was advised to buy a blood glucose meter to self-monitor blood glucose levels. Each patient was also advised by a certified clinical nutritionist regarding dietary analysis and lifestyle recommendations for patients with diabetes. Women were prescribed the following diets: 25 kcal/kg for women who were overweight or obese; 30 kcal/kg for those with a normal weight, and 35 kcal/kg for women who were underweight. The diet was divided into 3 full meals and four snacks consisting of 50% carbohydrates, 30% fat, and 20% protein. Glycemic control during pregnancy was evaluated by a daily chart that included four measurements of fasting and postprandial blood glucose levels (3 times). The postprandial measurements were taken 2 h after meals. The glucose chart was filled daily for 1 week, after which insulin was initiated if repeated fasting glucose values were >5.5 mmol/L, or repeated if post-prandial values were >6.7 mmol/L. Repeated elevated values were noted when at least 20% of the glucose measurements were elevated beyond the values described above. The daily glucose charts were continued until delivery and the same values were used to adjust insulin dosage.[13]

Patients with GDM who were willing to buy a blood glucose meter to self-monitor blood glucose at home comprised the study group. They visited the obstetric clinic every 2 weeks from 28 to 36 gestational weeks and were followed up every week after 36 weeks of pregnancy. Re-examination included measurement of blood pressure, body weight, uterine height, abdominal circumference, fetal heart rate, blood glucose meter calibration and diet adjustment according to blood glucose monitoring results, and insulin treatment when necessary. Patients with GDM who were unwilling to buy a blood glucose meter to self-monitor blood glucose at home comprised the control group. They visited the obstetric clinic every week. Re-examination included measurement of blood pressure, body weight, uterine height, abdominal circumference, fetal heart rate, fasting and 2-hour postprandial blood sugar levels, dietary recommendations, and insulin therapy if necessary.

The women were divided into 8 subgroups according to whether they used a motion pedometer, dietary diary, or neither. The following classification was chosen for analysis:

Study group (self-measured blood glucose levels with a routine revisit)

(1) Subgroup 1: self-measured blood glucose only
(2) Subgroup 2: dietary diary
(3) Subgroup 3: motion pedometer
(4) Subgroup 4: dietary diary + motion pedometer

Control group (non-self-measured blood glucose levels with 2 revisits)

(1) Subgroup 5: **2** revisits only
(2) Subgroup 6: dietary diary only
(3) Subgroup 7: motion pedometer only
(4) Subgroup 8: dietary diary + motion pedometer

The database of clinical background characteristics included parity, maternal age, pre-pregnancy body mass index,[14] gestational weight gain, gestational age at delivery, delivery mode, including vaginal delivery or cesarean section, and neonatal parameters, including birth weight, Apgar score (1 min after birth), blood glucose levels, and perinatal mortality.

Maternal pregnancy complications included preeclampsia, gestational hypertension, polyhydramnios, premature rupture of the membranes, and amniotic fluid fecal staining. Pre-pregnancy body weight was determined on the basis of self-reporting at the first prenatal visit. Gestational age was determined using the last menstrual period or measurement of crown–rump length using ultrasound in early pregnancy. Gestational hypertension was defined as sustained blood pressure readings of $\geq$140/90 mmHg during pregnancy after 20 weeks of gestation in a previously normotensive status without preeclampsia, which normalized by 3 months postpartum. Preeclampsia was defined as the condition of hypertension accompanied by at least 1 of the following complications with new onset after 20 weeks of gestation, with all symptoms normalizing by 3 months postpartum: proteinuria,

Table 1

Clinical characteristics of the women.

	Study group (n=424)	Control group (n=411)	χ^2 or *t* value	*P* value
Maternal age (yr)	27.9±4.3	27.6±3.8	1.07	>.05
Gestational age at GDM diagnosis (wk)	26.1±1.7	26.3±1.6	1.75	>.05
BMI before pregnant (Kg/m^2)	22.3±2.6	22.5±2.9	1.05	>.05
Nullipara-n (%)	248 (58.5%)	237 (57.6%)	0.059	>.05
Results of 75g OGTT (mmol/L)				
FPG	4.6±0.7	4.5±0.6	1.78	>.05
1-h PG	7.7±4.5	7.8±4.3	0.33	>.05
2-h PG	6.9±3.4	6.7±3.1	0.89	>.05
Glycated hemoglobin Ac (HbAc) %	53.9±6.8	54.7±6.5	1.73	>.05
HGB (g/L)	116±25.2	117±24.7	0.58	>.05
Educational background bachelor degree or above-n (%)	291 (68.6%)	245 (59.6%)	7.29	<.05
Not working during pregnancy-n (%)	139 (32.8%)	162 (39.4%)	3.98	<.05
dietary diary + motion pedometer	79 (18.6%)	81 (19.7%)	0.16	>.05
dietary diary	123 (29%)	101 (24.6%)	40.58	<.05
motion pedometer	81 (19.1%)	78 (19.0%)	0.002	>.05
self-measured blood glucose only	141 (33.3%)	–	–	–
routine revisit only	–	151 (36.7%)	–	–

