Evaluation of the Value of Fasting Plasma Glucose in the First Prenatal Visit to Diagnose Gestational Diabetes Mellitus in China

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OBJECTIVE—To evaluate the value of fasting plasma glucose (FPG) value in the first prenatal visit to diagnose gestational diabetes mellitus (GDM).

RESEARCH DESIGN AND METHODS—Medical records of 17,186 pregnant women attending prenatal clinics in 13 hospitals in China, including the Peking University First Hospital (PUFH), were examined. Patients with pre-GDM were excluded; data for FPG at the first prenatal visit and one-step GDM screening with 75-g oral glucose tolerance test (OGTT) performed between 24 and 28 weeks of gestation were collected and analyzed.

RESULTS—The median ± SD FPG value was 4.58 ± 0.437. FPG decreased with increasing gestational age. FPG level at the first prenatal visit was strongly correlated with GDM diagnosed at 24–28 gestational weeks ($\chi^2 = 959.3$, $P < 0.001$). The incidences of GDM were 37.0, 52.7, and 66.2%, respectively, for women with FPG at the first prenatal visit between 5.10 and 5.59, 5.60 and 6.09, and 6.10–6.99 mmol/L. The data of PUFH were not statistically different from other hospitals.

CONCLUSIONS—Pregnant women ($6.10 \leq FPG < 7.00$ mmol/L) should be considered and treated as GDM to improve outcomes; for women with FPG between 5.10 and 6.09 mmol/L, nutrition and exercise advice should be provided. An OGTT should be performed at 24–28 weeks to confirm or rule out GDM. Based on our data, we cannot support an FPG value ≥5.10 mmol/L at the first prenatal visit as the criterion for diagnosis of GDM.

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Gestational diabetes mellitus (GDM) is a one of the most common medical conditions associated with pregnancy. It was earlier defined as "hyperglycemia first recognized during pregnancy" and has more recently (2012) been described by the American Diabetes Association (ADA) as diabetes diagnosed during pregnancy that is not clearly overt diabetes (1). GDM has health consequences for both the mother and her offspring not only in the short term but also in the long term. Mothers with history of GDM have significantly higher risk of GDM during subsequent pregnancies (2) and type 2 diabetes and premature cardiovascular disease in the medium and long term, while offspring of GDM pregnancy have greater risk of developing obesity, diabetes, hypertension, cardiovascular disease, etc., in youth and adult life (3–5).

The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study demonstrated that the risk of adverse maternal, fetal, and neonatal outcomes continuously increases as a function of maternal glycemia at 24–28 weeks even within ranges previously considered normal for pregnancy (6). After reviewing the results of the HAPO Study, many international diabetes study groups, including the International Association of Diabetes and Pregnancy Study Groups (IADPSG) (7) and ADA (1), have adopted the 75-g oral glucose tolerance test (OGTT) at 24–28 weeks as a screening and diagnostic test and defined new lower cutoff values for GDM diagnosis. Other studies support the new criteria (8–10). These new criteria also mean that more women will be diagnosed with GDM compared with the past; e.g., in the United Arab Emirates, more cases of GDM are diagnosed using the new standard compared with the old one (37.7 vs. 12.9%, respectively) (10). The Ministry of Health (MOH) of China published the diagnostic criteria for GDM on 1 July 2011, which have been put into effect from 1 December 2011 (11); it recommends screening with a fasting plasma glucose (FPG) test at the first prenatal visit to rule out previously undiagnosed preexisting diabetes and a 75-g OGTT between 24 and 28 weeks' gestation for GDM diagnosis. The debate on GDM screening and diagnosis still persists in the global academic circles and professional societies; e.g., in the U.S., the American College of Obstetricians and Gynecologists continues to recommend

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the old diagnostic criteria of 2011 (100-g, 3-h OGTT test) (12).

The possibility that women may have previously undiagnosed type 2 diabetes when they enter pregnancy is increasingly real and likely as the age of onset of type 2 diabetes keeps decreasing, whereas the age of conception keeps increasing. How to screen women at the first prenatal visit to rule out preexisting diabetes not previously known is an important issue. Performing an FPG test at first prenatal visit has been recommended for screening. The feasibility and applicability of this in low-resource settings are obvious issues (13). However, when feasible, another point of debate is the cutoff value to make the diagnosis. IADPSG and ADA have different opinions on this matter. IADPSG uses fasting glucose ≥5.10 mmol/L as the GDM diagnostic criteria at the first prenatal visit and the whole duration of pregnancy, while the ADA recommends that the first prenatal fasting glucose test only be used to identify overt diabetes (≥7.00 mmol/L) and that OGTT during the 24–28th weeks is needed for GDM screening and diagnosis. A study in 2009 reported that higher first-trimester fasting glucose increases the risk for some complications and implied that high-risk women would not get appropriate attention if the diagnosis was not made during the first prenatal visit (14). Mills et al. (15) have shown that there is physiological reduction in FPG concentration in normal pregnancy. In China, as in many other developing countries, the time for the first prenatal visit varies a lot in urban and rural settings; therefore, the value of FPG during the first prenatal visit to screen for preexisting previously undiagnosed diabetes as well as for GDM diagnosis in the first prenatal visit requires further investigation.

