Comparison of different criteria for diagnosis of gestational diabetes mellitus

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ABSTRACT

Introduction: The International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria for gestational diabetes mellitus (GDM) has been adopted by most associations across the world including the American Diabetes Association and World Health Organization (WHO). We conducted a study comparing the IADPSG and previous WHO criteria and their effects on neonatal birth weight. **Methods:** The study was carried out in Obstetrics and Gynaecology Department of a tertiary care institute in South India in collaboration with Endocrinology Department. Thousand two hundred and thirty-one antenatal cases with at least one risk factor for GDM and gestational age of more than 24 weeks were included in the study. Both criteria were compared on the basis of 75 g oral glucose tolerance test results. **Results:** The prevalence of GDM using IADPSG and previous WHO criteria were 12.6% and 12.4%, respectively. The prevalence of GDM was 9.9% when both criteria had to be satisfied. Both GDM criteria groups did not differ in neonatal birth weight and macrosomia rate. However, there was a significant increase in lower segment cesarean section in IADPSG criteria group. Elevated fasting plasma glucose alone picked up only one GDM in the previous WHO criteria group. **Conclusions:** A single 2 h plasma glucose is both easy to perform and economical. A revised WHO criterion using a 2 h threshold of \geq 140 mg % can be adopted as a one-step screening and diagnostic procedure for GDM in our country.

Key words: Gestational diabetes mellitus, International Association of Diabetes in Pregnancy Study Group, macrosomia, outcomes, World Health Organization

INTRODUCTION

Diabetes is one of the most common medical complications of pregnancy. It complicates two to five percent of pregnancies, of which 90% is contributed by gestational diabetes mellitus (GDM).^[1] GDM has been defined as any degree of glucose intolerance with onset or first

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recognition during pregnancy and does not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with pregnancy.^[1] It is important to screen for GDM in pregnancy because glucose intolerance is associated with adverse maternal and fetal outcomes and women with history of GDM, and their children are at risk of developing diabetes in future.^[2,3] The hyperglycemia and adverse pregnancy outcomes study involving 25,505 pregnant women showed that the risk of adverse maternal, fetal, and neonatal outcome increased even within ranges previously considered normal for pregnancy.^[4]

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Asian women have a fivefold increase in risk of developing GDM compared to Caucasian women.^[5] Among the ethnic groups in South Asia, Indian women have the highest incidence of GDM.^[6] In India, a community-based study involving 12,056 pregnant women found the prevalence of GDM to be 13.9%.^[7] Hence, screening for GDM during pregnancy, especially in high-risk cases has become necessary. Currently, there is no standard single test for diagnosing GDM. Different criteria proposed for the screening of GDM includes American Diabetes Association (ADA) and previous World Health Organization (WHO) criteria. Recently, both ADA and WHO adopted the criteria proposed by International Association of Diabetes in Pregnancy Study Group (IADPSG).^[8-10] Our study aimed to compare IADPSG and previous WHO criteria for diagnosing GDM and to examine its effects on neonatal birth weight.

Methods

This prospective clinical study was carried out in the Department of Obstetrics and Gynaecology in coordination with Department of Endocrinology of a tertiary care medical institute in South India after obtaining ethical committee approval. Antenatal cases of gestational age ≥ 24 weeks attending outpatient department with any one of the following risk factors for GDM were included in the study: Obesity, chronic hypertension, bad obstetric history e.g. past history of preeclampsia, gestational diabetes, premature delivery, unexplained neonatal death, intrauterine death, stillbirth, delivery of a large infant (\geq 3.5 kg), recurrent pregnancy loss $(\geq 3$ spontaneous abortions in first or second trimester), and family history of diabetes. Known cases of Type I or Type II diabetes mellitus were excluded from the study. All women satisfying the inclusion criteria were subjected to clinical examination after getting a detailed history and informed consent. Weight and height were obtained from antenatal records. Body mass index (BMI) was calculated by dividing the pre-pregnancy weight in kilograms by the square of height in meters. Venous blood samples were collected from them in fasting, 1 h and 2 h following 75 g of oral glucose load. The plasma glucose was estimated by glucose oxidation and peroxidation method.

