

Impact of New International Association of Diabetes in Pregnancy Study Group Criteria for Diagnosis of Gestational Diabetes on Pregnancy Outcome at a Tertiary Care Hospital Setting in Southern India

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ABSTRACT

Aim: To find the correlation of maternal and perinatal outcome with a single abnormal oral glucose tolerance test (OGTT) value and with at least two abnormal values, in women with gestational diabetes diagnosed as per International Association of Diabetes in Pregnancy Study Group (IADPSG) criteria.

Materials and methods: This was a prospective observational study. Women diagnosed with gestational diabetes as per IADPSG criteria were divided into four groups with a single abnormal value (fasting/one hour/two hour) and at least two abnormal values. Pregnancy outcomes were compared between the groups using Chi-squared test.

Results: Among 392 women with gestational diabetes, 146 (37.2%), 44 (11.2%), 50 (12.8%) had fasting value, 1-hour value and 2-hour value abnormal, respectively, and 152 (38.8%) had at least two values abnormal. Women with risk factors for gestational diabetes had at least two abnormal values followed by the fasting abnormal group. Requirement of oral hypoglycemics and/or insulin was in 42/152 (27.6%) and 14/152 (9.2%), respectively, in the groups with at least two values deranged, 34/146 (23.3%) and 6/146 (4.1%) in the fasting abnormal group, which are higher compared to other groups ($p = 0.01$). Recurrent urinary infection (28%) and polyhydramnios/macrosomia (38%) were significantly in the group with at least two abnormal values. Preterm labor/PROM was more with groups with fasting hyperglycemia (37%) and 2nd hour glucose abnormality (36%).

Conclusion: Though more than two abnormal GTT values and fasting hyperglycemia were higher in high risk women who also required antiglycemic medications, the maternal and perinatal outcome was not specifically associated with any of the abnormal GTT value individually.

Clinical significance: The study may have a role in decision-making regarding the screening and diagnostic strategies of gestational diabetes to be adopted in the Indian setting.

Keywords: Gestational diabetes, Glucose tolerance test, Glycemic control, Pregnancy outcome, Prospective study.

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INTRODUCTION

Gestational diabetes mellitus (GDM) is one of the most common metabolic disorders encountered in pregnancy. Glucose intolerance usually peaks in the second and third trimesters of pregnancy and results in hyperglycemia of varying severity.¹ Currently GDM accounts for a major economic burden for the healthcare system as a result of rise in the prevalence of obesity and increased maternal age.^{1,2} Women with GDM are prone to develop various pregnancy-related complications such as macrosomia, shoulder dystocia, increased frequency of cesarean delivery, and neonatal hypoglycemia.³ In addition to this, women with gestational diabetes have a substantially increased risk for developing type II diabetes mellitus and cardiovascular disease following pregnancy, while offspring of women with GDM are at a higher risk of developing obesity and type II diabetes mellitus in the early period of life.⁴⁻⁶ Hence, strategies for effective prevention, and proper early diagnosis and treatment of GDM are mandatory. In 2010, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) published new diagnostic guidelines based on the Hyperglycemia Associated Pregnancy Outcome (HAPO) study outcomes to minimize adverse maternal and fetal outcomes associated with GDM.⁶ There is a limited number of retrospective and prospective studies supporting the new guidelines.

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India is known to be the diabetic capital of the world. Recent studies have documented the prevalence of GDM in India as 35-41% and have estimated that about four million women are affected by GDM in India, at any given time point.⁷⁻⁹ Studies that compared IADPSG criteria with WHO and ADA criteria have reported a nearly

three times increased prevalence of GDM.^{10,11} It is important to establish that the increased prevalence is genuine and does reflect on the outcome related to GDM.

With this background, we intended to study the impact of the new IADPSG criteria and their individual cutoffs on maternal and perinatal outcome in our setting.

OBJECTIVE

The objective of the study was to find the correlation of the maternal and perinatal outcome with a single abnormal glucose tolerance test (GTT) value (fasting/one hour/two hours) and with at least two abnormal GTT values, in women with gestational diabetes diagnosed as per IADPSG criteria.

MATERIALS AND METHODS

Ours is a prospective observational study, carried out between March 2016 and March 2017, in the Department of Obstetrics and Gynecology, in a tertiary care hospital in Southern India.