RESEARCH DESIGN AND METHODS

The World Diabetes Foundation Denmark funded a project in 2010 in collaboration with the Department of Hospital Administration, MOH of China; the perinatology chapter of the Chinese Medical Association; and the Peking University to help establish GDM centers in China (project number WDF 10-517). In the first year of its implementation, 13 hospitals in different parts of China participated in the training and agreed on the GDM guidelines and protocol for care, which were also endorsed by the MOH in China. In these hospitals, pregnant women were tested for FPG at the first prenatal visit using venous blood sample collected after at least 8 h of fasting. Women were asked to return between 24 and 28 weeks in the fasting state for repeat testing, and this time a 75-g OGTT was performed. Venous blood samples were collected at 0, 1, and 2 h after a 75-g glucose load. Medical records of 17,186 pregnant women who received care at the GDM centers established in 13 hospitals in China, including Peking University First Hospital (PUFH), were studied; at PUFH, these records pertained to women registered at the prenatal clinic between 1 January 2010 and 31 December 2011 (the records after 1 May followed the new criteria), while at the other 12 hospitals, records pertained to women registered between 1 July 2011 and 29 February 2012. Data of FPG at the first prenatal visit and one-step GDM screening using 75-g OGTT at 24–28 weeks were analyzed. Previously known diabetic patients were excluded from the study. For women with FPG ≥7.00 mmol/L at the first prenatal visit, medical care for diabetes was provided; for those with FPG <7.00 mmol/L, no interventions were made until GDM screening at 24–28 weeks. The data of 14,039 pregnant women (7,829 from PUFH) with blood glucose test results linked to gestational week were available for analysis.

Diagnostic criteria for GDM

After an FPG test was performed at the first prenatal visit to exclude diabetes (≥7.00 mmol/L), a diagnostic 75-g OGTT at the 24–28th weeks of gestation was done. According to the criteria established by MOH China, diagnosis of GDM can be made when any one of the following values is met or exceeded in the75-g OGTT: 0 h (fasting), ≥5.10 mmol/L; 1 h, ≥10.00 mmol/L; and 2 h, ≥8.50 mmol/L.

Quality control

The participating centers used the glucose oxidase method for estimating plasma glucose values. Given that there may be inconsistencies between the various laboratories, the data from PUFH, which contributed half of the data, were also analyzed separately for comparison with the data pooled from all the centers.

Statistical methods

Data were analyzed using the Predictive Analysis Software Statistics 18.0; correlation between FPG and GDM was tested using the receiver operating characteristic curve analysis. Results of women attending prenatal services at PUFH alone with pooled data from all centers were compared. FPG values were segmented into six groups starting with <4.10 as the first group, with subsequent increments of 0.50 mmol/L between groups and >6.10 mmol/L as the last group.

RESULTS

The median ± SD pregnancy week for the first prenatal visit and FPG test was 13.4 ± 3.5. The median FPG value at the first visit for all pregnant women was 4.58 ± 0.44; 3,002 (17.5%) women were diagnosed with GDM. Among women seen at PUFH, the median FPG value of 4.68 ± 0.385 was not statistically different from other hospitals, and 1,169 (14.8%) women were diagnosed with GDM.

Association between FPG at the first prenatal visit and subsequent diagnosis of GDM

As shown in Table 1, with every 0.50 mmol/L increase in FPG level >4.10 at the first prenatal visit, the incidence of GDM diagnosis later in pregnancy increased. FPG at the first prenatal visit was strongly correlated with subsequent GDM diagnosis (Pearson χ^2 = 959.3,