BMI=body mass index, FPG=fasting plasma glucose, GDM=gestational diabetes mellitus, HbAc = glycated hemoglobin Ac, HGB = hemoglobin OGTT=oral glucose tolerance test, PG=plasma glucose.

other maternal organ dysfunction, such as liver involvement without any underlying chronic diseases, progressive kidney dysfunction, stroke and neurological complications, hematological complications, and uteroplacental dysfunction. These criteria are from the ninth edition of Obstetrics and Gynecology.[15] Small-for-gestational age (SGA) was defined as a birth weight < the 10th percentile for Chinese neonates.[16] Large-for-gestational age (LGA) was defined as a birth weight > the 90th percentile for Chinese neonates.[17]

2.2. Statistical analysis

Data are shown as mean ± SE. The Shapiro–Wilk test was used to examine normality of each variable. Multiple group comparisons were made using either 1-way or 2-way analysis of variance followed by Dunnett's or Bonferroni post-hoc tests where appropriate. Direct comparisons were made using the 2-tailed unpaired Mann–Whitney *U* test. Comparison of rates was performed using the chi-square test. In all cases, a *P* value <.05 was considered significant. SPSS13.0 was used for statistical analysis.

3. Results

3.1. Characteristics of the study participants

There were no significant differences in maternal age, gestational age at diagnosis of GDM, body mass index, parity, OGTT results, and hemoglobin values between the 2 groups (Table 1). However, the academic qualifications of the study group were significantly higher than those in control group ($P<.05$). The proportion of women who were not working during pregnancy in the study group was significantly lower than that in the control group ($P<.05$). The proportion of dietary diaries recorded in the study group was significantly higher than that in the control group ($P<.05$).

Maternal and neonatal complications are shown in Table 2. The cesarean section rate was significantly lower in the study group than in the control group ($P<.05$). The prevalence of LGA and macrosomia was significantly lower in the study group than in the control group (both $P<.05$). The prevalence of appropriate-for-gestational age was significantly higher in the study group than in the control group ($P<.05$). Birth weight in the study group was significantly lower than that in the control

Table 2

Maternal and neonatal complications.

	Study group (n=424)	Control (n=411)	χ^2 or *t* value	*P* value
HDP-n (%)	37 (8.7%)	45 (10.9%)	1.16	>.05
Cesarean section-n (%)	164 (38.7)	198 (48.2%)	7.66	<.05
Polyhydramnios	5 (1.1%)	11 (2.7%)	2.48	>.05
preterm	23 (5.4%)	24 (5.8%)	0.068	>.05
SGA infants-n (%)	14 (3.3%)	15 (3.6%)	0.075	>.05
LGA infants-n (%)	22 (7.3%)	39 (9.9%)	5.70	<.05
AGA infants-n (%)	388 (91.5%)	357 (86.9)	4.69	<.05
Macrosomia	20 (4.7%)	35 (8.5%)	4.89	<.05
Neonate asphyxia (Apgar <7)-n (%)	16 (3.8%)	17 (4.1%)	0.07	>.05
birth weight (g)	3379±253	3672±332	27.05	<.05
Hypoglycemia-n (%)	13 (3.1%)	19 (4.6%)	1.37	>.05
OGTT was normal at 42d-12wk of postpartum n-(%)	375 (88.4%)	365 (88.8%)	0.027	>.05

AGA=appropriate-for-gestational-age, HDP=hypertensive disorders of pregnancy, LGA=large-for-gestational-age, SGA=small-for-gestational-age.

Table 3

Control of blood sugar.

	Study group (n=424)	Control group (n=411)	χ^2 or *t* value	*P* value
Average time for blood sugar control (d)*	8.3±3.3	12.9±4.2	17.55	<.05
Need insulin therapy-n (%)	32 (7.5%)	49 (11.9%)	4.56	<.05
Average time from doctor's recommendation to patient's compliance (d)†	5.2±1.6	7.7±2.4	17.60	<.05

* From the time when obstetricians and nutritionists gave advice to when at least 80% of repeated fasting glucose values were <5.3 mmol/L and at least 80% of repeated post-prandial values were <6.7 mmol/L.
† The time from the doctor's recommendation of insulin treatment to the patient's acceptance of the advice.

group ($P<.05$). The prevalence rates of hypertensive disorders of pregnancy, preterm, polyhydramnios, SGA, neonatal asphyxia, and hypoglycemia were not significantly different between the 2 groups. Most patients with GDM had a normal OGTT reexamination from 42 days to 12 weeks postpartum.