Approval and Registration

Prior to enrollment of patients, Institutional Ethical Committee clearance was obtained (IEC251/2016). All women were explained the purpose of the study and a written informed consent was taken in the language best understood by them.

Methodology

Women receiving antenatal care underwent oral glucose tolerance test (OGTT) at 24–30 weeks as per standard protocol. Oral GTT was done with 75 g glucose after overnight (8–14 hours) fasting and after at least 3 days of unrestricted diet and normal physical activity.

Glucose estimation was done from venous blood plasma using the glucose oxidase/oxidase method, since the estimation of glucose by this method is relatively free of interference from lipids, bilirubin, ascorbic acid, and antidiabetic drugs. Plasma glucose was measured by this method and read with a Hitachi 912 autoanalyzer.

The IADPSG criteria was considered for the diagnosis of GDM, and GTT was considered abnormal if fasting plasma glucose (FPG) was more than 92 mg/dL, 1-hour level more than 180 mg/dL and 2-hour level more than 153 mg/dL. Women were designated to have GDM if any one value was abnormal. Women with GDM thus identified were included in the study. Those with overt diabetes and those on corticosteroids were excluded.

Women with GDM had a sugar profile which included fasting and 2-hour postprandial (breakfast, lunch, and dinner) glucose estimation. Sugar profile was considered abnormal if the fasting level was more than 100 mg/dL and the 2-hour postprandial level was more than 140 mg/dL. Women were advised medical nutritional therapy (MNT) and exercise. Those requiring further glycaemic control were prescribed an oral hypoglycemic agent (OHA) and/or insulin.

Data regarding family history of diabetes and demographic data were collected using standardized questionnaires. Women received regular antenatal care and were followed up until delivery. Following are the various outcome measures included in the study.

Maternal and Fetal Outcome Variables

Following outcome variables are considered:

- Urinary tract infection (UTI): symptomatic UTI or asymptomatic bacteriuria (colony count $\geq 10^5$).

- Preeclampsia: blood pressure (BP) was recorded at every antenatal visit. Preeclampsia is defined as systolic BP ≥ 140 mm Hg and/or diastolic BP ≥ 90 mm Hg, two or more times, with a minimum of 6 hours apart with proteinuria of $\geq 1+$ dipstick or ≥ 300 mg/24 hours. It was classified as gestational hypertension if the criteria were met for elevated BP but not proteinuria, after 20 weeks of gestation.
- Preterm labor: delivery between 28 weeks to prior and 37 weeks
- Preterm prelabor rupture of membranes (PPROM): spontaneous rupture of membranes before term (28–37 weeks)
- Mode of delivery: vaginal delivery—spontaneous or instrumental (vacuum/forceps)—or cesarean delivery
- Fetal demise: intrauterine death of the fetus after 28 weeks before delivery
- Fetal growth restriction (FGR): ultrasound estimated fetal weight ≤ 10 th centile for the gestational age (calculated using the Hadlock four formula)
- Macrosomia: ultrasound estimated fetal weight ≥ 90 th centile for gestational age (calculated using the Hadlock four formula)
- Polyhydramnios: amniotic fluid index (AFI) ≥ 25 or single vertical pocket (SVP) ≥ 8
- Shoulder dystocia: vaginal cephalic delivery that required additional obstetric maneuvers to deliver the fetus after the head had delivered and gentle traction had failed.

Neonatal Outcome Variables

Following are the main neonatal outcome variables considered:

- Birth weight: ≥ 90 th percentile for the gestational age or < 10 th percentile for gestational age
- Hyperbilirubinemia: requiring phototherapy or at least one laboratory value of bilirubin level ≥ 20 mg/dL,
- Hypoglycemia: if there were symptoms of neonatal hypoglycemia and/or treatment with a glucose infusion or a laboratory report of a glucose value ≤ 30.6 mg/dL (1.7 mmol/L) in the first 24 hours and/or ≤ 45 mg/dL (2.5 mmol/L) after the first 24 hours.
- Hypothermia: body temperature below the normal range (36.5–37.5°C)

Also respiratory distress (RDS) in neonate, convulsions and sepsis were documented.

Women were categorized into four groups based on the following.