Table 1—*Incidence of GDM by FPG stratification*

	All		PUFH	
FPG group (mmol/L)	*n* (%)	GDM, *n* (% outcome)	*n* (%)	GDM, *n* (% outcome)
<4.10	1,938 (11.3)	186 (9.6)	395 (5.0)	32 (8.1)
4.10–4.59	7,055 (41.1)	872 (12.4)	2,955 (37.4)	302 (10.2)
4.60–5.09	6,234 (36.3)	1,165 (18.7)	3,512 (44.5)	506 (14.4)
5.10–5.59	1,668 (9.7)	617 (37.0)	918 (11.6)	271 (29.5)
5.60–6.09	226 (1.3)	119 (52.7)	103 (1.3)	50 (48.5)
6.10–6.99	65 (0.4)	43 (66.2)	11 (0.1)	8 (72.7)
Total	17,186 (100.0)	3,002 (17.5)	7,894 (100.0)	1,169 (14.8)

$P < 0.001$). With FPG levels between 5.60 and 6.1 0 mmol/L, the incidence of GDM was ~50%; with FPG level of 6.10, the incidence of GDM was 66.2%. The data from PUFH show similar trends.

Pregnant women with FPG ≥5.10 mmol/L at the first prenatal visit constituted 11.4% of the total study population and accounted for 26% of all GDM diagnoses. In PUFH, 13.0% had FPG ≥5.1 mmol/L, accounting for 28.2% of all subsequent GDM diagnoses (Table 1). Not all pregnant women with FPG ≥5.1 mmol/L at the first prenatal visit developed GDM; only 39.8% were diagnosed as GDM during 24–28 weeks, and in the PUFH population the proportion was 31.9%.

Among women with FPG ≥5.10 mmol/L at the first prenatal visit, increasing levels of FPG increase the chance that fasting glucose level at 24–28 weeks (75-g OGTT, 0 h) will still be >5.10 mmol/L (Table 2). However, of all pregnant women with FPG value of ≥5.10 mmol/L at 24–28 weeks (75-g OGTT at 0 h), only 30.3% also had an FPG value ≥5.10 mmol/L at the first prenatal visit for the whole study population; this ratio was 23.4% at PUFH. This shows that FPG at the first visit is not consistent with the fasting glucose level at 24–28 weeks. Less than one-third of women could maintain fasting glucose >5.10 mmol/L between the first prenatal visit and 24–28 weeks' gestation. In order to explore the changes in FPG, we further analyzed FPG values at different gestational weeks.

FPG changes with increasing gestational age

In 14,039 case records (7,829 from PUFH), first-visit FPG record date could be linked more precisely to the gestational week. Table 3 shows that from 4–6 to 24–28 weeks' gestation, FPG decreases consistently with the rising gestational age. The trend begins to slow down at ~10 weeks and moderates further from 16 weeks. The data from PUFH are comparable with the whole study population and show a similar trend. There was a negative correlation between the FPG and gestational week (χ^2 test F value 127.5, $P < 0.001$).

Considering that age of pregnant women will have a bearing on FPG, we made multiple linear regression correlations using age and pregnancy week as independent variables and FPG as the dependent variable. The coefficient of correlation of the model is 0.235, regression coefficient of pregnancy week −0.027, and regression coefficient of age 0.009 ($P < 0.001$). It shows that both age and week of pregnancy have independent associations with FPG.

Receiver operating characteristic curve

We have noted that FPG values at the first prenatal visit have implications for GDM diagnosis at 24–28 weeks and also that FPG in pregnancy has a downward trend, so using 5.10 mmol/L in the first prenatal visit as the diagnostic cut point for GDM as suggested by IADPSG is perhaps inappropriate. We used the 75-g OGTT at 24–28 weeks as the gold standard for diagnosis and then created receiver operating characteristic curves to test the value of FPG in the first prenatal visit to diagnose GDM, and each point was analyzed as a screening node.

Area under the receiver operating characteristic curve was 0.654 (95% CI 0.643–0.665; SE 0.006, $P < 0.001$). FPG at the first prenatal visit has diagnostic value. When the cut point reached 5.60 mmol/L, specificity was 0.99, while positive and negative predictive values were in the rational range; when the cut point reached 6.10 mmol/L, specificity was 1 (Table 4).

Table 2—*Relationship between FPG at the first visit and OGTT, 0 h, at 24–28 weeks*

	All			PUFH		
FPG group	*N*	OGTT 0 h >5.1 (*n*)	%	*N*	OGTT 0 h >5.1 (*n*)	%
<5.10	15,227	915	6.0	6,862	340	5.0
5.10–5.59	1,668	452	27.1	918	190	20.7
5.60–6.09	226	102	45.1	103	44	42.7
6.10–6.99	65	40	61.5	11	8	72.7
Total	17,186	1,509	8.8	7,894	582	7.4