Table 3 shows the control of blood sugar. The mean time for blood sugar control and that from the doctor's recommendation of insulin treatment to the patient's compliance in the study group were significantly shorter than those in the control group (both $P<.05$). The proportion of insulin required in the study group was significantly lower than that in control group ($P<.05$).

Figure 1 show there was no significant difference on the time of controlling blood sugar among the 4 subgroups in the study group. Among the 4 sub-groups of control group, the time of controlling blood sugar in the sub-group with dietary diary was shorter than that of the other 2 groups.

Figure 2 show there was no significant difference on insulin compliance among the 4 subgroups in the study group. Among the 4 sub-groups of control group, the compliance of the sub-group with dietary diary was better than that of the other 2 groups.

4. Discussion

In China, with liberalization of the 2-child policy, the incidence of GDM has increased with an increase in older mothers. However, medical resources are limited. Grade A hospitals are over-crowded, and the daily visits to obstetric clinics can reach 120 per person-time. In such a situation, many patients with GDM may lose control because of unregistered or unwilling frequent visits to crowded obstetric clinics.[18] Many obstetricians will ask patients with GDM to buy a blood glucose meter, record daily blood glucose values at fasting and 2 hour after 3 meals, record a dietary diary, and perform daily steps to improve the efficiency of each visit. Obstetricians can appropriately extend the interval of an obstetric examination according to the level of blood sugar control.

However, not every patient with GDM has good compliance. We found that academic qualifications of the study group were significantly higher and the rate of not working during pregnancy was significantly lower in the study group than in the control group. This suggests that pregnant women with a high education level and persistent work during pregnancy have better self-

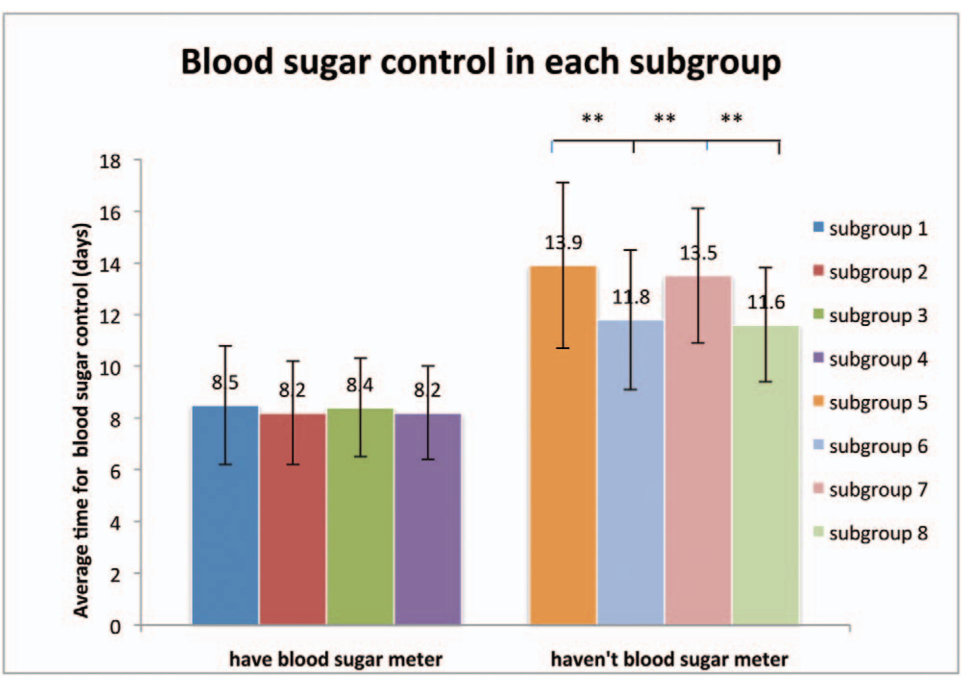

Figure 1. Blood sugar control in each subgroup.