- Only fasting value abnormal in OGTT (≥ 92 mg/dL) with the other two values normal
- Only 1-hour value abnormal (≥ 180 mg/dL) with the other two values normal
- Only 2-hour value abnormal (≥ 153 mg/dL) with the other two values normal
- At least two values abnormal in OGTT.

Maternal and perinatal outcome variables were compared between the four groups.

Statistical Analysis

Statistical analysis to determine the significance of observed difference in proportion was done using the Chi-squared test. Statistical significance was set at 95% interval ($p < 0.05$).

OBSERVATIONS AND RESULTS

Women diagnosed as GDM as per IADPSG criteria were included in the study. During the study period, from March 2016 to March

2017, 418 women were diagnosed as GDM. Of these, 26 women either failed to turn up for further antenatal checkups or delivered elsewhere. The remaining 392 women were considered for statistical analysis. The demographic profile of the included women is shown in Table 1.

The study included 392 women, out of whom 146 (37.2%) had only fasting plasma glucose abnormal, 44 (11.2%) had only 1-hour value deranged, 50 (12.8%) had only 2-hour value abnormal, and 152 (38.8%) women had at least two values exceeding the diagnostic threshold. Among the women in the last category, 116/152 (76.31%) had abnormal FPG. The risk factors and outcome variables were compared between these four groups.

Women with risk factors for GDM had at least two values exceeding the threshold followed by fasting glucose abnormality. This was consistent with individual risk factors except in the presence of the history of polycystic ovary syndrome (PCOS) where women had either at least two values abnormal or 2-hour value abnormal (Table 2).

Sugar profile remained normal in 284 (72.4%) participants. Among the 108 (27.6%) women with abnormal sugar profile, 54 (50%) were in the OGTT diagnostic group of at least two values abnormal and 38 (35%) were in the fasting abnormal group of OGTT. The proportion of women with abnormal sugar profile declined through the groups at least two values abnormal (36%), FPG (26%), 2-hour (20%), and 1-hour (14%) in this order (Table 3).

In the study group, 286 out of 392 women (72.9%) were managed with diet alone and the rest required treatment with either OHA (metformin) or insulin. Requirement of OHA and/or insulin was high in group with at least two values abnormal followed by high FPG group and then high 2-hour value group. This distribution was statistically significant (Table 3).

Table 1: Demographic profile and risk factors for gestational diabetes mellitus among the subjects (n = 392)

Variables	Number (%)
Family history of diabetes	46 (11.7)
Age	
20–35 years	352 (89.8)
≥35 years	40 (10.2)
Parity	
Primi	232 (59)
Multi	160 (41)
Previous GDM	16 (4)
Previous unexplained pregnancy losses or infertility history	44 (11.2)
Previous PCOS	14 (3.6)

Table 2: Risk factors and test abnormality for diagnosis of gestational diabetes mellitus (n = 392)

Risk factor for GDM	Fasting >92 mg/dL (n = 146) (%)	1-hour >180 mg/dL (n = 44) n (%)	2-hour >153 mg/dL (n = 50) n (%)	≥2 values are abnormal (n = 152) (%)	p value ^a
>35 (n = 40)	13 (30)	8 (20)	6 (15)	14 (35)	0.25
Family history of diabetes (n = 46)	14 (30.4)	4 (8.7)	10 (21.7)	18 (39.2)	0.23
GDM in previous pregnancy (n = 16)	4 (25)	0 (0)	2 (12.5)	10 (62.5)	0.36
Previous unexplained pregnancy losses or infertility (n = 44)	10 (22.7)	8 (18.2)	10 (22.7)	16 (36.4)	0.03
History of PCOS (n = 14)	2 (14.4)	0 (0)	6 (42.8)	6 (42.8)	0.01

^aChi-squared test

The maternal and fetal outcomes in various groups were analysed. Out of 392 women, 90 (23%) had recurrent UTI, 76 (19.4%) had high BP or preeclampsia, 126 (32%) had preterm labor, 50 (12.7%) had a difficult vaginal delivery, 118 (30.1%) had macrosomia in the fetus (by USG), and 218 (55.6%) had a cesarean delivery.

Maternal recurrent UTI and macrosomia/polyhydramnios were found to be more frequent in the group with at least two abnormal values. Preterm labor/PROM was more with groups with FPG and 2-hour glucose abnormality. No group was found to be consistently associated with preeclampsia, difficult vaginal delivery/shoulder dystocia, and cesarean delivery (Table 4).