All participants were diagnosed as GDM using IADPSG criteria (anyone abnormal value in oral glucose tolerance test (OGTT): Fasting plasma glucose (FPG) \geq 5.11 mmol/l, 1 h plasma glucose \geq 10 mmol/l and 2 h plasma glucose \geq 8.5 mmol/l) and WHO criteria (anyone abnormal value in OGTT: FPG \geq 7 mmol/l, and 2 h plasma glucose \geq 7.78 mmol/l). They were stratified into the following groups: Normal glucose tolerance (NGT) by

both IADPSG and WHO, GDM by IADPSG only, GDM by WHO only, and GDM by both IADPSG and WHO criteria [Figure 1]. Antenatal women diagnosed to have GDM by either IADPSG or WHO criteria were managed initially with medical nutrition therapy and daily moderate exercise for 30 min or more.^[11] They were followed up with self-monitoring of blood glucose (after an overnight fast, 2 h after breakfast, 2 h after lunch, and 2 h after dinner) at home. Those having FPG >5.28 mmol/l and/or 2 h postprandial plasma glucose >7.8 mmol/l (more than 30%) of glucose measurements above the recommended value) despite lifestyle modification for 2 weeks were treated either with metformin (1000-1500 mg daily) or insulin according to patient's choice. Those with FPG >6.1 mmol/l in OGTT were given human regular and NPH insulin subcutaneous injections directly. The patients were followed up to delivery. The preterm delivery, if any and the mode of delivery (lower segment cesarean section [LSCS] vs. instrumental vs. vaginal) were noted. After delivery, the birth weight and APGAR scores (1 and 5 min) were recorded for all newborns. Macrosomia was defined as the birth weight ≥ 3.5 kg in our study.^[12]

The data collected were analyzed using the SPSS software version 17. Descriptive statistics was used for demographic variables and categorical data were compared using χ^2 test. The level of agreement in GDM diagnosed between the criteria was assessed by pairwise comparisons using kappa statistics (k). All statistical analysis was carried out at 5% level of significance, and P < 0.05 was considered as significant.

RESULTS

In our study, 1231 cases with at least one risk factor for GDM were studied. Among them, 155 cases (12.6%) were diagnosed as GDM by IADPSG criteria and 153 cases (12.4%) by



Figure 1: Detection rate of gestational diabetes mellitus by different criteria

previous WHO criteria. Both criteria picked up 122 (9.9%) GDM subjects [Figure 1]. There was a good level of agreement between the two diagnostic criteria, and $\kappa = 0.754$ (P < 0.001). In WHO group, all patients except one were picked up by 2 h plasma glucose value alone [Table 1]. However, 70% of those diagnosed by IADPSG criteria alone had isolated elevated FPG. Most of the women (82-83%) diagnosed with GDM by either IADPSG or WHO criteria were managed with diet alone. Both the groups had a good control of blood glucose. Twenty-five subjects in the WHO group and 27 cases in the IADPSG group required metformin along with diet. Three patients on metformin had nausea and mild gastric intolerance which resolved with dose reduction. Five cases diagnosed as GDM by WHO criteria and 7 cases diagnosed by IADPSG required insulin. Two patients in WHO and 3 in IADPSG group opted for insulin from beginning. In addition, 2 patients in WHO and 3 in IADPSG group were initiated on insulin directly as their FPG in OGTT was >6.1 mmol/l. Rest one patient in each group was given added insulin following suboptimal glycemic control with metformin.