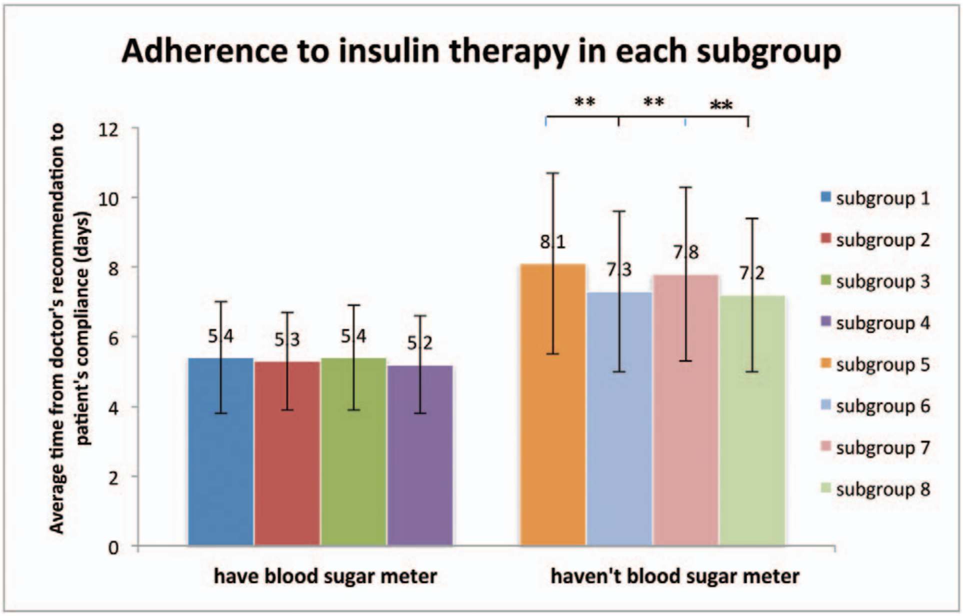

Figure 2. Adherence to insulin therapy in each subgroup.

discipline and compliance. These women will consider less consumption factors and are willing to purchase a blood glucose meter, and record dietary diaries to complete self-blood glucose monitoring and dietary control. They are reluctant to accept suggestions to increase the number of maternity examinations for job. There was no significant difference in the proportion of pedometers between the 2 groups, which may be related to their simple operation and no additional recording.

The outcome of pregnancy was evaluated in our study by the occurrence of maternal and fetal complications, such as hypertensive disorders of pregnancy, polyhydramnios, premature, macrosomia, SGA, LGA, neonatal hypoglycemia, and asphyxia. Our findings suggest that patients with GDM who have a high education level and keep working during pregnancy are more willing to choose to buy a blood glucose meter for self-monitoring, more likely to follow the doctor's advice, have better blood glucose control, and then have better a pregnancy outcome.

Multi-cohort comparison showed that there was no significant difference in blood sugar control between women who had self-measured blood sugar levels with a routine obstetric examination and those with self-measured blood sugar levels with a routine obstetric examination + dietary diary + motion pedometer. We believe that self-monitoring blood sugar could encourage patients with GDM to adjust their diet and motion properly. If patients with GDM refuse to buy a blood glucose meter for self-monitoring, increasing the number of maternity examinations and recording dietary diaries are more conducive for controlling blood glucose levels. However, pregnancy outcomes and blood sugar control levels were not as good in these women as in those in the self-measured blood sugar group. Our data showed that a pedometer was not helpful in controlling blood sugar levels.

From the point of view of simplicity and practicability, purchasing a blood glucose meter to record fasting blood glucose levels and blood glucose levels 2 hour after 3 meals is the most effective way of controlling blood glucose levels. Having a blood glucose meter can also help doctors improve the treatment efficiency of patients with GDM and save limited medical resources. If patients with GDM are unwilling to self-monitor blood sugar levels, increasing the number of maternity examinations and recording dietary diaries are helpful for controlling blood sugar.

Notably, some patients with GDM and a low education level, unstable job, or no job at all were not willing to buy a blood glucose meter because of family financial difficulties. Therefore, they had poor blood glucose control and adverse pregnancy outcomes. Consequently, the relevant government departments will hopefully provide a free blood glucose meter for patients with GDM and financial difficulties. This may provide another way of improving the perinatal quality of patients with GDM, besides doctors' diagnosis and treatment.

There are some limitations of this study. One limitation of this study is that the sample size was small. Furthermore, because of policy problems, doctors could not recommend a uniform blood glucose meter and test paper to patients. There may have been deviation in measurements among the blood glucose meters. Perhaps in the future, the government will apply for funds to provide patients with GDM with a consistent model of a free blood glucose meter. Future studies on this issue need to standardize and expand the sample size, and further improve the research results.

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