Perinatal outcome variables such as hyperbilirubinemia and hypoglycemia/hypothermia were more common in groups with at least two abnormal values and fasting hyperglycemia compared with the other two groups. Respiratory distress was common in groups with fasting hyperglycemia, 1-hour abnormal and group with at least two abnormal values (Table 5). However, the observations were not statistically significant.

DISCUSSION

The diagnosis of GDM is still a topic of controversy. Various diagnostic criteria have been proposed and many more are in line in various parts of the world. Thresholds which yielded an odds ratio of 1.75 times the likelihood of adverse outcomes at mean glucose value at each of the three time points were chosen as the diagnostic criteria by IADPSG based on the HAPO study.⁶ The main aim of the HAPO study was to establish internationally acceptable criteria for diagnosis and classification of GDM. Obvious inflection points for various adverse outcomes could not be established even by the HAPO study.

Age is an independent risk factor for GDM and the risk progressively increases as the age advances.¹² In the present study, in the women aged >35 years, there was no clustering of cases into any of the groups and they were almost equally distributed, implying that all the values of OGTT would increase as the age advances. Kuo et al. found that 63% of the women diagnosed as GDM aged >35 years in their study group had fasting levels less than 92 mg/dL, implying that if only FPG is taken into account, 63% of cases would be missed out.¹³

There was no association between parity and FPG, 1-hour, or 2-hour levels in our study. This data reflect what was seen in earlier studies that parity is not directly linked to the deterioration of insulin sensitivity in pregnancy but linked through the confounding factor maternal age.^{14,15}

Studies have shown that GDM is more prevalent among women with a history of diabetes in family, especially maternal, previous

Table 3: Sugar profile and management of gestational diabetes mellitus in the diagnostic groups

		Fasting >92 mg/dL (n = 146) (%)	1-hour > 180 mg/dL (n = 44) (%)	2-hour > 153 mg/dL (n = 50) (%)	≥2 values abnormal (n = 152) (%)	Total (n = 392) (%)	p value ^a
Sugar profile	Normal	108 (74)	38 (86)	40 (80)	98 (64)	284 (72.4)	0.01
	Abnormal	38 (26)	6 (14)	10 (20)	54 (36)	108 (27.6)	
Management	Diet	106 (73)	40 (91)	44 (88)	96 (63)	286 (72.9)	0.01
	OHA	34 (23)	4 (9)	6 (12)	42 (28)	86 (22)	
	Insulin	6 (4)	0 (0)	0 (0)	14 (9)	20 (5.1)	

^aChi-squared test

Table 4: Maternal and fetal outcome variables in different diagnostic groups

	Fasting >92 mg/dL (n = 146) (%)	1-hour > 180 mg/dL (n = 44) (%)	2-hour > 153 mg/dL (n = 50) (%)	≥2 values (n = 152) (%)	p value ^a
Recurrent UTI	36 (25)	4 (9)	8 (16)	42 (28)	0.04
High BP/preeclampsia	26 (18)	8 (18)	14 (28)	28 (18.4)	0.43
Preterm labor/PROM	54 (37)	6 (13.6)	18 (36)	48 (31.5)	0.03
Macrosomia/polyhydramnios	38 (26)	12 (27)	10 (20)	58 (38)	0.03
Difficult vaginal delivery/shoulder dystocia	18 (12)	8 (18)	0 (0)	24 (15.7)	0.06
Cesarean delivery	76 (52)	32 (72.7)	26 (52)	84 (55.2)	0.11

^aChi-squared test

Table 5: Perinatal outcome variables in the different diagnostic groups

Parameter		Fasting >92 mg/dL (n = 146) (%)	1-hour > 180 mg/dL (n = 44) (%)	2-hour > 153 mg/dL (n = 50) (%)	≥2 values (n = 152) (%)	p value ^a
Birthweight categories	SGA	14 (9.6)	8 (18)	6 (12)	10 (6.6)	0.11
	AGA	108 (74)	25 (55)	36 (72)	106 (69.8)	
	LGA	24 (16.4)	12 (27)	8 (16)	36 (23.6)	
Hyperbilirubinemia		42 (28)	8 (18)	12 (24)	52 (34)	0.16
Hypoglycemia/hypothermia		26 (18)	4 (9)	8 (16)	32 (21)	0.32
RDS		16 (11)	4 (9)	2 (4)	12 (8)	0.48

^aChi-squared test

history of pregnancy losses or infertility treatment, and a history of PCOS and GDM in earlier pregnancy.¹⁶⁻¹⁸ Our study has also observed these risk factors and found clustering of these cases in the group where at least two values exceeded the threshold of GDM.