CONCLUSIONS—The burden of diabetes in China is huge. Yang et al. (16) reported a diabetes prevalence rate of 9.7% for the whole population (8.8% for women) and a prediabetes prevalence rate of 15.5% (14.9% for women). In ~61.3% of men with diabetes and 59.8% of women with diabetes, the condition had not previously been diagnosed. Of the participants with undiagnosed diabetes (44.1% of men and 50.2% of women), 46.6% had isolated increased 2-h plasma glucose levels after an OGTT, and fasting glucose level alone would have failed to identify these cases. As age of onset of diabetes is coming down, the risk that some young women may have undiagnosed type 2 diabetes when they become pregnant is quite real. Early diagnosis and early intervention for diabetes are necessary to improve pregnancy outcomes. While not the gold standard for diagnosing type 2 diabetes, FPG measurement at the first prenatal visit or at the time of booking could be critical to screen for previously undiagnosed preexisting diabetes. A value of FPG ≥7.00 mmol/L as recommended in the Chinese GDM guidelines would seem reasonable for this purpose.

Our study also shows that FPG at the first visit could provide a pointer for subsequent GDM diagnosis. GDM screening should be made at 24–28 weeks using the 75-g OGTT according to the new ADA and IADPSG guideline. Riskin-Mashiah et al. (14) reported that mild hyperglycemia during early pregnancy could lead to adverse outcomes. Our study supports the idea by showing that two-thirds of the pregnant women with FPG ≥6.10 mmol/L at the first prenatal visit quite likely will progress to GDM without further intervention. If blood glucose is not controlled for this group, we probably will miss the opportunity for reducing risks for poor outcomes. Therefore, we propose that women with FPG ≥6.10 mmol/L may be treated as GDM and that medical nutrition therapy and exercise advice be given to them, and at 24 weeks, OGTT should be performed again to diagnose GDM. In addition, women with FPG between 5.60 and 6.09 mmol/L, half of whom have a chance of developing GDM, can be treated as a high-risk group for GDM. Proper attention to their nutrition and exercise advice must be provided.

IADPSG has recommended that FPG >5.10 mmol/L at any time during pregnancy can be diagnosed as GDM. Based on our current study and our previous work (17), we believe that a cutoff point of FPG >5.10 mmol/L at the first visit is not appropriate to make GDM diagnosis.

Table 3—*FPG variation by gestational week*

	All			PUFH		
Week	*N*	FPG median	SD	*N*	FPG median	SD
4–6	217	4.95	0.46	182	5.02	0.41
6–8	765	4.85	0.42	707	4.89	0.40
8–10	1,105	4.70	0.39	977	4.74	0.36
10–12	2,171	4.67	0.41	1,482	4.68	0.36
12–14	3,694	4.62	0.40	2,177	4.66	0.37
14–16	2,477	4.53	0.41	1,235	4.60	0.37
16–18	2,193	4.45	0.43	725	4.57	0.35
18–20	928	4.45	0.44	294	4.52	0.38
20–22	324	4.45	0.44	41	4.48	0.30
20–24	165	4.38	0.49	9	4.37	0.44
Total	14,039	4.59	0.43	7,829	4.68	0.38

A cohort study of 361 healthy pregnant women by Mills et al. (15) in 1998 showed that the fasting blood glucose levels decrease with advancing pregnancy and a plateau occurs around 10–20 weeks. Even though our study was not a cohort study, data from 14,039 women showed that FPG had a trend to decrease. Maternal age and pregnancy duration each are independently associated with FPG. It also shows that FPG at the first visit is not consistent with the fasting glucose level at 24–28 weeks. No more than one-third of the women whose FPG was >5.10 mmol/L at the first prenatal visit could maintain fasting glucose >5.10 mmol/L at 24–28 weeks. The new criterion (24- to 28-week OGTT, 0 h: 5.10 mmol/L) already identifies more women with GDM. If we use 5.10 mmol/L as the cutoff value to diagnose GDM at any time during pregnancy, even more women will be diagnosed; this will not only burden the already overstretched health system but also create stress and psychological burden for patients, which in itself may not be good for their overall well being during pregnancy. These considerations must be used to find the right balance. We have consistently used the phrase "first prenatal visit" rather than "early pregnancy" throughout this article, as there are two extreme situations regarding the timing of the first visit in China. On one hand, it is relatively late in rural areas because of lack of medical resources or lack of relevant knowledge; on the other hand, in urban areas, e.g., Beijing, the first prenatal visit can be as early as 4–5 weeks because of new population policy, population migration, and preference for "luckier" years (e.g., Dragon baby). Therefore, we recommend FPG measurement at the first visit for all women to identify diabetes, GDM, and GDM risk.