The GDM subjects diagnosed by either IADPSG or WHO criteria were significantly older with greater weight and BMI compared to their non-GDM counterparts [Table 2]. Most

Table 1: Comparison between IADPSG and previousWHO criteria								
Parameters	GDM (IADPSG only) <i>N</i> =33 (%)	GDM (WHO only) <i>N</i> =31 (%)	GDM (IADPSG ± WHO) <i>N</i> =155 (%)	GDM (WHO ± IADPSG) <i>N</i> =153 (%)				
Only FPG elevated	23 (70)	00	31 (20)	1 (<1)				
Only 1 h PG elevated	08 (24)	NA	36 (22.6)	NA				
Only 2 h PG elevated	00	31 (100)	23 (14.8)	145 (95)				
Any 2 values elevated	02 (6)	00	30 (20)	07 (4.6)				
All 3 values elevated	00	NA	35 (22.6)	NA				

FPG: Fasting plasma glucose, PG: Plasma glucose, GDM: Gestational diabetes mellitus, IADPSG: International Association of Diabetes in Pregnancy Study Group, WHO: World Health Organization of those diagnosed as GDM had a vaginal delivery. The GDM subjects diagnosed by IADPSG criteria had a higher rate of LSCS as compared to NGT group (15.5% vs. 9.2%, P = 0.01). In contrast, those diagnosed by WHO criteria had similar LSCS rate.

The babies born to GDM mothers diagnosed by either criteria had increased birth weight and macrosomia rate as compared to non-GDM mothers [Table 2]. In total, 14.9% and 17.1% of those diagnosed as GDM by IADPSG and WHO, respectively, had babies with birth weight \geq 3.5 kg (macrosomia) as compared to 5% among non-GDM mothers. Of 79 babies with birth weight \geq 3.5 kg in this study, 27 (34%) babies were born to mothers identified as having GDM. All but one (26/27) macrosomic babies were identified by WHO criteria versus only 85% (23/27) by IADPSG criteria). There was a stillbirth in WHO group and one intrauterine death in IADPSG group in the study.

DISCUSSION

The detection rate of GDM by either IADPSG or previous WHO criteria was similar (12.4% vs. 12.6%) with around 75% of agreement in our study. The prevalence of GDM varied from 6.6% to 24.3% in various studies from South-East Asia.^[13-16] The pickup rate of GDM by both criteria has been different across various studies. It was higher by WHO criteria (24.3% vs. 20.4%) in a study involving 2772 pregnant women done at a referral maternity center in Vietnam.^[13] However, IADPSG criteria detected more GDM cases in the studies by Gilder *et al.*^[14] from Thailand (6.6% vs. 10.1%) and Dahanayaka *et al.*^[15] from Srilanka (7.2% vs. 8.9%). These disparities in GDM burden can be explained by the varying ethnicity of study population, the type of screening (universal vs. risk-based) used and the setting (community vs. tertiary care hospital)

Table 2: Comparison between GDM and non-GDM group								
Parameters	GDM (IADPSG ± WHO) <i>N</i> =155	GDM (WHO ± IADPSG) <i>N</i> =153	NGT <i>N</i> =1045	<i>P</i> * (A vs. C)	<i>P</i> * (B vs. C)			
Age (years)	27.19±4.65	26.92±4.85	24.98±4.02	0.0001	0.0001			
Primigravida (%)	60 (38.7)	63 (41.2)	431 (41.4)	0.52	0.96			
Height (m)	1.53±0.07	1.53±0.07	1.53±0.06	0.26	0.67			
Weight (kg)	63.21±12.34	62.73±13.07	59.58±12.17	0.001	0.003			
BMI (kg/m ²)	26.87±5.32	26.75±5.41	25.49±5.12	0.002	0.005			
Instrumental delivery (%)	09 (5.8)	08 (5.2)	70 (6.7)	0.80	0.60			
LSCS (%)	24 (15.5)	18 (11.8)	96 (9.2)	0.01	0.31			
Preterm (%)	03 (1.9)	05 (3.3)	18 (1.7)	0.74	0.20			
Birth weight (kg)	2.97±0.44	3±0.47	2.86±0.34	0.003	0.001			
BW >3.5 kg (%)	23 (14.9)	26 (17.1)	52 (5)	0.0001	0.0001			
APGAR-1	7.94±0.52	7.94±0.52	7.98±0.25	0.28	0.28			
APGAR-5	8.94±0.47	8.95±0.47	8.99±0.20	0.28	0.27			