The frequency of GDM detected by each value differs from place to place. In the HAPO study, overall, FPG was the diagnostic value in 55%, 1-hour value was diagnostic in 33%, and 2-hour value resulted in diagnosis in 12%, and 25% had two values deranged in GTT.¹⁹ There was a substantial center-to-center variation even in the HAPO group.²⁰ Two studies involving Indian women found that 91% of GDM by the IADPSG criteria had elevated FPG and that FPG ≥92 mg/dL alone had a sensitivity of 91% for the diagnosis of GDM by the IADPSG criteria.^{8,10} Even in our group, FPG seems to be the most important criteria as we had FPG as one of the two abnormal glucose values in 76.3% of women in the group that had at least two values abnormal besides isolated FPG abnormality in 37.2%.

Almost three quarters of our study population had a normal sugar profile following the deranged OGTT and only one-fourth had an abnormal sugar profile. This may imply that application of IADPSG criteria results in overdiagnosis of GDM or it is just the “milder form of GDM” which is being recognized. Proportion of women with abnormal sugar profile and those requiring OHA and insulin was high in groups where at least two values and/or FPG

exceeded the OGTT threshold. Probably these are the women who represented the actual GDM.

In our study, the proportion of women with recurrent UTI and polyhydramnios/macrosomia was high in the group who had at least two values exceeding the threshold. Proportions of women with preterm labor was higher in the FPG deranged group followed by the 2-hour deranged group and when at least two values were higher than the threshold. However, in the HAPO study, association of preterm was seen with the one- and two-hour glucose values, but not with the fasting glucose value.¹⁹ In our study majority of the large for gestation newborns were in women with first hour glucose abnormality and then in the group with at least two abnormal values. But in the HAPO study, significant association of this variable was seen with each of the glucose values.¹⁹ Incidence of preeclampsia, instrumental deliveries, and the primary cesarean rate did not vary with the groups similar to the observation in the HAPO study.¹⁹ Shoulder dystocia was the same in FPG, one-hour, and at least two values abnormal groups in the present study. In the HAPO study, a significant association of shoulder dystocia was seen with each of the abnormal glucose values.¹⁹

Also variables like hyperbilirubinemia and hypoglycemia were apparently more in the babies of women who exceeded at least two values in OGTT, in our study. In the HAPO study, hyperbilirubinemia

was significantly associated with each of the glucose values but hypoglycemia was associated with fasting and 2-hour values.¹⁹

In the present study, majority of the women with GDM had at least two values abnormal followed by abnormal fasting glucose levels. Among those with risk factors such as family history of diabetes, previous GDM, PCOS, infertility history or pregnancy loss had at least two values deranged. The groups where GDM was diagnosed based on fasting value abnormality and at least two values abnormality had significantly more women with abnormal sugar profile, increased need for intervention in terms of diet management, OHAs, and insulin therapy. Except recurrent UTI, polyhydramnios/macrosomia, and preterm labor/PPROM, no significant association was found between outcome variables and the diagnostic groups.

The strength of this study is that it is a prospective study. As in India there is geographical variations in the prevalence of GDM due to varying sociocultural background, the study conducted in a setting different from previously reported studies will add to the understanding of GDM. However, larger study groups and a control group would have provided stronger associations. Management of diagnosed GDM too would have influenced the outcome.

CONCLUSION

Women with risk factors of GDM had mainly at least two values and/or fasting glucose abnormal at OGTT. More women in these groups had abnormal sugar profile requiring medical therapy. However, maternal and perinatal outcomes were not significantly associated with any single OGTT group, except for recurrent UTI, polyhydramnios/macrosomia, and preterm labor/PPROM which were higher in the groups with at least two values and/or fasting glucose abnormal.

We recommend that more studies with larger samples in different settings and with a control group of normoglycemic women be conducted to study the social impact of the diagnosis of GDM by IADPSG criteria.

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