This study has some limitations. BMI is a known confounding factor for GDM risk. Because of the lack of accurate prepregnancy weight and other missing data, we have not been able to analyze the influence of BMI and other potential risk factors on the relationship between FPG and GDM. We also do not have multiple data from one panel to show when the most opportune week for screening is. In the future, we will set a cohort in which pregnant women will participate in the first trimester to trace the influence of BMI and factors on blood glucose.

Besides, the diagnosis of preexisting previously undetected diabetes or GDM high risk evaluation relies on FPG measurement, which in itself is not a reliable tool in the Chinese population, as seen in the study by Yang et al. (16). Moreover, the accuracy and repeatability of the measurement need to be guaranteed. Laboratory quality control is definitely necessary, as is ensuring that women have truly been fasting. This often proves challenging, as often women do not come fasting at the time of the first prenatal visit and have to be asked to come back the subsequent day for the test, and some of them do not come back, especially in the rural areas; also, samples have to be taken before 9:00 A.M. to prevent prolonged fasting.

Based on our study, we recommend that an FPG test be performed for all pregnant women at the time of booking and the first prenatal visit, that FPG value ≥7.00 mmol/L be considered diagnostic of previous undiagnosed diabetes, and that women with FPG between 6.10 and 6.99 mmol/L be treated as GDM to improve outcomes of both mothers and offspring. For women with FPG 5.10–6.09 mmol/L, nutrition and exercise advice should be given to improve outcomes of both mothers and offspring. An OGTT

Table 4—*FPG cutoff values of GDM diagnosis*

Cut point	Sensitivity	Specificity	FPR	FNR	Youden index	+LR	−LR	PPV	NPV
4.0	0.95	0.09	0.91	0.05	0.04	1.05	0.51	0.18	0.90
4.1	0.93	0.14	0.86	0.07	0.07	1.08	0.51	0.19	0.90
4.2	0.89	0.22	0.78	0.11	0.11	1.13	0.51	0.19	0.90
4.3	0.84	0.29	0.71	0.16	0.13	1.18	0.56	0.20	0.89
4.4	0.78	0.38	0.62	0.22	0.16	1.26	0.58	0.21	0.89
4.5	0.71	0.48	0.52	0.29	0.19	1.36	0.61	0.22	0.89
4.6	0.63	0.58	0.42	0.37	0.21	1.51	0.64	0.24	0.88
4.7	0.55	0.68	0.32	0.45	0.22	1.69	0.67	0.26	0.88
4.8	0.47	0.76	0.24	0.53	0.23	1.97	0.69	0.29	0.87
4.9	0.39	0.83	0.17	0.61	0.22	2.30	0.73	0.33	0.87
5.0	0.31	0.89	0.11	0.69	0.20	2.77	0.78	0.37	0.86
5.1	0.24	0.92	0.08	0.76	0.16	3.07	0.82	0.39	0.85
5.2	0.18	0.95	0.05	0.82	0.13	3.57	0.86	0.43	0.85
5.3	0.13	0.97	0.03	0.87	0.10	4.21	0.90	0.47	0.84
5.4	0.09	0.98	0.02	0.91	0.07	4.61	0.92	0.49	0.84
5.5	0.07	0.99	0.01	0.93	0.06	5.50	0.94	0.54	0.83
5.6	0.05	0.99	0.01	0.95	0.04	6.10	0.96	0.56	0.83
5.7	0.04	0.99	0.01	0.96	0.03	7.02	0.97	0.60	0.83
5.8	0.03	1.00	0.00	0.97	0.03	7.57	0.98	0.62	0.83
5.9	0.02	1.00	0.00	0.98	0.02	9.45	0.98	0.67	0.83
6.0	0.02	1.00	0.00	0.98	0.01	8.88	0.99	0.65	0.83
6.1	0.01	1.00	0.00	0.99	0.01	8.97	0.99	0.66	0.83

FNR, false-negative rate; FPR, false-positive rate; NPV, negative predictive value; PPV, positive predictive value.

should be performed at 24–28 weeks to confirm or rule out GDM. We do not recommend FPG ≥5.10 mmol/L at first visit as the criteria to diagnose GDM. These data are from China, and the results may only be applicable to Chinese subjects.

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W.-w.Z. collected and analyzed data and wrote the manuscript. H.-x.Y. designed the research, contributed to discussion, and reviewed and edited the manuscript. Y.-m.W. collected medical data. J.Y. edited the manuscript. Z.-l.W., X.-l.L., H.-r.W., N.L., M.-h.Z., X.-h.L., H.Z., Y.-h.W., J.-m.N., Y.-j.G., L.-r.Z., and Y.-f.W. collected medical data. A.K. contributed to discussion and edited the manuscript. H.-x.Y. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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