BMI: Body mass index, LSCS: Lower segment cesarean section, BW: Birth weight, *A: GDM (IADPSG ± WHO) group, B: GDM (WHO ± IADPSG) group, C: NGT group, GDM: Gestational diabetes mellitus, IADPSG: International Association of Diabetes in Pregnancy Study Group, NGT: Normal glucose tolerance, WHO: World Health Organization

in which the study was conducted. Universal screening picked up more GDM cases compared to a risk-based approach.^[15,17] The risk factor based approach missed up to one-third of GDM cases by IADPSG criteria in the study from Srilanka.^[15]

The primary differences between these two GDM diagnostic criteria are lower FPG and 2 h in IADPSG and WHO criteria, respectively.^[8,9] This fact was reaffirmed in our study. All but one GDM mother were picked up by 2 h PG in WHO criteria in contrast to the majority of them identified by FPG in IADPSG criteria [Table 1]. Similar findings were also reported in other studies.^[15,18] Thirty-one GDM subjects were diagnosed by WHO criteria alone in contrast to 33 cases in IADPSG group alone in this study [Table 1]. In other words, 16.7% and 17.7% were missed by either criteria alone. This figure varies from 16.3% to 32.6% in the literature.^[15,18]

The GDM subjects in either group were older with higher weight/BMI compared to their non-GDM counterparts. These findings are uniform across various studies.^[7,13] A study from Vietnam found that age and BMI at antenatal booking were the strongest predictors of development of GDM.^[13] Similarly, both age ≥ 25 years and BMI ≥ 25 kg/m² had a significant independent association with GDM in a study by Seshiah *et al.*^[7] In a recent meta-analysis of twenty studies, the unadjusted odds ratios of developing GDM were 2.14 (95% confidence interval [CI], 1.82–2.53), 3.56 (3.05–4.21), and 8.56 (5.07–16.04) among overweight, obese, and severely obese compared with normal-weight pregnant women, respectively.^[19]

GDM women diagnosed by either criteria are at higher risk for both LSCS and large for gestational age (LGA), but macrosomia is associated with only GDM mothers diagnosed by WHO criteria in two meta-analyses.^[20,21] Additionally, these associations are more consistent in WHO group. The treatment of GDM reduces both macrosomia (relative risk [RR] = 0.47; 95% CI, 0.34–0.65) and LGA birth (RR = 0.57; 95% CI, 0.47–0.71) in the meta-analysis by Falavigna et al.[22] Compared to WHO criteria, IADPSG criteria reduced the incidence of LGA by 0.32% (0.09-0.63%) in addition.^[23] However, there was no statistically significant reduction in the cesarean section with treatment for GDM in either group.^[22] That means treatment of gestational diabetes may not able to prevent all adverse outcomes associated with GDM. Similar findings were found in our study too. GDM subjects diagnosed by either criteria had increased birth weight and macrosomic babies compared to non-GDM mothers. However, the prevalence of LSCS rate was more frequent only in IADPSG group.

The strength of our study was its large sample size with uniform protocol for screening and treatment of all GDM cases at a single antenatal care center. There are also few limitations in this study. As this was a hospital-based study in a semi-urban setting, the results may not be applicable to the general population. Second, all the parameters related to feto-maternal outcomes were not evaluated.

To conclude, the diagnostic pick-up rate of GDM was similar with both IADPSG and previous WHO criteria in our hospital-based study. The neonatal birth weight and macrosomia rate among GDM women diagnosed with either criteria were comparable. Being easy to perform and economical, a revised WHO criterion of a 2 h PG threshold level of \geq 140 mg % may logistically serve as a one-step screening and diagnostic procedure for GDM.

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Conflicts of interest

There are no conflicts of interest.

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